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Delegations will find in the Annex comments from the French delegation. The English translation will follow.

ANNEXE

NOTE DES AUTORITÉS FRANCAISES A LA PRÉSIDENCE DU CONSEIL

sur la proposition de règlement du Parlement européen et du Conseil relatif aux médicaments vétérinaires () – articles 1 à 103 inclus

Les autorités françaises font suite à la demande de commentaires adressée par la Présidence aux États membres et formulent des propositions concernant les articles 1 à 103.

Considérations générales

Les autorités françaises saluent la proposition législative sur la table et partagent l'analyse de la Commission qui a conduit à l'actualisation du corpus législatif, car elles considèrent que les spécificités du secteur vétérinaire doivent être mieux prises en compte et pour cette raison, une législation différente en certains points de celle du médicament à usage humain doit être mise en place.

1. Les autorités françaises partagent les cinq objectifs du texte :

- Accroître la disponibilité des médicaments vétérinaires,
- Diminuer la charge administrative,
- Favoriser la compétitivité et l'innovation,
- Améliorer le fonctionnement du marché intérieur,
- Prendre en compte le risque pour la santé publique et animale de la résistance aux antibiotiques

Les autorités françaises souhaitent réaffirmer leur attachement au principe que la défense des intérêts économiques et de la compétitivité du secteur ne doit pas porter atteinte à la sécurité sanitaire et environnementale.

2. La cohérence avec la législation relative aux aliments médicamenteux doit être prise en compte :

Les autorités françaises rappellent la nécessité d'assurer la cohérence entre le règlement relatif à l'aliment médicamenteux (AM) et celui relatif aux médicaments vétérinaires, et elles souhaitent une entrée en vigueur concomitante de deux législations. Elles proposent des modifications rédactionnelles aux articles **2, 7, 28 et 30** pour faire le lien avec les exigences applicables aux aliments médicamenteux.

3. Une forte limitation de l'usage préventif des antibiotiques doit être introduite et les règles d'usage prudent et raisonné des antibiotiques doivent être prises en compte :

Les autorités françaises saluent les dispositions relatives à la lutte contre l'antibiorésistance, notamment le fait que le projet de règlement prenne en compte l'antibiorésistance comme motif de refus de l'AMM, mais elles estiment qu'il faut aller plus en avant (amendements à l'article 32) :

- En premier lieu, en interdisant l'octroi d'une AMM à un médicament vétérinaire destiné à être incorporé à un aliment médicamenteux si celui-ci contient un antibiotique avec une indication d'usage préventif.

- En second lieu, en interdisant l'octroi d'une AMM si le conditionnement du médicament n'est pas adapté aux nécessités du traitement et ne permet pas de respecter les règles d'usage prudent et raisonné des antibiotiques.

De plus, il conviendrait de préciser que ces dispositions relatives à la lutte contre l'antibiorésistance ne s'appliquent qu'aux « antibiotiques » et non aux « antimicrobiens » car le terme antimicrobien a un champ plus large et aussi d'ajouter dans le texte un certain nombre de définitions manquantes telles que celle des termes **«** antibiotiques » et des « traitements préventifs », « métaphylactiques » et « curatifs » par exemple.

Par ailleurs, les autorités françaises considèrent qu'il est important d'harmoniser prioritairement les résumés des caractéristiques des antibiotiques anciens dont les AMM doivent, si possible, être préservées et elles font des propositions en ce sens à l'article 70.

4. L'harmonisation doit être mieux assurée pour les conditions de fabrication et de vente en gros des médicaments vétérinaires et doit également s'appliquer aux auto-vaccins, qui ne sont pas pris en compte dans le projet de règlement :

Les autorités françaises regrettent notamment l'absence de référence aux bonnes pratiques de fabrication de pharmacovigilance, et de distribution en gros puisqu'il est prévu que les autorisations de distribution en gros soient valables dans toute l'Union européenne. Elles proposent de les réintroduire pour qu'elles deviennent opposables dans tous les États membres.

En cohérence avec la position des chefs d'agence (HMA), les autorités françaises estiment qu'il est nécessaire d'harmoniser les conditions de fabrication et d'utilisation des auto-vaccins qui peuvent pallier l'absence de médicaments disponibles. Les autorités françaises proposent ainsi que les chapitres VI et VII du projet de règlement s'appliquent aux auto-vaccins.

5. Sur l'extension du champ d'application de la procédure centralisée et le maintien des différentes procédures d'AMM :

Les autorités françaises saluent l'extension du champ d'application de l'AMM centralisée et elles prennent acte du maintien des autres procédures dans le souci d'assurer la disponibilité des médicaments vétérinaires dans tous les États membres.

6. Le respect du traité de Lisbonne et des règles de fonctionnement des institutions européennes doit être garanti dans le cadre des procédures décentralisées et de reconnaissance mutuelle :

Les autorités françaises s'inquiètent de constater que la procédure d'adoption des avis au sein du CMDv s'écarte des règles de fonctionnement des institutions européennes et puisse conduire à ne pas respecter les traités en vigueur.

En effet, la proposition prévoit, qu'en l'absence de consensus, les avis du CMDv soient adoptés par un vote à la majorité simple de l'ensemble des seuls Etats-membres présents au CMDv, alors que la décision d'octroi ou le refus de l'autorisation s'appliqueraient à tous les États membres concernés par la procédure. Les autorités françaises font part de leur désaccord sur cette évolution, car une décision prise à la majorité simple des présents au CMDv ne saurait s'imposer à l'ensemble des États membres. Elles souhaitent que les débats pour l'adoption de la décision finale aient lieu au sein d'un comité gestionnaire du risque, composé des représentants des États membres et présidé par la Commission, et que les règles de vote du traité de Lisbonne soient respectées (amendements à la section 5 du chapitre III).

7. L'innovation doit être stimulée en protégeant mieux la documentation technique :

L'article 33 du projet de règlement maintient la notion d'AMM globale (regroupant toutes les autorisations de toutes les formes, voies d'administration, dosages). Les autorités françaises souhaitent favoriser l'innovation en proposant que les formes pharmaceutiques nouvelles soient considérées comme ne faisant pas partie de la même AMM de manière à pouvoir bénéficier des mêmes avantages en termes de durée de protection des données qu'une AMM nouvelle.

Pour favoriser la lutte contre l'antibiorésistance et la recherche dans ce domaine, les autorités françaises proposent également d'exclure les médicaments antibiotiques du champ d'application de l'AMM globale. Les laboratoires seront incités à développer des thérapies plus efficaces dans un souci de préserver la santé publique et animale.

La protection des nouvelles études ou des nouveaux essais conduits post-autorisation doit permettre d'inciter au développement ou à l'amélioration de produits existants, qu'ils soient princeps ou déjà génériques.

8. L'évaluation du risque environnemental dans la procédure d'AMM doit être renforcée :

Les autorités françaises souhaitent le développement de monographies des substances actives utilisées en médecine humaine et vétérinaire afin de mieux connaître le risque environnemental lié aux médicaments à usage humain et vétérinaire, et de faciliter le partage des connaissances.

Le système de monographies présente l'avantage d'harmoniser les données issues de toutes les études relatives à une même substance active. Par ailleurs, ces informations pourraient être rendues publiques, tout en protégeant la propriété intellectuelle des fournisseurs de données, pour un meilleur partage des informations existantes. La mise en place d'une base de données relative aux substances actives semble être un préalable indispensable à une évolution significative de l'évaluation du risque environnemental dans les autorisations de mise sur le marché des médicaments à usage humain et des médicaments vétérinaires. Les autorités françaises feront part de leur analyse et de leurs propositions sur le sujet dans une note spécifique.

9. La disponibilité des médicaments vétérinaires pour les chevaux destinés à la consommation humaine doit être augmentée pour limiter le recours à la cascade, dans un objectif de protection de la santé publique :

Les autorités françaises notent que la proposition de la Commission allège les conditions de la dérogation permettant de délivrer des AMM aux médicaments pour chevaux non destinés à la consommation humaine. En effet, l'article 7.4 de la proposition ne reprend pas deux conditions de la dérogation qui étaient prévues à l'article 6(3) de la directive 2001/82 en vigueur : la substance active ne doit pas être inscrite sur le tableau 1 du règlement n°37/2010 et le médicament vétérinaire ne doit pas être utilisé pour une maladie pour laquelle un médicament vétérinaire est déjà autorisé pour les équidés. Par conséquent, la proposition législative de la Commission n'encourage pas l'industrie à développer des médicaments avec un temps d'attente spécifique pour les chevaux destinés à la consommation humaine.

Cet allègement de la législation inquiète les autorités françaises car elles craignent un recours excessif à la cascade pour les chevaux qui sont déclarés comme destinés à l'abattage pour la consommation humaine. Or l'étude d'impact de la Commission indique que la situation actuelle a déjà pour conséquence un recours à la cascade fréquent pour les chevaux, en raison de la faible disponibilité des médicaments pour cette filière.

Aussi, les autorités françaises demandent qu'une réflexion soit engagée par la Commission et la Présidence du Conseil pour introduire des dispositions visant à inciter l'industrie à développer des médicaments vétérinaires avec un temps d'attente adapté pour les équidés, et ainsi limiter le recours à la cascade. Les autorités françaises feront part de leur analyse et de leurs propositions sur le sujet dans une note spécifique.

Commentaires spécifiques

1. Autorisations de mise sur le marché (AMM) et procédures d'AMM

a) Durée de validité de l'AMM et clause de caducité (amendements à l'article 5) :

Les autorités françaises considèrent qu'il serait imprudent qu'une AMM soit accordée d'emblée pour une durée illimitée. Les premières années de vie du médicament sont une période où les risques ne sont pas forcément bien identifiés et l'efficacité du nouveau dispositif de pharmacovigilance n'a pas encore pu être mise à l'épreuve. Elles sont donc favorables au **passage de 5 à 10 années de la durée de validité de l'AMM**.

Par ailleurs, les autorités françaises souhaitent **le maintien de la clause de caducité tout en faisant part de propositions d'amélioration pour son application** : une extension du délai de non commercialisation à 5 ans consécutifs et sous réserve que l'absence de commercialisation soit constatée dans tous les Etats membres concernés par la procédure d'AMM.

b) Approbation des essais cliniques (amendement à l'article 8)

L'interdiction de réintroduire dans la chaîne alimentaire les animaux ayant fait l'objet d'essais cliniques est susceptible d'avoir des conséquences néfastes sur l'équilibre économique des laboratoires pharmaceutiques et sur la conduite de recherche clinique au sein de l'Union européenne. Pour favoriser l'innovation et la recherche clinique, il apparaît donc nécessaire **d'autoriser, dans la chaîne alimentaire, les animaux ayant reçu des médicaments contenant une substance bénéficiant déjà d'une limite maximale de résidus et pour laquelle un temps d'attente pourra être fixé.**

c) Etiquetage et notice des médicaments vétérinaires (amendements aux articles 9 à 15)

Les autorités françaises considèrent que **certaines mentions essentielles à une utilisation conforme et sans risque du médicament sont manquantes** (comme le numéro d'AMM ou le temps d'attente). De plus, il convient d'introduire des **dispositions en lien avec la notion de division** (« dividing up ») afin d'encadrer notamment l'étiquetage qui s'applique aux unités issues de la division.

d) <u>Introduction du principe d' « AMM soumises à condition » (amendement à l'article 31)</u>

Les autorités françaises souhaitent introduire le principe d' « AMM soumises à condition » pour pouvoir autoriser un médicament vétérinaire même si le dossier n'est pas complet et ainsi promouvoir la disponibilité rapide d'un médicament vétérinaire important.

Après consultation du demandeur, une AMM pourra ainsi être accompagnée d'obligations spécifiques, visant à assurer une balance bénéfices/risques positive du produit, comme la mise en place de plans de gestion de risque, la surveillance de la résistance aux antimicrobiens et la protection de l'environnement.

e) <u>AMM marché limité et circonstances exceptionnelles (amendements aux articles 21, 22, 82 et 83)</u>

Pour ce qui concerne plus spécifiquement des dossiers d'AMM marchés limités et de circonstances exceptionnelles, les autorités françaises **souhaitent que le principe d' « AMM soumises à condition » précédemment défini s'applique en particulier à ces catégories d'AMM aux exigences allégées**, sans pour autant aboutir à imposer l'ensemble des exigences prévues à l'article 7 pour une AMM classique.

De plus, les autorités françaises demandent que **les exigences applicables en matière de qualité soient systématiquement présentes dans les dossiers d'autorisation** quel que soit le type de marché auquel l'autorisation est destinée (marché limité, circonstances exceptionnelles ou autres).

<u>2. Fonctionnement du marché intérieur :</u>

La jurisprudence communautaire a reconnu la possibilité aux entreprises de commercialiser un médicament vétérinaire autorisé dans un autre Etat membre de l'Union européenne dès lors qu'il est identique à un médicament vétérinaire autorisé dans leur pays. Il convient de transposer cet acquis de la jurisprudence dans ce projet de règlement en qualifiant cette activité d'**importation parallèle ou de distribution parallèle** et de définir un dispositif d'encadrement de cette activité dans l'Union Européenne.

Les autorités françaises proposent un dispositif d'encadrement entre les sections 2 et 3 du chapitre III, qui prévoit l'octroi d'une autorisation préalable par l'autorité compétente nationale avant toute importation ou distribution parallèle et qui permet ainsi la mise œuvre de contrôles par les autorités douanières de chaque Etat membre sur de ce type de flux de médicaments vétérinaires.

De même, il sera nécessaire de prévoir un dispositif d'encadrement pour les **importations à but thérapeutique** dans le cadre de la cascade.

3. Pharmacovigilance (cf amendements aux articles 72 à 81) :

a) Responsabilités des titulaires d'AMM

Les autorités françaises considèrent que le rôle et les responsabilités des titulaires d'AMM doivent être davantage précisés.

Elles proposent de mettre en place une **« autorisation unique du système de pharmacovigilance »** pour encadrer le concept de « dossier permanent », car les inspections et les contrôles *a posteriori* prévus par le projet ne leur apparaissent pas suffisants.Cette autorisation unique sera préalable à l'octroi d'AMM (avec un suivi des modifications de ces dossiers après l'autorisation) et sera reconnue dans toute l'Union européenne, comme le sont les autorisations de fabrication et de distribution en gros. Elle sera enregistrée dans une base européenne de données.

Par ailleurs, **une personne unique doit être responsable de la pharmacovigilance** et donc du dossier permanent du système de pharmacovigilance.

Concernant les effets indésirables**,** les autorités françaises souhaitent que **le rôle d'évaluation des effets indésirables par les laboratoires soit systématiquement maintenu** sans qu'il ne soit nécessaire que les autorités compétentes ou l'Agence en fassent la demande. Les résultats de ce suivi et de cette évaluation doivent être consignés dans la base de données de pharmacovigilance et communiqués à l'autorité compétente et à l'Agence.

b) Mise en place de rapports bénéfice/risque par le titulaire d'AMM en remplacement des rapports périodiques actualisés de sécurité (PSURs, periodic safety update reports)

Les autorités françaises ne sont pas favorables à la suppression complète des PSURs. En effet, les PSURs contiennent aujourd'hui des informations importantes telles que les données de la littérature, les cas des essais cliniques, une évaluation bénéfice/risque par le titulaire, et une conclusion sur l'adéquation ou non du résumé des caractéristiques du produit avec les données observées.

Pour permettre de répondre aux objectifs de simplification administrative et de sécurité sanitaire, elles proposent de **remplacer les PSURs par des rapports d'évaluation du bénéfice/risque dont le contenu et le rythme de présentation seront définis par la Commission lors de l'octroi de l'AMM, sur la base d'une analyse de risque en fonction de la nature du produit**. Les autorités françaises proposent en ce sens une harmonisation européenne :

- des calendriers de dépôt des évaluations scientifiques du rapport bénéfice-risque,
- de la mise en œuvre du processus de détection,
- et des périodicités minimales d'évaluation.

Par ailleurs, en cas d'effets indésirables déclarés, **le nombre de déclarations n'est pas un critère suffisant pour évaluer un risque lié à l'utilisation d'un médicament**. Il convient également de pouvoir disposer des données de vente en unité de traitements pour estimer le nombre d'animaux traités et l'incidence des effets indésirables. L'absence de ces données conduira les autorités compétentes à les demander. Aussi, dans un souci de simplification administrative, il serait plus simple de rendre obligatoire la transmission de ces informations indispensables, dès lors que les rapports font état de la survenue d'effets indésirables.

c) <u>Rôle de l'Agence européenne du médicament (EMA) dans la pharmacovigilance</u>

Les autorités françaises ne sont pas favorables au nouveau rôle d'évaluation attribué à l'EMA et elles considèrent qu'une approche harmonisée au niveau européen en matière de pharmacovigilance serait facilitée par la mise en place d'un groupe de travail « pharmacovigilance working party ».

Nouveau règlement **Version anglaise**	**Amendements de la délégation FR** **(en langue anglaise)**	**Observations/Justifications** **(en langue française)**
Chapter I **Subject matter, scope and definitions**		
Article 1 *Subject matter*		
This Regulation lays down rules for the placing on the market, manufacture, import, export, supply, pharmacovigilance, control and use of veterinary medicinal products.		

Article 2 - Scope		
1. This Regulation shall apply to veterinary medicinal products prepared industrially or by a method involving an industrial process and intended to be placed on the market. 2. In addition to the products referred to in paragraph 1, Chapter VI shall also apply to active substances, intermediate products and excipients used as starting materials in veterinary medicinal products. 3. In addition to the products referred to in paragraph 1, Chapter VII shall also apply to: a) substances that have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties and that may be used in animals; b) veterinary medicinal products prepared in a pharmacy in accordance with a veterinary prescription for an individual animal or a small group of animals ('magistral formula');	1. This Regulation shall apply to veterinary medicinal products prepared industrially or by a method involving an industrial process and intended to be placed on the market. **In addition to the products referred to in paragraph 1, this regulation shall also apply to veterinary medicinal products used for the manufacture of medicated feedingstuffs.**	Les autorités françaises (AF) souhaitent souligner la nécessité de coordonner le règlement relatif aux médicaments vétérinaires avec celui sur les aliments médicamenteux, et, à cet effet, d'**introduire dans le champ d'application la référence aux médicaments vétérinaires destinés aux aliments médicamenteux**.

c) veterinary medicinal products prepared in a pharmacy in accordance with the directions of a pharmacopoeia and intended to be supplied directly to the end-user (‘officinal formula’).		
2. In addition to the products referred to in paragraph 1, Chapter VI shall also apply to active substances, intermediate products and excipients used as starting materials in veterinary medicinal products. 3. In addition to the products referred to in paragraph 1, Chapter VII shall also apply to: a) substances that have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties and that may be used in animals;	**3a. In addition to the products referred to in paragraph 1, chapter VI and VII shall also apply to inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or those animals in the same locality or epidemiologically linked »**	**S’agissant des auto-vaccins**, en lien avec la position des chefs d’agence (HMA) sur la nécessaire harmonisation dans l’UE des conditions de préparation des autovaccins dans des établissements autorisés et qui respectent des règles de bonnes pratiques (BP), **les AF souhaitent que les chapitres VI et VII du projet de règlement relatifs respectivement à la fabrication, à l’importation, à l’exportation, à la fourniture et à l’utilisation s’appliquent aux auto-vaccins.** Les AF **demandent d’introduire la notion de lien épidémiologique** pour étendre la possibilité d’utiliser des autovaccins dans des élevages ayant un lien épidémiologique entre eux (vaccination des ascendants en volaille à partir d’un pathogène prélevé chez les descendants), et **de définir la notion de same locality,** conformément aux recommandations de HMA. **S’agissant des thérapies nouvelles** : les AF

b) veterinary medicinal products prepared in a pharmacy in accordance with a veterinary prescription for an individual animal or a small group of animals ('magistral formula'); c) veterinary medicinal products prepared in a pharmacy in accordance with the directions of a pharmacopoeia and intended to be supplied directly to the end-user ('officinal formula').	**3b. The Commission may, by means of implementing acts, adopt decisions stipulating which chapter shall be applied on specific veterinary medicinal products as radiopharmaceutical veterinary medicinal products, cellular therapy products or any novel therapy. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2)."**	estiment utile de **clarifier et d'harmoniser la réglementation applicable et elles souhaitent que les pouvoirs de la Commission soient renforcés par voie d'acte d'exécution.**

4. This Regulation shall not apply to:	4. This Regulation shall not apply to:	
a) inactivated immunological veterinary medicinal products which are manufactured from pathogens and antigens obtained from an animal or animals from a holding and used for the treatment of that animal or those animals in the same locality;	**a)deleted**	**Les AF souhaitent la suppression du (a) du point 4** qui exclut les auto-vaccins du champ d'application du règlement puisqu'elles proposent une application partielle du règlement (cf proposition au point 3 a).
b) veterinary medicinal products containing autologous or allogeneic cells or tissues that have not been subjected to an industrial process;	***a)*** veterinary medicinal products containing autologous or allogeneic cells or tissues that have not been subjected to an industrial process;	
c) veterinary medicinal products based on radio-active isotopes;	***b)*** veterinary medicinal products based on radio-active isotopes;	

d) feed additives as defined in Regulation (EC) No 1831/2003 of the European Parliament and of the Council ; e) veterinary medicinal products intended for research and development.	***c)*** feed additives as defined in Regulation (EC) No 1831/2003 of the European Parliament and of the Council ; ***d)*** veterinary medicinal products intended for research and development.	
Article 3 *Conflict of laws*	Article 3 Conflict of laws **and regulatory status of products »**	Les AF proposent une modification du titre pour renvoyer clairement au statut réglementaire des produits.
1. Where a veterinary medicinal product referred to in Article 2(1) also falls within the scope of Regulation (EU) No 528/2012 of the European Parliament and of the Council or Regulation (EC) No 1831/2003 of the European Parliament and of the Council, and there is a conflict between the provisions of this Regulation and the provisions of Regulation (EU) No 528/2012 or Regulation (EC) No 1831/2003, the provisions of this Regulation shall prevail.	**1.a)** Where a veterinary medicinal product referred to in Article 2(1) also falls within the scope of Regulation (EU) No 528/2012 of the European Parliament and of the Council or Regulation (EC) No 1831/2003 of the European Parliament and of the Council, and there is a conflict between the provisions of this Regulation and the provisions of Regulation (EU) No 528/2012 or Regulation (EC) No 1831/2003, the provisions of this Regulation shall prevail.	Les AF s'interrogent sur les raisons pour lesquelles une restriction a été apportée à la primauté du règlement sur les seuls règlements relatifs aux biocides et aux additifs.

	1.b) In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'veterinary medicinal product' and within the definition of a product covered by other Community legislation, the provisions of this regulation shall apply.	Elles s'interrogent sur l'absence de base juridique pour des actions en cas de mise sur le marché d'un produit litigieux ne relevant pas des règlements pré-cités et elles **demandent que la primauté du règlement continue à s'appliquer en cas de doute**, comme cela était déjà prévu dans la directive 2001/82/CE, pour toute catégorie de produit réglementé.
2. The Commission may, by means of implementing acts, adopt decisions on whether a specific product or group of products is to be considered as a veterinary medicinal product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	2. The Commission may, **at the request of a Member State or on its own initiative**, by means of implementing acts, adopt decision on whether a specific product or group of products is to be considered as a veterinary medicinal product. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	Elles jugent par ailleurs **nécessaire qu'un État membre puisse demander à la Commission de prendre un acte d'exécution afin de déterminer le statut d'un produit** :

Article 4 ***Definitions***		
En préambule, les AF s'interrogent de façon globale sur la cohérence de cet article : pourquoi **certaines notions sont définies dans les dispositions spécifiques du règlement et non dans l'article 4 relatif aux définitions (comme par exemple la notion de distribution de gros) ?**		
For the purposes of this Regulation, the following definitions shall apply: 1. 'veterinary medicinal product' means any substance or combination of substances which fulfils at least one of the following conditions: a) it is presented as having properties for treating or preventing disease in animals; b) its purpose is to be used in or administered to animals with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis; c) its purpose is to be used for euthanasia of animals;		

2. ‘substance’ means any matter of the following origin: a) human, b) animal, c) vegetable, d) chemical;	2) ‘substance’ means any matter of the following origin: a) human, b) animal, c) vegetable, d) chemical;	

	e) Active substance" means any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.	Les AF demanderont l'ajout d'une définition sur la substance active. **Etant donné que de nombreuses substances actives sont communes aux médicaments à usage humaine et aux médicaments vétérinaires et dans la mesure où les bases de données européennes sur les médicaments à usage humain et vétérinaires devront être développées selon la même architecture de données notamment la même base de référence pour les substances qui devra respecter les normes ISO IDMP/ SPOR conformément au plan stratégique informatique en cours d'adoption au niveau de l'EMA. Aussi, les AF proposent de reprendre la définition dans la législation sur le médicament à usage humain** (directive 2001/83/CE – article 1,point 3a), en ajoutant un point e) au paragraphe 2 de l'article 4. Par ailleurs, les AF demanderont à la Commission si elle a intégré dans sa réflexion la question des médicaments falsifiés (pour mémoire la définition de substance active a été introduire dans la directive 2001/83/CE par la directive 2011/62/UE sur les médicaments falsifiés).

3. ‘immunological veterinary medicinal product’ means a veterinary medicinal product **consisting of vaccines, toxins, sera or allergen products and intended to be administered to an animal in order to produce active or passive immunity or to diagnose its state of immunity;**	3. immunological veterinary medicinal product’ means a veterinary medicinal product **intended to be administered to an animal in order to produce active or passive immunity or to diagnose its state of immunity and defined by its immunological mechanisms(s) of action and i.e vaccines, toxins, sera or allergen products**.	Pour les médicaments vétérinaires immunologiques qui provoquent une immunité active ou passive**, la définition doit renvoyer à leur mode d’action plutôt qu’à une liste de produits.** Dès lors, si on **se réfère au mode d’action, cette définition inclura des produits qui peuvent être chimiquement ou non chimiquement définis.** En conséquence, **seuls les médicaments vétérinaires immunologiques qui peuvent être chimiquement définis et donc reproduits pourront bénéficier d’une autorisation de mise sur le marché** pour médicament générique défini au point 6.
4. ‘biological veterinary medicinal product’ means a veterinary medicinal product an active substance of which is a biological substance;		
5. ‘biological substance’ means a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with knowledge of the production process and its control;		

6. ‘generic veterinary medicinal product’ means a veterinary medicinal product which has the same qualitative and quantitative composition of active substances and the same pharmaceutical form as the reference medicinal product, and with regard to which appropriate bioavailability studies have demonstrated a bioequivalence with the reference veterinary medicinal product;	6. generic veterinary medicinal product’ means a veterinary medicinal product**, except immunological veterinary medicinal product non chemically defined,** which has the same qualitative and quantitative composition of active substances and the same pharmaceutical form as the reference medicinal product, and with regard to which appropriate bioavailability studies have demonstrated a bioequivalence with the reference veterinary medicinal product.	Cf commentaire à l’article 3
7. ‘homeopathic veterinary medicinal product’ means a veterinary medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias used officially in Member States;		
8. ‘antimicrobial resistance’ means the ability of microorganisms to survive or to grow in the presence of a concentration of an antimicrobial agent which is usually sufficient to inhibit or kill microorganisms of the same species;		

9. ‘clinical trial’ means a study which aims to examine under field conditions the safety or efficacy of a veterinary medicinal product or both under normal conditions of animal husbandry or as part of normal veterinary practice for the purpose of obtaining a marketing authorisation or a change thereof;		
10. ‘pre-clinical study’ means a study not covered by the definition of clinical trial which aims to investigate the safety or efficacy of a veterinary medicinal product for the purpose of obtaining a marketing authorisation or a change thereof;		
11. ‘benefit-risk balance’ means an evaluation of the positive effects of the veterinary medicinal product in relation to the following risks relating to the use of that product: a) any risk relating to the quality, safety and efficacy of the veterinary medicinal products as regards animal or human health; b) any risk of undesirable effects on the environment; c) any risk relating to the development of antimicrobial resistance;		

12. ‘common name’ means the international non-proprietary name recommended by the World Health Organisation for a veterinary medicinal product, or, if one does not exist, the name generally used;12)		
13. ‘strength’ means the content of active substances in a veterinary medicinal product, expressed quantitatively per dosage unit, per unit of volume or per unit of weight according to the pharmaceutical form;		
14. ‘competent authority’ means an authority designated by a Member State in accordance with Article 136;		
15. ‘labelling’ means information on the immediate packaging or the outer packaging;	.	
16. ‘outer packaging’ means packaging in which is placed the immediate packaging;		
17. ‘immediate packaging’ means the container or any other form of packaging that is in direct contact with the veterinary medicinal product;		
18. ‘package leaflet’ means a documentation leaflet on a veterinary medicinal product which contains information to ensure its safe and efficacious use;		

19. ‘letter of access’ means an original document, signed by the data owner or its representative, which states that the data may be used for the benefit of a third party by the competent authorities, the Agency or the Commission for the purposes of this Regulation;		
20. ‘limited market’ means a market for one of the following product types: a) veterinary medicinal products for the treatment or prevention of diseases that occur infrequently or in limited geographical areas; b) veterinary medicinal products for animal species other than cattle, **sheep, pigs, chickens, dogs and cats;**	20. ‘limited market’ means a market for one of the following product types: a) veterinary medicinal products for the treatment or prevention of diseases that occur infrequently or in limited geographical areas; b) veterinary medicinal products for animal species other than cattle, **pigs, chickens, dogs, cats, salmon and sheep reared for their meat;**	Les AF émettent une **réserve générale sur la notion de « marché limité ».** A ce stade, les AF souhaitent modifier le point b) de la définition pour être en cohérence avec la position de l'agence européenne du médicament : les **saumons**, ainsi que les **moutons destinés à l'alimentation humaine** (a contrario des brebis élevées pour leur lait) doivent être considérés comme des **espèces majeures**. Les AF s’interrogent sur le **sens donné au terme « unfrequently ».**

21. **'pharmacovigilance' means the process of monitoring and investigating adverse events;**	21. **Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem"**	Les AF proposent que la définition de la pharmacovigilance soit celle de l'OMS (cf chapitre IV section 6) Les AF relèvent l'absence de définitions des termes « events », « adverse events ».
22. 'pharmacovigilance system master file' means a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised veterinary medicinal products;		
23. 'control' means any task performed by a competent authority, including inspections, for the verification of compliance with this Regulation;		
24. 'veterinary prescription' means any prescription for a veterinary medicinal product issued by a professional person qualified to do so in accordance with applicable national law;	24. veterinary prescription' means any prescription for a veterinary medicinal product **or for a medicinal product for human use** issued by a professional person qualified to do so in accordance with applicable national law**;**	Les AF proposent une modification concernant la prescription vétérinaire - car celle-ci peut aussi comprendre des médicaments à usage humain. -

25. ‘withdrawal period’ means the minimum period between the last administration of a veterinary medicinal product to an animal and the production of foodstuffs from that animal which under normal conditions of use is necessary to ensure that such foodstuffs do not contain residues in quantities harmful to public health;		
	26. Reference medicinal product” shall mean a product authorized within the meaning of Article 5 in accordance with the provisions of Article 12	Les AF souhaitent que soient ajoutées les définitions de médicament de référence et de distribution en gros.
	27. Wholesale dealing in veterinary medicinal products: **Any activity which includes the purchase, sale, import, export, or any other commercial transaction in veterinary medicinal products, whether or not for profit, except for:** **- the supply by a manufacturer of veterinary medicinal products manufactured by himself,** **- retail supplies of veterinary medicinal products by persons entitled to carry out such supplies in accordance with Article 107.**	

26. ‘making available on the market’ means any supply of a veterinary medicinal product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;	**28.** ‘making available on the market’ means any supply of a veterinary medicinal product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;	Modification de la numérotation
27. ‘placing on the market’ means the first making available of a veterinary medicinal product on the Union market.	**29.** ‘placing on the market’ means the first making available of a veterinary medicinal product on the Union market.	
	30. ‘parallel importation’ means the importation into a Member State of a veterinary medicinal product authorized in another Member State in accordance with this Regulation and having the same characteristics as the veterinary medicinal product authorised in the Member State of import, in particular with: **a) the same qualitative and quantitative composition in terms of active substances and excipients and the same pharmaceutical form;** **b) the same therapeutic indications and target species.** **The medicinal product authorised in the Member State and the product imported in parallel must have been either harmonised under Article 69 or 70 or authorised in accordance with Articles 46 and 48.**	La jurisprudence communautaire a reconnu la possibilité aux entreprises de commercialiser un médicament vétérinaire autorisé dans un autre Etat membre dès lors qu’il est identique à un médicament vétérinaire autorisé dans le pays. Il convient de transposer cet acquis de la jurisprudence dans ce projet de règlement en qualifiant cette activité d’importation parallèle ou de distribution parallèle et de définir un dispositif d’encadrement de cette activité d dans l’Union Européenne. L’importation parallèle ne doit pas s’appliquer aux importations effectuées par les vétérinaires à des seules fins thérapeutiques pour une ou plusieurs exploitations ou propriétaires d’animaux.

	31. 'parallel distribution' means distribution from one Member State to another of a veterinary medicinal product authorised under a centralised procedure by an establishment authorised as referred to in Article 105 which is independent of the holder of the marketing authorisation.	L'amendement proposé introduit les définitions d'importation parallèle et distribution parallèle et introduit également deux articles nouveaux sur les autorisations d'importation et les demandes liées (cf articles 56 a et 56 b).
	32. 'antimicrobial' means any compound with a direct action on microorganisms that is used for treatment or prevention of infections. Antimicrobials include anti-bacterials/antibiotics, antivirals, anti-fungals and antiprotozoals;	Certains termes clés ne sont pas définis par la Commission et méritent d'être clarifiés et précisés afin d'éviter les confusions et de pouvoir être utilisés à bon escient dans le cadre de ce règlement.
	33. 'antibiotic' is synonymous with 'antibacterial';	
	34 curative (therapeutic) treatment' means treatment of an ill animal or group of animals, when the diagnosis of disease or infection has been made;	Les définitions proposées par les AF sont celles reprises du HMA et de l'EMA.

	35 metaphylaxis. In addition to treatment of clinically affected animals there is a need for administration of of a veterinary medicinal product to other animals in the same group, still clinically healthy but likely to be infected due to close contact with diseased animals **36 prophylaxis (preventive treatment): The term "treatment" refers to the treatment of an individual animal, or a group of animals showing clinical signs of an infectious disease. The term "prevention", refers to the administration of the product at the same time to other in-contact animals, to prevent them from developing clinical signs, and to prevent further spread of the disease. The presence of the disease in the group/flock must be established before the product is used.**	

	37 **Dividing up: all the operations which consist in retailing a veterinary medicinal product in units without opening or impairing the immediate packaging of the veterinary medicinal product.** **Immediate packaging : the container or other form of packaging immediately in contact with the medicinal product.**	Le terme “division” mentionné à l’article 91 n’est pas défini dans le règlement. Les AF proposent donc de le définir ici et de définir également à l’article 11bis l’étiquetage qui s’applique aux unités résultant de ces opérations de division. Les AF proposent également de définir la notion de conditionnement primaire en lien avec celle de division.

4. ‘biological veterinary medicinal product’ means a veterinary medicinal product an active substance of which is a biological substance;		
5. ‘biological substance’ means a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with knowledge of the production process and its control;		

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7. ‘homeopathic veterinary medicinal product’ means a veterinary medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias used officially in Member States;		

8. ‘antimicrobial resistance’ means the ability of microorganisms to survive or to grow in the presence of a concentration of an antimicrobial agent which is usually sufficient to inhibit or kill microorganisms of the same species;		
9. ‘clinical trial’ means a study which aims to examine under field conditions the safety or efficacy of a veterinary medicinal product or both under normal conditions of animal husbandry or as part of normal veterinary practice for the purpose of obtaining a marketing authorisation or a change thereof;		
10. ‘pre-clinical study’ means a study not covered by the definition of clinical trial which aims to investigate the safety or efficacy of a veterinary medicinal product for the purpose of obtaining a marketing authorisation or a change thereof;		

11. ‘benefit-risk balance’ means an evaluation of the positive effects of the veterinary medicinal product in relation to the following risks relating to the use of that product: a) any risk relating to the quality, safety and efficacy of the veterinary medicinal products as regards animal or human health; b) any risk of undesirable effects on the environment; c) any risk relating to the development of antimicrobial resistance;		
12. ‘common name’ means the international non-proprietary name recommended by the World Health Organisation for a veterinary medicinal product, or, if one does not exist, the name generally used;12)		

13. ‘strength’ means the content of active substances in a veterinary medicinal product, expressed quantitatively per dosage unit, per unit of volume or per unit of weight according to the pharmaceutical form;		

14. ‘competent authority’ means an authority designated by a Member State in accordance with Article 136;		
15. ‘labelling’ means information on the immediate packaging or the outer packaging;	.	
16. ‘outer packaging’ means packaging in which is placed the immediate packaging;		
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19. ‘letter of access’ means an original document, signed by the data owner or its representative, which states that the data may be used for the benefit of a third party by the competent authorities, the Agency or the Commission for the purposes of this Regulation;		
20. ‘limited market’ means a market for one of the following product types: a) veterinary medicinal products for the treatment or prevention of diseases that occur infrequently or in limited geographical areas; b) veterinary medicinal products for animal species other than cattle, **sheep, pigs, chickens, dogs and cats;**	20. ‘limited market’ means a market for one of the following product types: a) veterinary medicinal products for the treatment or prevention of diseases that occur infrequently or in limited geographical areas; b) veterinary medicinal products for animal species other than cattle, **pigs, chickens, dogs, cats, salmon and sheep reared for their meat;**	Les AF émettent une **réserve générale sur la notion de « marché limité ».** (1) A ce stade, les AF souhaitent modifier le point b) de la définition pour être en cohérence avec la position de l'agence européenne du médicament : les **saumons**, ainsi que les **moutons destinés à l'alimentation humaine** (a contrario des brebis élevées pour leur lait) doivent être considérés comme des **espèces majeures**.

		(2) Les AF s'interrogent sur le **sens donné au terme « unfrequently ».**
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22. 'pharmacovigilance system master file' means a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised veterinary medicinal products;		
23. 'control' means any task performed by a competent authority, including inspections, for the verification of compliance with this Regulation;		

24. ‘veterinary prescription‘ means any prescription for a veterinary medicinal product issued by a professional person qualified to do so in accordance with applicable national law;	24. veterinary prescription‘ means any prescription for a veterinary medicinal product **or for a medicinal product for human use** issued by a professional person qualified to do so in accordance with applicable national law**;**	Les AF proposent une modification concernant la prescription vétérinaire - car celle-ci peut aussi comprendre des médicaments à usage humain. -
25. ‘withdrawal period’ means the minimum period between the last administration of a veterinary medicinal product to an animal and the production of foodstuffs from that animal which under normal conditions of use is necessary to ensure that such foodstuffs do not contain residues in quantities harmful to public health;		
	26. Reference medicinal product” shall mean a product authorized within the meaning of Article 5 in accordance with the provisions of Article 12	Les AF souhaitent que soient ajoutées les définitions de médicament de référence et de distribution en gros.

	27. Wholesale dealing in veterinary medicinal products: **Any activity which includes the purchase, sale, import, export, or any other commercial transaction in veterinary medicinal products, whether or not for profit, except for:** **- the supply by a manufacturer of veterinary medicinal products manufactured by himself,** **- retail supplies of veterinary medicinal products by persons entitled to carry out such supplies in accordance with Article 107.**	
26. 'making available on the market' means any supply of a veterinary medicinal product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;	**28.** 'making available on the market' means any supply of a veterinary medicinal product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;	Modification de la numérotation
27. 'placing on the market' means the first making available of a veterinary medicinal product on the Union market.	**29.** 'placing on the market' means the first making available of a veterinary medicinal product on the Union market.	

	30. 'parallel importation' means the importation into a Member State of a veterinary medicinal product authorized in another Member State in accordance with this Regulation and having the same characteristics as the veterinary medicinal product authorised in the Member State of import, in particular with: **a) the same qualitative and quantitative composition in terms of active substances and excipients and the same pharmaceutical form;** **b) the same therapeutic indications and target species. The medicinal product authorised in the Member State and the product imported in parallel must have been either harmonised under Article 69 or 70 or authorised in accordance with Articles 46 and 48.** **31. 'parallel distribution' means distribution from one Member State to another of a veterinary medicinal product authorised under a centralised procedure by an establishment authorised as referred to in Article 105 which is independent of the holder of the**	La jurisprudence communautaire a reconnu la possibilité aux entreprises de commercialiser un médicament vétérinaire autorisé dans un autre Etat membre dès lors qu'il est identique à un médicament vétérinaire autorisé dans le pays. Il convient de transposer cet acquis de la jurisprudence dans ce projet de règlement en qualifiant cette activité d'importation parallèle ou de distribution parallèle et de définir un dispositif d'encadrement de cette activité d dans l'Union Européenne. L'importation parallèle ne doit pas s'appliquer aux importations effectuées par les vétérinaires à des seules fins thérapeutiques pour une ou plusieurs exploitations ou propriétaires d'animaux. L'amendement proposé introduit les définitions d'importation parallèle et

	marketing authorisation. **32. 'antimicrobial' means any compound with a direct action on microorganisms that is used for treatment or prevention of infections. Antimicrobials include anti-bacterials/antibiotics, antivirals, anti-fungals and antiprotozoals;** **33. 'antibiotic' is synonymous with 'antibacterial';** **34 curative (therapeutic) treatment' means treatment of an ill animal or group of animals, when the diagnosis of disease or infection has been made;** **35 metaphylaxis. In addition to treatment of clinically affected animals there is a need for administration of of a veterinary medicinal product to other animals in the same group, still clinically healthy but likely to be infected due to close contact with diseased animals**	distribution parallèle et introduit également deux articles nouveaux sur les autorisations d'importation et les demandes liées (cf articles 56 a et 56 b). . (3) Certains termes clés ne sont pas définis par la Commission et méritent d'être clarifiés et précisés afin d'éviter les confusions et de pouvoir être utilisés à bon escient dans le cadre de ce règlement. Les définitions proposées par les AF sont celles reprises du HMA et de l'EMA.

	36 prophylaxis (preventive treatment): The term "treatment" refers to the treatment of an individual animal, or a group of animals showing clinical signs of an infectious disease. The term "prevention", refers to the administration of the product at the same time to other in-contact animals, to prevent them from developing clinical signs, and to prevent further spread of the disease. The presence of the disease in the group/flock must be established before the product is used.	
	37 **Dividing up: all the operations which consist in retailing a veterinary medicinal product in units without opening or impairing the immediate packaging of the veterinary medicinal product.** **Immediate packaging : the container or other form of packaging immediately in contact with the medicinal product.**	Le terme "division" mentionné à l'article 91 n'est pas défini dans le règlement. Les AF proposent donc de le définir ici et de définir également à l'article 11bis l'étiquetage qui s'applique aux unités résultant de ces opérations de division. Les AF proposent également de définir la notion de conditionnement primaire en lien avec celle de division.

Chapitre II **Marketing authorisations - General provisions and rules on applications**		
SECTION 1 **GENERAL PROVISIONS**		
Article 5 *Marketing authorisations*		
1. A veterinary medicinal product shall be placed on the market only when a marketing authorisation has been granted **in respect of the product** by a competent authority in accordance with Articles 44, 46 or 48 or by the Commission in accordance with Article 40.	***1.*** *A veterinary medicinal product shall be placed on the market only when a marketing authorisation has been granted by a competent authority in accordance with Articles 44, 46 or 48 or by the Commission in accordance with Article 40.*	Les AF proposent la suppression **des termes « in respect of the product ».**

2. A marketing authorisation for a veterinary medicinal product shall be valid for **an unlimited period of time.**	2. A marketing authorisation for a veterinary medicinal product shall be valid for **ten years. The authorisation may be renewed after ten years on the basis of a re-evaluation of the risk-benefit balance. To this end, the marketing authorisation holder shall submit, at least six months before the marketing authorization, all complementary necessary informations in order to detect and evaluate any variation of the risk-benefit balance, including informations regarding antimicrobial resistance development if the renewal of the marketing authorization is for an antimicrobial veterinary medicinal product.**	Les AF considèrent qu'accorder d'emblée une durée illimitée à l'AMM, au lieu de 5 ans dans la directive actuelle, risque de diminuer fortement l'implication des laboratoires au cours des premières années de vie du médicament qui est la période où les risques ne sont pas encore bien identifiés. Les AF proposent de fixer **la durée de validité de l'AMM à 10 ans.**

3. Decisions to grant, refuse, suspend, withdraw or vary a marketing authorisation shall be made public.		
4. Applicants for marketing authorisations and marketing authorisation holders shall be established in the Union.	***5. If, after receiving marketing authorisation, a veterinary medicinal product is not marketed in any of the Member States concerned within five years, the authorisation shall lapse.*** ***The competent authority may, in exceptional circumstances, and on grounds of the protection of human or animal health, grant exemptions from the first paragraph.***	Les AF souhaitent **le maintien de la clause de caducité.** Cependant, il est proposé d'assouplir cette clause par l'extension du délai de non commercialisation à 5 ans consécutifs, et sous réserve que l'absence de commercialisation soit constatée dans tous les Etats membres concernés par la procédure d'AMM.

Article 6 *Submission of applications for marketing authorisations*		
1. Applications shall be submitted to the competent authority where they concern the granting of marketing authorisations in accordance with any of the following procedures: a) the national procedure laid down in Articles 42, 43 and 44; b) the decentralised procedure laid down in Articles 45 and 46; c) the mutual recognition procedure laid down in Articles 47 and 48. 2. Applications for the granting of marketing authorisations in accordance with the centralised marketing authorisation procedure laid down in Articles 38 to 41 shall be submitted to the European Medicines Agency ('the Agency') established by Regulation (EC) No 726/2004. 3. Applications shall be submitted		

electronically. For applications submitted in accordance with the centralised marketing authorisation procedure, the formats made available by the Agency shall be used.		
4. The applicant shall be responsible for the accuracy of the documents and data submitted.		
5. Within 15 days of receipt of the application, the competent authority or the Agency shall notify the applicant of whether all data required in accordance with Article 7 have been presented. 6. Where the competent authority or the Agency considers that the application is incomplete, it shall inform the applicant accordingly and shall set a time limit for submitting the missing information		

SECTION 2 **DOSSIER REQUIREMENTS**		
Article 7 *Data to be submitted with the application*		
1. An application for a marketing authorisation shall contain the following information: a) the administrative information set out in Annex I; b) technical documentation satisfying the requirements set out in Annex II; c) the information to be provided in the immediate packaging, outer packaging and the package leaflet in accordance with Articles 9 to 14.	1. An application for a marketing authorisation shall contain the following information **necessary for demonstrating the quality, safety and efficacy of the veterinary medicinal product in question and for demonstrating that the risk-benefit balance is positive** : a) the administrative information set out in Annex I; b) technical documentation satisfying the requirements set out in Annex II; c) the information to be provided in the immediate packaging, outer packaging and the package leaflet in accordance with Articles 9 to 14.	Pour pouvoir évaluer correctement la balance bénéfice/risque des médicaments vétérinaires il est nécessaire que les dossiers déposés contiennent l'ensemble des données nécessaires. Cet amendement permet que soient explicitement exprimés les objectifs de la documentation fournie dans le dossier d'AMM, à savoir la démonstration de la qualité, de la sécurité et de l'efficacité du médicament vétérinaire, ainsi que la démonstration d'une balance bénéfices/risques positive

2. Where the application concerns an antimicrobial veterinary medicinal product, the following shall be submitted in addition to the information listed in paragraph 1: a) documentation on the direct or indirect risks to public or animal health of use of the antimicrobial veterinary medicinal product in animals, b) information about risk mitigation measures to limit antimicrobial resistance development related to the use of veterinary medicinal product.		

	2bis. Where the application concerns a veterinary medicinal product intended to be used for the manufacture of medicated feedingstuffs, the following shall be submitted in addition to the information listed in paragraph 1 : **a) all technical documentation, including a detailed and full description of the tests, studies and trials conducted, relevant and of sufficient quality to demonstrate the quality, safety and efficacy of the medicated feedingstuffs intended to be manufactured with the veterinary medicinal product;** **b) sufficient data to establish that the veterinary medicinal products incorporated into the feed create with the feed a stable mixture for all the storage life of the medicated feedingstuffs.**	L'article 5 de la proposition de règlement relative aux aliments médicamenteux prévoit qu'un aliment médicamenteux ne peut être fabriqué qu'à partir d'un médicament vétérinaire autorisé spécifiquement pour être incorporé dans un aliment médicamenteux. Cette disposition doit s'accompagner en miroir de mesures dans le règlement relatif aux médicaments vétérinaires : les AF proposent l'ajout d'un paragraphe 7.2bis (données à fournir avec la demande), d'un paragraphe 28. 1 c) bis et d'un paragraphe 30.1 l).

3. Where the application concerns a veterinary medicinal product intended for food-producing target species and containing pharmacologically active substances that are not listed in Table 1 of the Annex to Regulation (EU) No 37/2010 for the animal species in question, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council shall be submitted in addition to the information listed in paragraph 1.	**3. A veterinary medicinal product may not be the subject of a marketing authorisation for the purpose of administering it to one or more food-producing species unless the pharmacologically active substances which it contains appears in table 1 of the Annex to Regulation EU No 37/2010 for the animal species in question.** **In the case of veterinary medicinal product which are intended for food-producing target species contains pharmacologically active substances which have not yet been included, for the species in question, in Table 1 of the Annex to Regulation (EU) No 37/2010, the application shall contain a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council.**	Les AF considèrent que la nouvelle proposition est moins claire que l'article 6 de la directive 2001/82 actuelle. Aussi, les AF proposent de réintroduire cet article.

4. Paragraph 3 shall not apply to veterinary medicinal products intended for animals of the equidae family that have been declared as not being intended for slaughter for human consumption in accordance with Commission Regulation (EC) 504/2008 and the active substances contained in those veterinary medicinal products are not listed in Table 2 of the Annex to Regulation (EU) No 37/2010.		Les autorités françaises notent que la proposition de la Commission allège les conditions de la dérogation permettant de délivrer des AMM aux médicaments pour chevaux non destinés à la consommation humaine. En effet, l'article 7.4 de la proposition ne reprend pas deux conditions de la dérogation qui étaient prévues à l'article 6(3) de la directive 2001/82 en vigueur : la substance active ne doit pas être inscrite sur le tableau 1 du règlement n°37/2010 et le médicament vétérinaire ne doit pas être utilisé pour une maladie pour laquelle un médicament vétérinaire est déjà autorisé pour les équidés. Par conséquent, la proposition législative de la Commission n'encourage pas l'industrie à développer des médicaments avec un temps d'attente spécifique pour les chevaux destinés à la consommation humaine.

		Cet allègement de la législation inquiète les autorités françaises car elles craignent un recours excessif à la cascade pour les chevaux qui sont déclarés comme destinés à l'abattage pour la consommation humaine. Or l'étude d'impact de la Commission indique que la situation actuelle a déjà pour conséquence un recours à la cascade fréquent pour les chevaux, en raison de la faible disponibilité des médicaments pour cette filière.
5. Where the application concerns a veterinary medicinal product containing or consisting of genetically modified organisms within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council the application shall in addition to the documents listed in paragraph 1 be accompanied by:	.	

a) a copy of the written consent of the competent authorities to the deliberate release into the environment of the genetically modified organisms for research and development purposes, as provided for in Part B of Directive 2001/18/EC; b) the complete technical file supplying the information required under Annexes III and IV to Directive 2001/18/EC; c) the environmental risk assessment in accordance with the principles set out in Annex II to Directive 2001/18/EC; and d) the results of any investigations performed for the purposes of research or development.		

6. Where the application is submitted in accordance with the national procedure laid down in Articles 42, 43 and 44, the applicant shall, in addition to the information listed in paragraph 1, submit a declaration stating that he has not submitted an application for a marketing authorisation for the veterinary medicinal product in another Member State.		
7. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to amend Annexes I and II to adapt the information and documentation requirements to technical and scientific progress.		

SECTION 3 **CLINICAL TRIALS**		
Article 8 Approval of clinical trials		
1. An application for the approval of a clinical trial shall be submitted to a competent authority of the Member State in which the clinical trial is to take place.		
2. Approvals of clinical trials shall be granted on condition that food-producing animals used in the clinical trials or their produce do not enter the human food chain unless: **a) the tested product is a veterinary medicinal product authorised for the food-producing species used in the clinical trial, and the withdrawal period set out in the summary of the product characteristics is respected, or**	**2. Member States shall not permit test animals to be used as a source of foodstuffs for human consumption unless the competent authorities have established an appropriate withdrawal period. Such period shall either :** **a) be at least as long as the withdrawal period laid down in Article 117, including, where appropriate, a safety factor reflecting the nature of the substance being tested; or**	Interdire aux animaux objets d'essais cliniques de rejoindre la chaîne alimentaire est susceptible d'avoir des conséquences très graves sur l'équilibre économique de la recherche clinique. Les animaux ayant reçu des médicaments contenant une substance bénéficiant déjà d'une limite maximale de résidus et pour laquelle un temps d'attente pourra être fixé devraient être autorisés à rejoindre la chaîne alimentaire.

b) the tested product is an authorised veterinary medicinal product for target species other than the food-producing species used in the clinical trial and the withdrawal period set out in accordance with Article 117 is respected.	**b) if maximum residue limits have been established by the Union in accordance with Regulation (EC) No 470/2009, the period shall be such as to ensure that those residue limits will not be exceeded in foodstuffs.**	

3. The competent authority shall issue a decision on the approval of a clinical trial within 60 days after the receipt of an application. Where the competent authority has not notified the applicant of its decision within that time limit, the clinical trial shall be considered to have been approved.		
4. The clinical trials referred to in paragraph 1 shall be carried out taking due account of the standards set by the international guidelines on good clinical practice of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.		
5. Results of clinical trials shall be submitted with the application for a marketing authorisation for the purposes of providing the documentation referred to in Article 7(1)(b).		

6. Data stemming from clinical trials conducted outside the Union may be taken into consideration for the assessment of an application for a marketing authorisation only if those trials were designed, implemented and reported in accordance with the standards set by the international guidelines on good clinical practice of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products. 3. The competent authority shall issue a decision on the approval of a clinical trial within 60 days after the receipt of an application. Where the competent authority has not notified its decision to the applicant within that time limit, the clinical trial shall be considered to have been approved.		
4. The clinical trials referred to in paragraph 1 shall be carried out taking into account the standards set by the International guidelines on good clinical practice of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products. 3. L'autorité compétente rend une décision sur l'approbation d'un essai clinique dans les soixante jours suivant la réception d'une demande. Lorsque l'autorité compétente n'a pas notifié sa décision au demandeur dans ce délai, l'essai clinique est considéré comme ayant été approuvé.		
5. Results of clinical trials shall be submitted with the application for a marketing authorisation for the purposes of providing the		
documentation referred to in Article 7(1)(b).		

6. Data stemming from clinical trials conducted outside the Union may be taken into consideration for the assessment of an application for a marketing authorisation only if those trials were designed, implemented and reported in accordance with the standards set by the international guidelines on good clinical practice of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.3. L'autorité compétente rend une décision sur l'approbation d'un essai clinique dans les soixante jours qui suivent la réception d'une demande. Lorsque l'autorité compétente n'a pas notifié sa décision au demandeur dans ce délai, l'essai clinique est considéré comme ayant été approuvé..		

SECTION 4. **LABELLING AND PACKAGE LEAFLET**		
En préambule, les AF souhaitent porter une proposition de modification commune aux articles 9 à 13 : les informations mentionnées à l'étiquetage et la notice doivent être conformes aux RCP		
Article 9 *Labelling of the immediate packaging of veterinary medicinal products*		
1. The immediate packaging of a veterinary medicinal product shall contain **only** the following information:	**"**The immediate packaging of a veterinary medicinal product shall contain the following information **and shall comply with the summary of the product characteristics":**	Les AF souhaitent **supprimer le terme « uniquement » de la première phrase du paragraphe 1**
a) the name of the veterinary medicinal	a) the name of the veterinary medicinal	

product, followed by its strength and pharmaceutical form; b) a statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using their common names; c) the batch number, preceded by the word "Lot"; d) the name or corporate name or logo name of the marketing authorisation holder; e) the target species; f) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp."; g) special storage precautions, if any.	product, followed by its strength and pharmaceutical form; b) a statement of the active substances expressed qualitatively and quantitatively per unit or according to the form of administration for a particular volume or weight, using their common names; c) the batch number, preceded by the word "Lot"; d) the name or corporate name or logo name of the marketing authorisation holder; e) the target species; f) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp."; (g) special storage precautions, if any.	

	h) the marketing authorisation number **i) the withdrawal period for veterinary medicinal products to be administered to food-producing species, for all the species concerned and for the various foodstuffs concerned (meat and offal, egg, milk, honey), including those for which the withdrawal period is zero** **j) particulars that are essential for safety or health protection, including any special precautions relating to use and any other warnings resulting from the clinical and pharmacological trials or from experience gained during the use of the veterinary medicinal product once it has been marketed.** **k) The words 'For animal treatment only'**	**Les AF proposent de rajouter des mentions parmi les informations portées sur le conditionnement primaire** (mentions qui existent actuellement dans la directive 2001/82/CE à l'article 58) : **le n° d'AMM, le temps d'attente, les informations imposées au titulaire d'AMM pour la sécurité ou pour la protection de la santé (informations imposées en vertu de l'article 26 de la directive 2001/82 en vigueur), ainsi que la mention « à usage vétérinaire », ou, dans le cas des médicaments soumis à prescription « à usage vétérinaire – à ne délivrer que sur ordonnance ».**

2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, or, where appropriate, abbreviations or pictograms common throughout the Union.	**or, in the case of the medicinal products subject to veterinary prescriptions, the words 'For animal treatment only — to be supplied only on veterinary prescription'.**	

Article 10 *Labelling of the outer packaging of veterinary medicinal products*		
1. The outer packaging of a veterinary medicinal product shall contain **only** the following information**:** a) the information listed in Article 9(1); b) the contents by weight, volume or number of immediate packaging units of the veterinary medicinal product; c) warning that the veterinary medicinal product must be kept out of the sight and reach of children; d) warning that the veterinary medicinal product is for animal treatment only; e) recommendation to read the package leaflet; f) requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or	**1.** The outer packaging of a veterinary medicinal product shall contain the following information **and shall comply with the summary of the product characteristics"**	Les AF souhaitent supprimer le terme « uniquement » de la **première phrase du paragraphe 1**

waste materials derived from the use of such products and, if appropriate, additional precautions as regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products; g) in case of homeopathic veterinary medicinal products, the statement "homeopathic veterinary medicinal product".	**(h) additional information concerning distribution, possession, sale or any necessary precautions in accordance with the national legislation of the Member State in which the product is placed on the market. Space shall be provided for the prescribed dose to be indicated.**	Les AF **proposent d'introduire un point h**) supplémentaire à la liste pour **prévoir les informations additionnelles concernant la distribution, la détention, la vente ou les mesures de précaution éventuelles en application de la législation nationale du pays où le médicament est mis sur le marché**. Les AF souhaitent également qu'un espace soit prévu pour indiquer la posologie prescrite.

2. The information listed in paragraph 1 shall appear in easily legible and clearly comprehensible characters, or, where appropriate, abbreviations or pictograms common throughout the Union. 3. Where there is no outer packaging, all the particulars listed in paragraph 1 shall appear on the immediate packaging.		
Article 11 *Labelling of small immediate packaging units of veterinary medicinal products*		
1. By way of derogation from Article 9, small immediate packaging units shall contain only the following information: a) the name of veterinary medicinal product; b) the quantitative particulars of the active substances;	1 By way of derogation from Article 9, small immediate packaging units shall contain only the following information **and shall comply with the summary of the product characteristics"** a) the name of veterinary medicinal product; b) the quantitative particulars of the active substances;	

c) the batch number, preceded by the word "Lot"; d) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp.".	c) the batch number, preceded by the word "Lot"; d) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp.". **e) the words « For animal treatment only »**	Les AF souhaitent que soit **indiquée la mention « à usage vétérinaire »** et que soit définie par actes d'application la notion de « unités de conditionnement de petite taille ». Par ailleurs, les AF souhaitent que ces dispositions s'appliquent aux unités résultant de la « division » (« dividing up ») du point 2 de l'article 91. Elles proposent une définition des notions **de « division » et d'unités.** Les AF souhaitent rappeler que cette opération de « division » ne doit pas conduire à un déconditionnement de la spécialité pharmaceutique de son conditionnement primaire et que les mentions

		minimales que doivent comporter les unités issues de cette division doivent être définies de façon harmonisée au niveau communautaire.
Article 11bis (new)	**Article 11bis (new)** **Labelling of units resulting from dividing up**	
	By way of derogation from Article 9, units resulting from dividing up shall contain only the following information and shall comply with the summary of the product characteristics : **a) the name of veterinary medicinal product;** **b) the strength of the veterinary medicinal product;** **c) the batch number, preceded by the word "Lot";** **d) the expiry date, in the format: "mm/yyyy", preceded by the abbreviation "Exp.".** e) **the words « For animal treatment only »**	

Article 12 *Package leaflet of veterinary medicinal products*		
	0. The inclusion of a package leaflet in the packaging of veterinary medicinal products shall be obligatory unless all the information required by this article can be conveyed on the immediate packaging and the outer packaging. Member States shall take all appropriate measures to ensure that the package leaflet relates solely to the veterinary medicinal product with which it is included.	Les AF souhaitent **réintégrer une des dispositions du premier alinéa du paragraphe 1 de l'article 61 de la directive 2001/82/CE** actuelle qui prévoit qu'il est obligatoire de joindre une notice au conditionnement du médicament vétérinaire, à moins que tous les renseignements exigés en vertu du présent article figurent sur le conditionnement primaire et l'emballage extérieur .
1. The package leaflet shall be available for each veterinary medicinal product **and** shall contain at least the following information:	1 . The package leaflet shall be available for each veterinary medicinal product, shall contain at least the following information **and shall comply with the summary of the product**	

a) the name or corporate name and permanent address or registered place of business of the marketing authorisation holder and of the manufacturer and, where applicable, of the representative of the marketing authorisation holder;	**characteristics :**	

b) the name of the veterinary medicinal product or, where applicable, a list of the names of the veterinary medicinal product, as authorised in different Member States; c) the strength and pharmaceutical form of the veterinary medicinal product; d) the target species, the dosage for each species, the method and route of administration and advice on correct administration, if necessary; e) the therapeutic indications; f) the contra-indications and adverse events in so far as this information is necessary for the		

use of the veterinary medicinal product; g) the withdrawal period, even if this is nil, in the event that the target species are food-producing animals; h) special storage precautions, if any; (i) information essential for safety or health protection, including any special precautions relating to use and any other warnings; j) requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, additional precautions regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the		

use of such products;		
k) the marketing authorisation number;		
l) in case of generic **veterinary medicinal products,** the statement 'generic veterinary medicinal product';	l) in case of generic **or hybrid or veterinary medicinal products which marketing authorization application is based on informed consent,** the statement **"**generic veterinary medicinal product" **or "hybrid veterinary medicinal product" or "veterinary medicinal product which marketing authorization application is based on informed consent", and the name of the reference veterinary medicinal product ;**	Par ailleurs, les AF proposent d'inclure dans le point l) du paragraphe 1, les autres médicaments mentionnés à la section 5 du chapitre II (médicaments hybrides, …) et d'indiquer dans la notice de ces médicaments le nom du médicament de référence et l'indication de l'EM dans lequel il a été autorisé. .
m) in case of homeopathic veterinary medicinal products, the statement	**m) deleted**	Point repris à l'article 13.1 Les AF se demandent si cet article 12 s'applique

"homeopathic veterinary medicinal product".		à tous les médicaments faisant l'objet d'un dossier abrégé et réduits de demande d'autorisation de mise sur le marché (tels qu'indiqués à l'annexe III du projet de règlement)
2. The package leaflet may bear additional information concerning distribution, possession or any necessary precaution in conformity with the marketing authorisation, provided that the information is not promotional. This additional information shall appear in the package leaflet clearly separated from the information referred to in paragraph 1.		
3. The package leaflet shall be written and designed to be clear and understandable, in terms that are comprehensible to the general public. 1.		

Article 13 *Package leaflet of homeopathic veterinary medicinal products*		
By way of derogation from Article 12(1), the package leaflet for homeopathic veterinary medicinal products registered in accordance with Articles 89 to 90 shall contain only the following information: a) the scientific name of the stock or stocks followed by the degree of dilution, using the symbols of the European Pharmacopoeia or, in the absence thereof, of the pharmacopoeias currently used officially in Member States; b) name and address of the marketing authorisation holder and, where appropriate, of the manufacturer; c) method of administration and, if necessary, route;	"By way of derogation from Article 12(1), the package leaflet for homeopathic veterinary medicinal products registered in accordance with Articles 89 to 90 shall contain only the following information **and shall comply with the summary of the product characteristics"**	Les AF s'interrogent sur la raison de la disparition de la mention « contenance du modèle de vente » des informations de la notice du médicament homéopathique vétérinaire.

d) the expiry date, in the format "mm/yyyy", preceded by the abbreviation "Exp."; e) pharmaceutical form; f) special storage precautions, if any; g) target species; h) a special warning if necessary for the medicinal product; i) the batch number, preceded by the word "Lot"; j) registration number; k) withdrawal period, if applicable. l) the statement "homeopathic veterinary medicinal product".		

Article 14 *Languages*		
1. The language or languages of the information on the labelling shall be determined by Member State where the veterinary medicinal product is made available on the market. 2. Member States shall communicate the languages determined by them for the purpose of paragraph 1 to the Commission. The Commission shall make this information public. 3. Veterinary medicinal products may be **labelled** in several languages**.**	1. The language or languages of the information on the labelling **and the package leaflet** shall be determined by the Member State where the veterinary medicinal product is made available on the market. 3. **Labelling and package leaflet of** veterinary medicinal products may be **written** in several languages.	Les AF proposent la modification ci-contre à l'article 14 afin d'intégrer la notice dans le champ d'application de l'article.

Article 15 *Abbreviations and pictograms common throughout the Union*		
The Commission shall, by means of implementing acts, adopt a list of the abbreviations and pictograms common throughout the Union to be used for the purposes of Article 9(2) and Article 10(2). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2		

SECTION 5 **DOSSIER REQUIREMENTS FOR GENERIC, COMBINATION AND HYBRID VETERINARY MEDICINAL PRODUCTS AND FOR APPLICATIONS BASED ON INFORMED CONSENT AND BIBLIOGRAPHIC DATA**		
Les AF demandent à la Commission d'introduire dans la section 5 un article supplémentaire spécifique aux « médicaments vétérinaires biologiques similaires » qui définirait les exigences applicables aux dossiers de demandes de ces produits en renvoyant à l'annexe III (point2).		
Article 16 *Generic veterinary medicinal products*		
1. By way of derogation from Article 7(1)(b), an application for a marketing authorisation for a generic veterinary medicinal products shall not contain **the documentation on safety and efficacy if all the following conditions are fulfilled:** a) the application satisfies the requirements set out in Annex III;	**1**.By way of derogation from Article 7(1)(b), an application for a marketing authorisation for a generic veterinary medicinal products shall not contain **the results of the safety and residue tests or of the pre-clinical and clinical trials** if all the following conditions are fulfilled :	Les AF souhaitent émettre **une réserve générale sur l'Annexe III mentionnée au a)** portant sur les exigences relatives aux dossiers abrégés et réduits de demande d'autorisation de mise sur le marché car cette annexe n'est pas assez détaillée. Les AF souhaitent modifier le paragraphe 1

b) the applicant can demonstrate that the application concerns a generic veterinary medicinal product of a veterinary medicinal product which has been authorised by a Member State or by the Commission, and the period of protection of the technical documentation in respect of that reference veterinary medicinal product laid down in Articles 34 and 35 has elapsed or is due to elapse in less than 2 years ('reference veterinary medicinal product'); c) documentation referred to in Article 7-1.b) is available for the reference veterinary medicinal product to the competent authority or to the Agency.		pour que la dérogation aux données à fournir à la demande soit plus explicite : **il ne faut pas viser l'absence de « documentation relative à l'innocuité et à l'efficacité » mais bien les résultats des tests d'innocuité et de résidus ou les résultats des études pré-cliniques ou cliniques.** Les AF s'interrogent sur le point c) du paragraphe 1 car il **ne paraît pas envisageable que l'EM de référence reçoive une copie de toute la demande du médicament de référence** : il convient de limiter la documentation requise aux informations minimales sur le médicament de référence (MIRP = minimum information on the reference product). Aussi, les AF s'interrogent: la documentation « à disposition » est-elle fournie obligatoirement ou uniquement sur demande ?

2. For the purpose of this Section, where the active substance consists of salts, esters, ethers, isomers and mixtures of isomers, complexes or derivatives differing from the active substance used in the reference veterinary medicinal product, it shall be considered to be the same active substance as that used in the reference veterinary medicinal product, unless it differs significantly in respect of properties with regard to safety or efficacy. Where it differs significantly in respect of those properties, the applicant shall submit additional information in order to prove the safety and/or efficacy of the various salts, esters or derivatives of the authorised active substance of the reference veterinary medicinal product.	2. For the purpose of this Section, where the active substance consists of salts, esters, ethers, isomers and mixtures of isomers, complexes or derivatives differing from the active substance used in the reference veterinary medicinal product, it shall be considered to be the same active substance as that used in the reference veterinary medicinal product, unless it differs significantly in respect of properties with regard to safety or efficacy. Where it differs significantly in respect of those properties, the applicant shall submit additional information in order to prove the safety and/or efficacy of the various salts, esters or derivatives of the authorised active substance of the reference veterinary medicinal product. **The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form** ».	Les AF proposent une **précision quant aux différentes formes orales à libération immédiate pour qu'elles soient considérées comme une seule et même forme pharmaceutique (comme prévu au point b) de l'article 13** de la directive 2001/82/CE en vigueur).

		De plus, les AF rappellent également **que cette section ne doit pas s'appliquer aux médicaments génériques immunologiques non définis chimiquement** (en cohérence avec la position exprimée précédemment par les AF sur l'exclusion de ces produits de la définition du médicament générique – article 4 point 6)
3. Where the reference veterinary medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted, or the application is submitted in accordance with Article 38(3) where the reference medicinal product **was authorised** in a Member State, the applicant shall indicate in its application the Member State in which the reference veterinary medicinal product has **been authorised.**	Where the reference veterinary medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted, or the application is submitted in accordance with Article 38(3) where the reference medicinal product **has a valid authorisation** in a Member State, the applicant shall indicate in its application the Member State in which the reference veterinary medicinal product has **a valid authorisation.**	Cette disposition permet que des médicaments génériques soient autorisés alors que les médicaments de référence ne disposent plus d'autorisation encore valide. De plus, les AF ne sont pas favorables à ce qu'une demande de générique puisse être déposée pour un médicament de référence qui n'est pas commercialisé ou dont l'AMM est suspendue ou supprimée.

4. The competent authority or the Agency may request information on the reference veterinary medicinal product from the competent authority of the Member State where it was authorised. Such information shall be transmitted to the requestor within 30 days of receipt of the request.		
5. The summary of the product characteristics of the generic veterinary medicinal product shall be identical to that of the reference veterinary medicinal product. However, that requirement shall not apply to those parts of the summary of the product characteristics of the reference veterinary medicinal product that refer to indications or pharmaceutical forms which are still covered by patent law at the time when the generic veterinary medicinal product is authorised.		Les AF sont favorables à cette disposition qui prévoit que le résumé des caractéristiques du produit (RCP) d'un médicament vétérinaire générique est identique à celui du médicament vétérinaire de référence, sauf pour les parties du RCP du médicament de référence qui renvoient à des indications ou à des formes pharmaceutiques encore protégées par le droit des brevets. Les AF soulignent que les temps d'attente peuvent varier selon la formulation pharmaceutique ou la voie d'administration.

6. A competent authority or the Agency may require the applicant to provide safety data concerning the potential risks posed by the generic veterinary medicinal product to the environment in case the marketing authorisation for the reference veterinary medicinal product was granted before 20 July 2000 or in case the second phase environmental risk assessment was required for the reference veterinary medicinal product. 7. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 concerning amendments to Annex III in order to adapt the requirements to technical and scientific progress.Article 22		

Article 17 *Combination veterinary medicinal products*		
By way of derogation from Article 7(1)(b) an application for a marketing authorisation for a veterinary medicinal product containing a combination of active substances that have each already been used in authorised veterinary medicinal products, but have not hitherto been authorised in that combination ('combination veterinary medicinal product') shall satisfy the following criteria: a) the application satisfies the requirements set out in Annex III; b) the applicant can demonstrate that the veterinary medicinal product is a combination of reference veterinary medicinal products as referred to in Article 16(1)(b);	By way of derogation from Article 7(1)(b**), and except for immunological veterinary medicinal products,** an application for a marketing authorisation for a veterinary medicinal product containing a combination of active substances that have each already been used in authorised veterinary medicinal products, but have not hitherto been authorised in that combination ('combination veterinary medicinal product') shall satisfy the following criteria: a) the application satisfies the requirements set out in Annex III; b) the applicant can demonstrate that the veterinary medicinal product is a combination of reference veterinary medicinal products as	Les AF souhaitent **exclure de cette disposition les médicaments immunologiques** (l'association de souches vaccinales étant plus complexe). Pour les autres médicaments (chimiques), **l'association doit être justifiée par un meilleur service médical rendu** comme par exemple : la diminution de la posologie, la diminution du nombre d'administrations ou des indications thérapeutiques plus larges. En effet, il convient d'éviter les associations inutiles ou inadaptées aux besoins thérapeutiques.

c) documentation referred to in Article 7(1)(b) is available for the reference veterinary medicinal products to the competent authority or to the Agency; d) documentation on the safety of that combination is provided.	referred to in Article 16(1)(b); c) documentation referred to in Article 7(1)(b) is available for the reference veterinary medicinal products to the competent authority or to the Agency; d) documentation on the safety of that combination is provided. **e) Documentation on the efficacy of that combination is provided**	
Article 18 *Hybrid veterinary medicinal products*		
1. By way of derogation from Article 16(1), the results of appropriate pre-clinical studies and clinical trials shall be required when the product does not meet all the characteristics of a generic veterinary medicinal product because:		

a) there are changes in the active substance(s), therapeutic indications, strength, pharmaceutical form or route of administration of the generic veterinary medicinal product compared to the reference veterinary medicinal product, or b) bioavailability studies cannot be used to demonstrate bioequivalence with the reference veterinary medicinal product, or c) there are differences relating to raw materials or in manufacturing processes of the biological veterinary medicinal product and the reference biological veterinary medicinal product.		

2. The pre-clinical studies or clinical trials may be conducted with batches of reference products manufactured in the Union or in third countries. When the batches are manufactured in third countries, the applicant shall demonstrate by state of the art analytical tests that the two reference products are so highly similar that they can substitute to each other in the clinical trials.		Les AF se demandent s'il n'est pas préférable de faire appliquer à tous les dossiers abrégés la disposition indiquant que les études précliniques et essais cliniques peuvent être conduits avec des lots de médicaments de référence fabriqués dans l'Union ou dans des pays tiers.

Article 19 *Application based on informed consent*		
By way of derogation from Article 16(1)(b), an applicant for a marketing authorisation for a generic veterinary medicinal product shall not be required to provide the documentation on safety and efficacy if he demonstrates in the form of a letter of access that he is allowed to use the documentation on safety and efficacy referred to in Article 7(1)(b) which is available for the reference veterinary medicinal product.	By way of derogation from Article 16(1)(b), an applicant for a marketing authorisation for a generic veterinary medicinal product shall not be required to provide the documentation on safety and efficacy if he demonstrates in the form of a letter of access that he is allowed to use the documentation on safety and efficacy referred to in Article 7(1)(b) which is available for the reference veterinary medicinal product. **The parties shall exchange on any additional available during the product life.**	Il est indispensable de prévoir que les deux parties échangent sur les données postérieures à l'AMM notamment les données relatives à la sécurité du médicament.

Article 20 *Application based on bibliographic data*		
1. By way of derogation from Article 7(1)(b), the applicant shall not be required to provide the documentation referred to therein if he demonstrates that the active substances of the veterinary medicinal product have been in well-established veterinary use within the Union for at least 10 years, that their efficacy is documented and that they provide an acceptable level of safety. 2. The application shall satisfy the requirements set out in Annex III.		1. Les AF se demandent si cet article recouvre bien les demandes fondées sur des données bibliographiques pour les médicaments vétérinaires homéopathiques et de phytothérapie.
Section 6 **Dossier requirements for applications for limited market and in exceptional circumstances**		

Article 21 *Reduced data requirements for applications for limited markets*		
2. 1. By way of derogation from Article 7(1)(b), a marketing authorisation for a veterinary medicinal product intended for a limited market shall be granted **although the quality and/or efficacy documentation required in accordance with Annex II has not been provided,** if all the following conditions are met: a) the benefit of the immediate availability on the market of the veterinary medicinal product to the animal or public health outweighs the risk inherent in the fact that certain documentation has not been provided;	3. 1. By way of derogation from Article 7(1)(b), a marketing authorisation for a veterinary medicinal product intended for a limited market shall be granted **in accordance with article 31 (1bis), although the efficacy documentation required in accordance with Annex II has not been provided,** if all the following conditions are met: a) the benefit of the immediate availability on the market of the veterinary medicinal product to the animal or public health outweighs the risk inherent in the fact that certain documentation has not been provided;	Les AF sont favorables à la procédure d'AMM de type « marché limité » dans les limites suivantes : - l'AMM marché limité est une autorisation soumis**e à conditions : elle doit être soumises à certaine**s **obligations spécifiques** (proposition de renvoi à l'article 31 1bis créé) - **toute la documentation en matière de qualité doit être fournie** (comme pour une demande d'AMM standard) afin de s'assurer que les exigences de sécurité sanitaire des médicaments utilisés soient maintenues notamment en ce qui concerne les médicaments destinés aux animaux producteurs de denrées destinées à la consommation humaine.

b) the applicant provides the evidence that the veterinary medicinal product is intended for a limited market.	b) the applicant provides the evidence that the veterinary medicinal product is intended for a limited market.	
4. 2. By way of derogation from Article 5(2), a marketing authorisation for a limited market shall be granted for a period of 3 years. 5.		
6. 3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only **a limited assessment of quality and/or efficacy has been conducted due to the lack of comprehensive efficacy and/or quality data.**	*3* Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only **limited comprehensive efficacy data have been submitted due to the lack of comprehensive efficacy data.**	- Il conviendrait de **modifier le paragraphe 3 de cet article 21 pour que le RCP du médicament issu de la procédure indique qu'une évaluation incomplète a été effectuée en raison de données limitées pour la partie « efficacité » uniquement**.

Article 22 *Data requirements for applications in exceptional circumstances*		
7. By way of derogation from Article 7(1)(b), in exceptional circumstances related to animal or public health, where the applicant has demonstrated that for objective, verifiable reasons he is unable to provide **the quality, safety and/or efficacy documentation required in accordance with Part 1, Part 2 and Part 3 of Annex II,** a marketing authorisation may be granted subject to any of the following: a) a requirement to introduce conditions or restrictions, in particular concerning the safety of the veterinary medicinal product;	By way of derogation from Article 7(1)(b), in exceptional circumstances related to animal or public health, where the applicant has demonstrated that for objective, verifiable reasons he is unable to provide **the whole safety and/or efficacy documentation required in accordance with Annex II,** a marketing authorisation may be granted **in accordance with Article 31 (1bis)** subject to any of the following:	Les AF demandent que toutes les données de qualité (fabrication, qualité des produits,…) soient disponibles. L'AMM circonstances exceptionnelles est une autorisation soumise à conditions : elle doit être soumises à certaines obligations spécifiques (proposition de renvoi à l'article 31 1bis créé)

b) a requirement to notify the competent authorities of any incident relating to the use of the veterinary medicinal product 8. c) a requirement to conduct post-authorisation studies.		
2. By way of derogation from Article 5-2., a marketing authorisation in exceptional circumstances shall be granted for a period of 1 year.		
3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only a limited assessment **of quality, safety and/or efficacy** has been conducted due to the lack of comprehensive **quality,** safety and/or efficacy data.	3. Where a medicinal product has been granted a marketing authorisation in accordance with this Article, the summary of product characteristics shall clearly state that only a limited assessment **of safety and/or efficacy** has been conducted due to the lack of comprehensive safety and/or efficacy data.	Les AF demandent que la qualité soit une exigence constante du dossier.

SECTION 7 **EXAMINATION OF APPLICATIONS AND GRANTING OF MARKETING AUTHORISATIONS**		**SECTION 7** **INSTRUCTION DES DEMANDES ET OCTROI DES AUTORISATIONS DE MISE SUR LE MARCHE**
Article 23 *Examination of an application*		
1. The competent authority or the Agency to which the application has been submitted in accordance with Article 6 shall: a) verify that the documentation submitted complies with the requirements laid down in Article 7-1. and is satisfactory for **granting a marketing authorisation;** b) assess the veterinary medicinal product regarding the quality, safety and efficacy documentation provided.	The competent authority or the Agency to which the application has been submitted in accordance with Article 6 shall : a) verify that the documentation submitted complies with the requirements laid down in Article 7(1) and is satisfactory for **the assessment of the veterinary medicinal product.** b) assess the veterinary medicinal product regarding the quality, safety and efficacy documentation provided.	9. Au point 1, les autorités françaises proposent la modification suivante, car le terme « octroi » d'autorisation de mise sur le marché (AMM) n'est pas approprié : à cette étape, il s'agit encore d'évaluation.

2. During the process of assessing applications for marketing authorisations for veterinary medicinal products containing or consisting of genetically modified organisms as referred to in Article 7(5), the necessary consultations shall be held by the Agency with the bodies set up by the Union or Member States in accordance with Directive 2001/18/EC.		
Article 24 *Request to laboratories in the course of the examination of applications*		
1. The competent authority or the Agency examining the application may require an applicant to provide samples of the veterinary medicinal product to the Union reference laboratory, an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose to:	1. The competent authority or the Agency examining the application may require an applicant to provide samples of the veterinary medicinal product to the Union reference laboratory, an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose to:	

a) test the veterinary medicinal product, its starting materials and if necessary intermediate products or other constituent materials in order to ensure that the control methods employed by the manufacturer and described in the application documents are satisfactory; b) verify, using samples provided by the applicant, that the analytical detection method proposed by the applicant for the purposes of safety tests and residue tests is satisfactory and suitable for use to reveal the presence of residue levels, particularly those exceeding the maximum residue level of the pharmacologically active substance established by the Commission in accordance with Regulation (EC) No 470/2009 and Commission Decision 2002/657/EC .	a) test the veterinary medicinal product, its starting materials and if necessary intermediate products or other constituent materials in order to ensure that the control methods employed by the manufacturer and described in the application documents are satisfactory; b) verify, using samples provided by the applicant, that the analytical detection method proposed by the applicant for the purposes of safety tests and residue tests is satisfactory and suitable for use to reveal the presence of residue levels, particularly those exceeding the maximum residue level of the pharmacologically active substance established by the Commission in accordance with Regulation (EC) No 470/2009 and Commission Decision 2002/657/EC .	
2. The time limits laid down in Articles	14. **deleted**	Les AF souhaitent supprimer le paragraphe 2 relatif à la suspension des délais pour **permettre que les échantillons soient fournis :** les AF considèrent que cette

40, 44, 46 and 48 shall be suspended until the samples requested in accordance with paragraph 1 have been provided.A competent authority or the Agency may request a Union reference laboratory, an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose to : 10. 11. 12. 13.		disposition ne présente pas d'intérêt et que les analyses doivent être réalisées dans les temps impartis par les procédures

Article 25 *Information on manufacturers*		
The competent authority shall ascertain that the manufacturers of veterinary medicinal products from third countries are able to manufacture the veterinary medicinal product concerned and/or carry out control tests in accordance with the methods described in the documentation submitted in support of the application in accordance with Article 7-1.		Les AF s'interrogent sur l'absence de dispositions en cas de litiges sur la reconnaissance des inspections (mentions relatives aux inspections Pays tiers et aux accords de reconnaissance mutuelle pour les inspections comme prévu à l'article 43.2 du règlement actuel 726/2004/CE).
Article 26 *Information to the applicant*		
		Les autorités françaises s'interrogent sur le calendrier en cas de réponse anticipée : est-ce que le calendrier démarre tout de suite ou bien faut-il attendre le consensus entre Etats membres (EM) et EM de référence ? Les autorités françaises se demandent également si les bonnes pratiques actuelles qui fixent des calendriers précis pour les procédures en procédure décentralisée (DCP) et

		reconnaissance mutuelle (RM) seront toujours compatibles avec cet article. De plus, les autorités françaises s'interrogent sur l'interruption des délais : concerne-t-elle la phase d'instruction ?
The competent authority or the Agency to which the application has been submitted in accordance with Article 6 shall inform the applicant if the documentation submitted in support of the application is insufficient. The competent authority or the Agency shall request the applicant to provide the documentation within a given deadline. In such case the time limits laid down in Articles 40, 44, 46 and 48 shall be suspended until the deadline has elapsed.	The competent authority or the Agency to which the application has been submitted in accordance with Article 6 shall inform the applicant if the documentation submitted in support of the application is insufficient. The competent authority or the Agency shall request the applicant to provide the documentation within a given deadline. In such case the time limits laid down in Articles 40, 44, 46 and 48 shall be suspended until the deadline has elapsed. **Similarly, these time-limits shall be suspended for any period which the applicant may be given to provide oral or written explanations**.	Enfin, les autorités françaises proposent de réintroduire la possibilité de suspension de délai pour permettre le cas échéant au demandeur de s'expliquer oralement ou par écrit (tel que prévu à l'article 33 de la directive actuelle). L'insertion de la phrase suivante à la fin de l'alinéa sera ainsi proposée.

Article 27 *Withdrawal of applications*		
Les AF s'interrogent sur les retraits partiels d'EM en cours de procédure : le titulaire doit-il aussi communiquer les raisons ? Les AF estiment qu'il est important de communiquer la liste des EM retirés de la procédure et que ces Etats aient la possibilité de publier leurs objections, ces dernières étant de fait retirées du rapport global de la procédure. En effet, cette transparence limitera les retraits d'EM par les titulaires dès lors qu'un ou plusieurs EM portent une objection sur la procédure. De plus, les AF souhaitent qu'une disposition soit introduite pour conserver la possibilité de référé en cas de retraits partiels d'EM en cours de procédure.		
1. An applicant may withdraw his application for marketing authorisation submitted to a competent authority or the Agency at any time before the decision referred to in Article 31 or 32 has been taken. 2. If an applicant withdraws his application for marketing authorisation submitted to a competent authority or the Agency before the assessment of the application as referred to in Article 23 has been completed, the applicant shall communicate its reasons for doing so to the competent authority or the Agency to		

which the application was submitted in accordance with Article 6. 3. If an assessment report or, in case of the centralised authorisation procedure, the opinion, has been drawn up, it shall be made public by the competent authorities or the Agency, after deletion of any commercially confidential information.		
Article 28 *Outcome of the **assessment***	Article 28 « Outcome of the **evaluation and closure of the procedure** »	Les AF feront observer que **la procédure de clôture étant semblable pour tous les types d'autorisation**, il leur semble pertinent de le prévoir au sein de cet article. Elles proposent donc la modification du titre de l'article.

1. In case of favourable assessment to grant a marketing authorisation, the competent authority or the Agency examining the application shall prepare an opinion including the following documents: a) a summary of the product characteristics containing the information laid down in Article 30; b) details of any conditions or restrictions to be imposed as regards the supply or use of the veterinary medicinal product concerned, including the classification of a veterinary medicinal product in accordance with Article 29; c) details of any conditions or restrictions which should be imposed as regards the safe and effective use of the veterinary medicinal product;	1. In case of favourable assessment to grant a marketing authorisation, the competent authority or the Agency examining the application shall prepare an opinion including the following documents: a) a summary of the product characteristics containing the information laid down in Article 30; b) details of any conditions or restrictions to be imposed as regards the supply or use of the veterinary medicinal product concerned, including the classification of a veterinary medicinal product in accordance with Article 29; c) details of any conditions or restrictions which should be imposed as regards the safe and effective use of the veterinary medicinal product;	

	c bis) details of any conditions or restrictions to be imposed as regards the use of the veterinary medicinal product concerned for the manufacturing of medicated feedingstuffs, when the veterinary medicinal product is specifically authorized for this purpose.	Cf commentaire à l'article 7 2 bis
d) the approved text of the labelling and package leaflet.	**d) the competent authority or the Agency shall make a public assessment report available after deletion of any commercially confidential information.**	Concernant le point d) du paragraphe 1), les **AF considèrent que l'étiquetage et la notice doivent être conformes au RCP. Cela relève de la responsabilité des industriels. La notification représente pour l'autorité compétente ou la Commission une importante charge administrative qui n'est pas justifiée.** Aussi, les AF proposeront la suppression du point d) et le renvoi systématique de la conformité aux RCP des mentions de l'étiquetage et de la notice (cf préambule indiqué avant les articles 9 à 13)

		Les AF souhaitent également que la transparence de l'évaluation soit assurée par la publication d'un rapport public d'évaluation (proposition au point d).
2. Where the application concerns a veterinary medicinal product for food-producing target species, the competent authority or the Agency shall prepare a statement related to the maximum residue levels of the pharmaceutical active substance in relation to specific foodstuffs and species, as established by the Commission in accordance with Regulation (EC) No 470/2009.	2. Where the application concerns a veterinary medicinal product for food-producing target species, the competent authority or the Agency shall prepare a statement related to the maximum residue levels of the pharmaceutical active substance in relation to specific foodstuffs and species, as established by the Commission in accordance with Regulation (EC) No 470/2009.	
3. Where the application concerns an antimicrobial veterinary medicinal product, the competent authority or the Commission	3. Where the application concerns an antimicrobial veterinary medicinal product, the competent authority or the Commission	

may require the marketing authorisation holder to conduct post-authorisation studies in order to ensure that the benefit-risk balance remains positive with a view to the possible development of antimicrobial resistance.	may require the marketing authorisation holder to conduct post-authorisation studies in order to ensure that the benefit-risk balance remains positive with a view to the possible development of antimicrobial resistance. 15. **4. Competent authorities shall make the assessment report publicly available, after deleting any commercially confidential information.** **5. In case of unfavourable assessment to grant a marketing authorisation, the competent authority or the Agency examining the application shall prepare an opinion explaining the reasons which lead to the refusal.** 16.	Cf remarque à l'article 48 Les AF souhaitent que soit également prévu le cas où l'évaluation de la demande conduit à un avis défavorable. Elles proposeront donc l'insertion d'un 4ème paragraphe 17.

Article 29 *Requirement for a veterinary prescription*		
1. A competent authority or the Commission shall classify the following veterinary medicinal products as subject to veterinary prescription: a) veterinary medicinal products which contain psychotropic drugs or narcotics, including those covered by the United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and the United Nations Convention on Psychotropic Substances of 1971; b) veterinary medicinal products for food-producing animals; c) antimicrobial veterinary medicinal products;		

d) products intended for treatments of pathological processes which require a precise prior diagnosis or the use of which may have effects which impede or interfere with subsequent diagnostic or therapeutic measures; e) officinal formulae intended for food-producing animals; f) veterinary medicinal products containing an active substance that has been authorised for less than 5 years in the U*nion.*		

2. A competent authority or the Commission may classify a veterinary medicinal product as subject to veterinary prescription where special precautions are contained in the summary of product characteristics referred to in Article 30, and in particular potential risks to : a) the target species, b) the person administering the products to the animal, c) the environment.	2. A competent authority or the Commission may classify a veterinary medicinal product as subject to veterinary prescription where special precautions are contained in the summary of product characteristics referred to in Article 30, and in particular potential risks to : (a) the target species **or non-target species in case of absolute contra-indication,** (b) the person administering the products to the animal, (c) the environment.	Les AF proposeront au paragraphe 2 de l'article 29, la modification du point a) afin de rajouter parmi les possibilités de classification le cas de contre-indication majeure dans une autre espèce :

3. By the way of derogation from paragraph 1, a competent authority or the Agency may not classify a veterinary medicinal product as subject to veterinary prescription if all of the following conditions are fulfilled: a) the administration of the veterinary medicinal product is restricted to pharmaceutical forms requiring no particular knowledge or skill in using the products; b) the veterinary medicinal product does not present a direct or indirect risk, even if administered incorrectly, to the animal(s) treated, to the person administering the product or to the environment; c) the summary of the product characteristics of the veterinary medicinal		

product does not contain any warnings of potential serious side effects deriving from its correct use; d) neither the veterinary medicinal product nor any other product containing the same active substance has previously been the subject of frequent adverse event reporting; e) the summary of the product characteristics does not refer to contraindications related to other veterinary medicinal products commonly used without prescription; f) the veterinary medicinal product is not subject to special storage conditions;		

g) there is no risk for public health as regards residues in food obtained from treated animals even where the veterinary medicinal products are used incorrectly; h) there is no risk to public or animal health as regards the development of resistance to anthelmintic substances even where the veterinary medicinal products containing those substances are used incorrectly.		Enfin, les AF s'interrogent sur la disposition portée au point h) : Comment objectiver le risque, surtout en cas d'administration incorrecte ? Quelles conséquences sur la possibilité de délivrer des vermifuges pour les animaux de compagnie sans ordonnance?

Article 30 *Summary of the product characteristics*		
1. The summary of the product characteristics referred to in Article 28(1)(a) shall contain the following information: a) name of the veterinary medicinal product followed by its strength and pharmaceutical form; b) qualitative and quantitative composition of the active substances or other constituents stating the common name or the chemical description of the substances or other constituents;	1. The summary of the product characteristics referred to in Article 28(1)(a) shall contain the following information: a) name of the veterinary medicinal product followed by its strength and pharmaceutical form; b) qualitative and quantitative composition of the active substances or other constituents stating the common name or the chemical description of the substances or other constituents, **and the qualitative and quantitative composition of constituents of the excipient, knowledge of which is essential for proper administration of the medicinal product**	Au paragraphe b), les autorités françaises souhaitent compléter la mention de la composition qualitative et quantitative du médicament vétérinaire dans le RCP avec celle des excipients dont la connaissance est nécessaire à une bonne administration du médicament (comme prévu à l'article 14 de la directive 2001/82/CE en vigueur) . Au point c), les autorités françaises souhaitent

c) clinical information: i) target species, ii) indications for use, iii) contra-indications, iv) special warnings for each target species, v) special precautions for use, including special precautions to be taken by the person administering the medicinal product to the animals, vi) frequency and seriousness of adverse events, vii) use during pregnancy, lactation or lay, viii) interaction with other medicinal products and other forms of interaction, ix) administration route and amounts to be	c) clinical information: i) target species ii) indications for use **specifying the target species** iii) contra-indications, iv) special warnings for each target species, v) special precautions for use, including special precautions to be taken by the person administering the medicinal product to the animals, **and special precautions for the protection of environment.** vi) frequency and seriousness of adverse events, vii) use during pregnancy, lactation or lay, viii) interaction with other medicinal products and other forms of interaction,	que : - ii) les indications d'utilisation mentionnées spécifient les espèces cibles ; *v)* les précautions particulières d'emploi mentionnées intègrent les précautions d'ordre environnemental

administered , x) overdose symptoms and emergency procedures and antidotes in the event of overdose, where applicable, xi) where appropriate, special indications or restrictions for use in accordance with Articles 107 to 109, xii) where appropriate, an indication of classification of an antimicrobial regarding its strategic use, xiii) special conditions for use, including restrictions on the use of antimicrobials in order to limit the risk of development of antimicrobial resistance,	ix) administration route and amounts to be administered , x) overdose symptoms and emergency procedures and antidotes in the event of overdose, where applicable, (xi) where appropriate, special indications or restrictions for use in accordance with Articles 107 to 109, (xii) where appropriate, an indication of classification of an antimicrobial regarding its strategic use, (xiii) special conditions for use, including restrictions on the use of antimicrobials in order to limit the risk of development of antimicrobial resistance,	
d) withdrawal periods, including animal species/foodstuffs combinations;	(d) withdrawal periods, including animal species/foodstuffs combinations **and including those for which the withdrawal**	Au point d), le temps d'attente (TA) doit être mentionné y compris lorsqu'il est nul.
e) pharmacological information:		

i) pharmacodynamics, ii) pharmacokinetics, iii) pharmaceutical particulars, iv) major incompatibilities, (v) shelf life, where applicable after reconstitution of the medicinal product or after the immediate packaging has been opened for the first time, vi) special precautions for storage, vii) nature and composition of immediate packaging, viii) requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products and, if appropriate, additional precautions regarding hazardous waste disposal of unused veterinary medicinal	**period is zero**; (e)pharmacological **or biological** information: (i) pharmacodynamics, (ii) pharmacokinetics, (iii) pharmaceutical particulars, (iv) major incompatibilities, (v) shelf life, where applicable after reconstitution of the medicinal product or after the immediate packaging has been opened for the first time, (vi) special precautions for storage, vii) nature and composition of immediate packaging, viii) requirement to use take-back schemes for veterinary medicinal products for the disposal of unused veterinary medicinal products or	Au point e), les propriétés du médicament couvrent également les informations biologiques (et non uniquement pharmaceutiques).

products or waste materials derived from the use of such products; f) name of the marketing authorisation holder; g) marketing authorisation number(s); h) if applicable, date of the first authorisation; i) the date of the last revision of the summary of the product characteristics; j) if applicable, for products authorised in accordance with Article 21 or Article 22, the statement 'market authorisation granted for a limited market/exceptional circumstances and therefore assessment based on customised	waste materials derived from the use of such products and, if appropriate, additional precautions regarding hazardous waste disposal of unused veterinary medicinal products or waste materials derived from the use of such products; f)name of the marketing authorisation holder; g)marketing authorisation number(s); h)if applicable, date of the first authorisation; i)the date of the last revision of the summary of the product characteristics; j) if applicable, for products authorised in accordance with Article 21 or Article 22, the statement 'market authorisation granted for a limited market/exceptional circumstances and	

requirements for documentation'.	therefore assessment based on customised requirements for documentation'. **(k) if applicable, for products authorised in accordance with article 16, 18, 19, shall mention that the product has been authorised under the procedures described in the articles 16, 18, 19, and the reference veterinary medicinal product.** **(l) if the veterinary medicinal product is authorised for the purpose of the manufacture of medicated feedingstuffs, all information regarding this specific purpose.**	Ajout d'un point k) pour préciser que l'AMM délivrée en application de procédures décrites aux articles 16 à 23 et répond à des exigences particulières Cf commentaire à l'article 7 2bis

2. In case of generic veterinary medicinal products, the parts of the summary of the product characteristics of the reference veterinary medicinal product that refer to indications or pharmaceutical forms which are protected by patent law in a Member State at the time of placing the generic veterinary medicinal product on the market may be omitted.		
Article 31 *Decisions granting marketing authorisations*		
1. Decisions granting marketing authorisations shall be taken on the basis of the documents prepared in accordance with Article 28 and shall set out the conditions attached to the placing on the market of the veterinary medicinal product and the summary of the product characteristics ('terms of the marketing authorisation').		Les autorités françaises souhaitent introduire le principe d' « AMM soumises à condition » pour pouvoir autoriser un médicament vétérinaire même si le dossier n'est pas complet et ainsi promouvoir la disponibilité rapide d'un médicament vétérinaire important Après consultation du demandeur, une AMM pourra ainsi être accompagnée d'obligations spécifiques, visant à assurer une balance

2. The competent authority or the Commission shall make the decision granting the marketing authorisation publicly available and record it in the database referred to in Article 51.	**1 bis. Following consultation with the applicant, an authorization may be granted subject to certain specific obligations. A list of these obligations is made available to the public**)	bénéfices/risques positive du produit, comme la mise en place de plans de gestion de risque, la surveillance de la résistance aux antimicrobiens et la protection de l'environnement.

Article 32 *Decisions refusing marketing authorisations*		Article 32 Décisions de refus des autorisations de mise sur le marché
1. The marketing authorisation shall be refused on any of the following grounds: a) the benefit-risk balance of the veterinary medicinal product is unfavourable; b) the applicant has not provided sufficient information on the quality, safety or efficacy of the veterinary medicinal product; c) the product is a zootechnical veterinary medicinal product or a performance enhancer, and the applicant has not sufficiently demonstrated the benefits of the product to the animal health and welfare or public health; d) the product is an antimicrobial		18. Au paragraphe 1, point b), les autorités françaises soutiennent la proposition qu'un des critères de refus d'AMM porte sur le cas où le demandeur n'a pas fourni suffisamment d'informations relatives à la qualité, à l'innocuité ou à l'efficacité du médicament vétérinaire.

veterinary medicinal product presented for use as performance enhancer in order to promote the growth of treated animals or to increase yields from treated animals; e) the withdrawal period is not long enough to ensure food safety; f) information to be provided in the immediate packaging, the outer packaging and the package leaflet of the veterinary medicinal product does not comply with the requirements set out in Articles 9 to 11; g) risk for public health in case of development of antimicrobial resistance outweighs the benefits of the product to animal health; h) the product has no therapeutic effect or		

the applicant has not provided sufficient proof of such effect as regards the target species; i) the qualitative or quantitative composition of the product is not as stated in the application.		
2. A marketing authorisation for an antimicrobial veterinary medicinal product shall be refused if the antimicrobial is reserved for treatment of certain infections in humans.	2. A marketing authorisation for an antimicrobial veterinary medicinal product shall be refused if the antimicrobial is reserved for treatment of certain infections in humans **or if the antimicrobial is intended to be incorporated in a medicated feed with a therapeutic indication to prevent diseases. A marketing authorisation for a veterinary medicinal product shall also be refused if the size of the package is not adapted for respecting article 110.3.**	Au paragraphe 2, les autorités françaises souhaitent ajouter comme critères de refus d'AMM : - le fait que le médicament vétérinaire contient un antibiotique et qu'il est destiné à être incorporé dans un aliment médicamenteux et utilisé à titre préventif. - le cas où la taille de conditionnement du médicament n'est pas adaptée au principe décrit à l'article 110.3, à savoir que la quantité délivrée est limitée à la quantité requise pour le traitement.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to establish rules for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of certain active substances in humans.	3. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to establish rules for the designation of the antimicrobials which are to be reserved for treatment of certain infections in humans in order to preserve the efficacy of certain active substances in humans. **The Commission shall, when establishing these rules, draw on the scientific opinions of the European Medicines Agency, not least in respect of species of animals, indications and routes of administration.**	(4) Afin que ces restrictions puissent être efficaces, elles doivent être basées exclusivement sur la science, et prendre dûment en considération les recommandations de l'agence européenne du médicament.
4. The Commission shall, by means of implementing acts, designate antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	**4.** Commission shall, by means of implementing acts **and drawing on the scientific recommendations made by the European Medicines Agency, the European Food Safety Authority, the European Centre for Disease Prevention and Control, and other relevant agencies or international bodies,** designate antimicrobials or groups of antimicrobials reserved for treatment of	

	certain infections in humans**, in accordance with the rules under paragraph 3.** Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	
Section 8 **Protection of technical documentation**		**SECTION 8** **PROTECTION DE LA DOCUMENTATION TECHNIQUE**
Article 33 *Protection of technical documentation*		
1. Without prejudice to the requirements and obligations laid down in Directive 2010/63/EU, technical documentation on quality, safety and efficacy originally submitted with a view to obtaining a marketing authorisation or a variation thereof shall not be used by other applicants for a marketing authorisation or a variation of the terms of a marketing authorisation for a veterinary medicinal product unless:		

(a) the period of the protection of technical documentation as set out in Articles 34 and 35 has elapsed, or (b) the applicants have obtained written agreement in the form of a letter of access with regard to that documentation.		
2. The protection of the technical documentation as referred to in paragraph 1 ('the protection of technical documentation') shall also apply in Member States where the product is not authorised or is no longer authorised.		

3. Any marketing authorisation or variation to the terms of a marketing authorisation differing from the previously granted marketing authorisation only with regard to strengths, **pharmaceutical forms**, administration routes or presentations shall be regarded as the same marketing authorisation as the one previously granted for the purpose of applying the rules of the protection of technical documentation.	**3.** Any marketing authorisation or variation to the terms of a marketing authorisation differing from the previously granted marketing authorisation only with regard to strengths, administration routes or presentations shall be regarded as the same marketing authorisation as the one previously granted for the purpose of applying the rules of the protection of technical documentation, **unless that authorisation was granted for an antimicrobial medicinal product.** .	(5) Les AF proposent de **retirer les formes pharmaceutiques de la notion d'AMM globale** pour permettre aux extensions d'être considérées comme de nouvelles AMM et bénéficier des mêmes avantages en termes de durée de protection des données. (6) Par ailleurs, l'amendement **exclut les médicaments antimicrobiens du champ d'application de l'AMM globale.** La recherche et l'innovation dans le domaine de l'antibiothérapie sera favorisée et les laboratoires seront incités à développer des thérapies plus efficaces ou qui permettent de réduire la quantité de médicament utilisée

Article 34 *Periods of the protection of technical documentation*		
1. The period of the protection of technical documentation shall be: a)10 years for the veterinary medicinal products for cattle, **sheep,** pigs, chickens, dogs and cats**;** b)**14 years** for antimicrobial veterinary medicinal products for cattle, **sheep**, pigs, chickens, dogs and cats containing an antimicrobial active substance which has not been an active substance in a veterinary medicinal product authorised within the Union on the date of the submission of the application; c) 18 years for veterinary medicinal	1. The period of the protection of technical documentation shall be: a)10 years for the veterinary medicinal products for cattle, **sheep reared for meat**, pigs, chickens, **salmon,** dogs and cats; b)**18 years** for antimicrobial veterinary medicinal products for cattle, **sheep reared for meat**, pigs, chickens, **salmon,** dogs and cats containing an antimicrobial active substance which has not been an active substance in a veterinary medicinal product authorised within the Union on the date of the submission of the application;	. Les AF demandent que la durée de 10 ans de protection des données ne s'applique qu'aux espèces majeures (donc inclure saumons et ovins viande) Les AF sont favorables à un allongement à 18 ans de la durée de protection pour les antibiotiques.

products for bees; d) 14 years for veterinary medicinal products for animal species other than listed in paragraph 1.a) and c).		
2. The protection shall apply from the day when the marketing authorisation for the veterinary medicinal product was granted in accordance with Article 7.		
	Article 34a (new) **Period of the protection of new technical documentation for existing products** **Any new studies and trials submitted by the holder of a marketing authorisation to the competent authorities shall have a period of protection of five years, provided that they are:** **(a) needed to extend a marketing**	L'étude d'impact de la Commission européenne et les chefs d'agences reconnaissent la nécessité de mieux protéger la documentation technique afin de stimuler l'innovation. La protection non cumulative de nouvelles études ou de nouveaux essais conduits post-autorisation doit permettre d'inciter au développement ou à l'amélioration de produits existants, qu'ils soient princeps ou déjà génériques.

	authorisation in respect of species, dosages, pharmaceutical forms or routes of administration, or **(b) needed for a re-evaluation requested by the Agency or the competent authorities post-authorisation.** **No other applicant may use those trials or studies for that five-year period without the written consent of the holder of the marketing authorisation in the form of a letter of access to those trials or studies.**	

Article 35 *Prolongation of the periods of the protection of technical documentation*		
Les AF saluent les dispositions visant à proroger la période de protection des données et la période d'introduction des nouvelles données.		
1. Where a variation is approved in accordance with Article 65 extending the marketing authorisation to another species listed in Article 34(1)(a), the period of the protection provided for in that Article shall be prolonged by **1 year** for each additional target species, provided that the variation has been submitted at least 3 years before the expiration of the protection period laid down in Article 34(1)(a).	1. Where a variation is approved in accordance with Article 65 extending the marketing authorisation to another species listed in Article 34(1)(a), the period of the protection provided for in that Article shall be prolonged by **2 years** for each additional target species, provided that the variation has been submitted at least 3 years before the expiration of the protection period laid down in Article 34(1)(a).	S'il est nécessaire de maintenir un différentiel pour la durée de protection entre espèces majeures et espèces mineures de manière à inciter les laboratoires à investir en faveur des espèces mineures, les AF estiment néanmoins insuffisante la prorogation d'une seule année pour les espèces majeures et souhaitent que cette durée soit portée à 2 ans.

2. Where a variation is approved in accordance with Article 65 extending the marketing authorisation to a another species not listed in Article 34(1)(a), the period of the protection provided for in Article 34 shall be prolonged by 4 years.		
3. The period of the protection of the first marketing authorisation prolonged by any additional periods of protection due to any variations or new authorisations belonging to the same marketing authorisation ('overall period of the protection of technical documentation') shall not exceed 18 years.		
4. Where an applicant for a marketing authorisation for a veterinary medicinal product or for a variation to the terms of the marketing authorisation submits an application in accordance with Regulation (EC) No 470/2009 for the establishment of a		Les AF se demandent comment la protection d'extension prévue pour une limite maximale de résidus (LMR) sera-t-elle en pratique appliquée aux génériques qui doivent être identiques au princeps ?

maximum residue limit, together with clinical trials during the application procedure, other applicants shall not use those trials for a period of 5 years from the granting of the marketing authorisation for which they were carried out, unless the other applicant has obtained written agreement in the form of a letter of access with regard to those trials.		
Article 36 *Patent-related rights*		
Conducting the necessary studies, tests and trials with a view to applying for a marketing authorisation in accordance with Article 16 and the consequential practical requirements shall not be regarded as contrary to patent-related rights or to supplementary-protection certificates for medicinal products		

Chapter III **Procedures for granting marketing authorisations**		
Section 1 **Marketing authorisations valid throughout the Union ('centralised marketing authorisations')**		
Les autorités françaises font remarquer qu'il n'existe pas d'article 37.		
Article 38 *Scope of the centralised marketing authorisation procedure*		
1. Centralised marketing authorisations shall be granted by the Commission in accordance with this Section. They shall be valid throughout the Union.	1. Centralised marketing authorisations shall be granted by the Commission in accordance with this Section. They shall be valid throughout the Union. **The Commission and the Agency shall develop and encourage use of the centralised procedure, particularly by facilitating access for SMEs.**	(7) Afin de tendre un jour vers une procédure unique centralisée, les barrières (économiques, réglementaires...) qui entravent l'accès à cette procédure doivent être identifiées et combattues.

2. Centralised marketing authorisation procedure shall apply in respect of the following veterinary medicinal products: a) veterinary medicinal products developed by means of one of the following biotechnological processes: i) recombinant DNA technology; ii) controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells; iii) hybridoma and monoclonal antibody methods; b) veterinary medicinal products intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals;		

c) veterinary medicinal products containing an active substance which has not been authorised as a veterinary medicinal product within the Union at the date of the submission of the application;		
d) biological veterinary medicinal products which contain or consist of engineered allogeneic tissues or cells;		19. 2. d) : Les AF accueillent favorablement l'ajout des thérapies cellulaires allogéniques. Elles s'interrogent sur l'encadrement des thérapies autologues qui sont exclues du projet de règlement (voir article 2 (b)) : quel niveau d'exigence sera défini pour ces produits ?
e) generic veterinary medicinal products of reference veterinary medicinal products authorised under the centralised authorisation procedure.		2. e) : Les autorités françaises attirent l'attention sur l'impact de cette mesure sur la charge de travail au niveau du comité des médicaments vétérinaires (CVMP ou Committee for Medicinal Products for Veterinary Use).

3. For veterinary medicinal products other than those listed in paragraph 2 a centralised marketing authorisation may be granted **if no other marketing authorisation has been granted for the veterinary medicinal product within the Union.**	3. For veterinary medicinal products other than those listed in paragraph 2 a centralised marketing authorisation may **also** be granted.	*(8)* Cette précision est inutile et ne va pas dans le sens d'une plus grande utilisation de la procédure centralisée, qui doit pourtant être plus largement accessible afin de promouvoir à terme la mise en place d'un véritable marché unique du médicament vétérinaire.
4. The Commission, taking into account the state of animal and public health in the Union, shall be empowered to adopt delegated acts in accordance with Article 146 in order to amend the list set out in paragraph 2.		

Article 39 *Application for centralised marketing authorisation*		
1. Applications for centralised marketing authorisations shall be submitted to the Agency. The application shall be accompanied by the fee payable to the Agency for the examination of the application.	Applications for centralised marketing authorisations shall be submitted to the Agency. The application shall be accompanied by the fee payable to the Agency for the examination of the application. **Information on refusals to grant a marketing authorisation in a Member State or in a third country and the reasons for the refusal should also be provided**.	Les autorités françaises indiquent que par souci du parallélisme des formes avec ce qui est demandé pour les AMM en reconnaissance mutuelle et décentralisées, les motifs de refus d'octroi de l'AMM doivent être transparents pour les AMM décentralisées
2. The application for a centralised authorisation of veterinary medicinal product shall state a single name for the veterinary medicinal product to be used throughout the Union. 3. Translations of the labelling, package leaflet and the summary of the product characteristics shall be submitted in the languages determined by the Member States in accordance with Article 14.		

Article 40 *Procedure for the centralised marketing authorisation*		
1. Centralised marketing authorisations shall be granted by the Commission following an assessment by the Agency.	**1. As an outcome of the assessment of an application for marketing authorisation for a veterinary medicinal product, the Agency shall draw up an opinion as referred to in Article 28.**	Aux points 1 et 2 de l'article 40, les autorités françaises demandent l'inversion de l'ordre des paragraphes 1 et 2. Cela paraît plus logique puisque l'évaluation précède l'octroi éventuel d'une AMM. Il est nécessaire d'introduire la notion de refus, car l'octroi d'une AMM n'est pas automatique. Cette notion doit être introduite ici, au cas où la proposition déjà faite en ce sens de modifier l'article 28(4) n'aurait pas été retenue
2. As an outcome of the assessment of an application for marketing authorisation for a veterinary medicinal product, the Agency shall draw up an opinion as referred to in Article 28.	**2. Centralised marketing authorisations shall be granted by the Commission following an assessment by the Agency**.	

3. The opinion shall be given within 210 days of receipt of a valid application. Exceptionally, where a particular expertise is required, the deadline may be extended by a maximum of 90 days.		3 : - L'article 26 couvre-t-il les demandes de compléments lors de la phase de recevabilité et les demandes de complément en cours d'instruction ? Si la phase de recevabilité n'est pas comprise dans les 210 jours, alors il manque la possibilité d'arrêt d'horloge pour les réponses aux listes de questions pendant la phase d'évaluation. - Comment la Commission justifie-t-elle l'extension de 90 jours, qui est une nouveauté par rapport à ce que prévoyait la directive 2001/82/CE ? Pourquoi cette durée n'est-elle pas prévue pour les autres procédures ? Si les arrêts d'horloge (clock-stop), n'existent plus, sont-ils compensés par cette durée fixe ?

4. When an application is submitted for a marketing authorisation in respect of veterinary medicinal products of major interest, particularly from the point of view of animal health and therapeutic innovation, the applicant may request an accelerated assessment procedure. The request shall be duly substantiated. If the Agency accepts the request, the time limit of 210 days shall be reduced to 150 days.	***deleted***	Au point 4, les autorités françaises estiment que la présentation de la procédure d'examen accéléré est rédigée de manière trop souple. Elles proposeront la suppression de cette disposition, étant entendu que l'agence a toujours la possibilité de raccourcir la durée de l'examen.
6. After the completion of the procedure referred to in paragraph 5 the opinion shall be forwarded without delay to the Commission.	**5.** After the completion of the procedure referred to in paragraph 5 the opinion shall be forwarded without delay to the Commission.	
7. The Commission may request clarifications from the Agency as regards the content of the opinion, in which case the Agency shall provide a response to this request within 90 days.	**6.** The Commission may request clarifications from the Agency as regards the content of the opinion, in which case the Agency shall provide a response to this request within 90 days.	

8. Within 15 days of receipt of the opinion, the Commission shall prepare a draft of the decision to be taken in respect of the application. Where a draft decision envisages granting of a marketing authorisation, it shall include or make reference to the documents listed in Article 28. Where the draft decision is not in accordance with the opinion of the Agency, the Commission shall annex a detailed explanation of the reasons for the differences. The draft decision shall be forwarded to Member States and the applicant.	**7.** Within 15 days of receipt of the opinion, the Commission shall prepare a draft of the decision to be taken in respect of the application. Where a draft decision envisages granting of a marketing authorisation, it shall include or make reference to the documents listed in Article 28. **Where the draft decision envisages refusing of a marketing authorisation, it shall explain the reasons in accordance with the Article 32.** Where the draft decision is not in accordance with the opinion of the Agency, the Commission shall annex a detailed explanation of the reasons for the differences. The draft decision shall be forwarded to Member States and the applicant.	Au point 8, **le cas d'un refus doit être pris en compte et expliqué.** Aussi, les autorités françaises proposent la modification suivante de l'article 40.8 (devenu point 7 compte tenu de la suppression du point 4).

9. The Commission shall, by means of implementing acts, take a final decision on the granting of a centralised marketing authorisation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).		
10. The Agency shall disseminate the documents referred to in Article 28 to the applicant.		.
11. The Agency shall make the opinion publicly available, after deleting any commercially confidential information.		

Article 41 *Re-examination of the opinion of the Agency*		
1. Where the applicant requests a re-examination of the opinion in accordance with Article 40(5), he shall forward to the Agency detailed grounds for the request within 60 days after receipt of the opinion.		
2. Within 60 days after receipt of the grounds for the request, the Agency shall re-examine its opinion. The reasons for the conclusions reached shall be annexed to the opinion.		
3. Within 15 days after its adoption, the Agency shall forward its opinion to the Commission and the applicant.		.

SECTION 2 **MARKETING AUTHORISATIONS VALID IN A SINGLE MEMBER STATE ('NATIONAL MARKETING AUTHORISATION')**		
Article 42 *Scope of national marketing authorisation*		
National marketing authorisations shall be granted by the competent authorities in accordance with this Section and applicable national provisions. A national marketing authorisation shall be valid in the Member State which granted it. National marketing authorisations shall only be granted in respect of veterinary medicinal products not falling within the scope of Article 38(2).		

Article 43 *Application for national marketing authorisation*		
Competent authorities shall verify whether an application for a national marketing authorisation has been submitted or granted for the same veterinary medicinal product in another Member State. Where that is the case, the competent authority of that Member State shall decline to assess the application and inform the applicant of the possibility to submit an application under the mutual recognition procedure or the decentralised authorisation procedure.		Les autorités françaises considèrent que cette disposition nécessite la mise en place d'une base de données opérationnelle permettant de vérifier qu'aucune procédure n'est engagée ou qu'une autorisation n'a déjà été délivrée dans un autre EM. Elles s'interrogent : comment la similarité entre les médicaments (nom, composition/ titulaire, forme pharmaceutique, espèces de destination) peut-elle être appréciée ?

Article 44 *Procedure for national marketing authorisation*		
1. The procedure for granting a national marketing authorisation for a veterinary medicinal product shall be completed within a maximum of 210 days after the submission of the complete application.	1. The procedure for granting a national marketing authorisation for a veterinary medicinal product shall be completed within a maximum of 210 days after the submission of the complete application. **2. Where the competent authority envisages granting of a marketing authorisation, it shall include or make reference to the documents listed in Article 28. Where the competent authority envisages refusing a marketing authorisation, it shall explain the reasons in accordance with the Article 32.**	Au point 1 : les autorités françaises se demandent si le délai comprend ou non les temps de suspension prévus à l'article 26. Par parallélisme des formes avec ce qui est prévu pour la procédure centralisée, elles proposent l'ajout d'un point 2 pour faire référence aux documents issus de l'évaluation du dossier dans la décision d'autorisation et en cas de refus rendre public le rapport d'évaluation.
2. Competent authorities shall make the assessment report publicly available, after deleting any commercially confidential information.	3. Competent authorities shall make the assessment report publicly available, after deleting any commercially confidential information…	

Section 3 : **MARKETING AUTHORISATIONS VALID IN SEVERAL MEMBER STATES (“ DECENTRALISED MARKETING AUTHORISATIONS”)**		
Article 45 *Scope of decentralised marketing authorisation*		
1. Decentralised marketing authorisations shall be granted by the competent authorities in accordance with this Section. They shall be valid in the Member States stated therein. 2. Decentralised marketing authorisations shall only be granted in respect of veterinary medicinal products for which no national marketing authorisation has been granted at the time of application for a decentralised marketing authorisation and which does not fall within the scope of Article 38(2).Article 46		Actuellement, les AMM nationales délivrées en application de la procédure décentralisée n’indiquent pas les autres États membres concernés par la procédure et elles ne sont pas valides dans les autres EM inclus dans la procédure. Les autorités françaises se demandent si elles le seront à l’avenir et s’interrogent sur la phrase « Ces autorisations sont valables dans les États membres qui y sont indiqués »

Article 46 *Procedure for decentralised marketing authorisation*		
La Commission prévoit l'implication et un avis de tous les EM, même ceux qui ne sont pas concernés par une commercialisation du médicament. Les autorités françaises font observer qu'l en résultera une augmentation conséquente de la charge de travail des agences, qui. ne leur paraît pas acceptable. Si ce fonctionnement devait être conservé, alors la procédure doit se terminer par une décision communautaire avec vote du comité permanent du médicament vétérinaire.		
1. Applications for decentralised marketing authorisation shall be submitted to the Member State chosen by the applicant ('reference Member State').		
2. The application shall list Member States where the applicant seeks to obtain a marketing authorisation ('Member States concerned').	2. The application shall list Member States where the applicant seeks to obtain a marketing authorisation ('Member States concerned').**The applicant shall submit an identical dossier in all Member States**	Au point 2, les autorités françaises font observer que tous les EM concernés, voire l'ensemble des États membres, doivent pouvoir disposer du dossier, si un vote est organisé. Il n'est pas envisageable qu'un EM ne dispose pas du dossier complet des médicaments qu'il est sensé évaluer voire autoriser. Le dossier est un élément également

		essentiel pour le suivi post-AMM des médicaments. À l'heure du dépôt électronique via un portail unique, cette exigence n'alourdit pas la charge administrative.
3. Within 120 days of receipt of a valid application, the reference Member State shall prepare an assessment report. The assessment report together with the approved summary of the product characteristics and text to appear in the labelling and package leaflet shall be forwarded to all Member States and the applicant, together with the list of the Member States concerned.	**3. The procedure for assessing a decentralised marketing authorization for a veterinary medicinal product shall be completed within a maximum of 210 days after the submission of the complete application. The assessment is conducted by the reference member state which prepares the assessment report and proposes the summary of the product characteristics and text to appear in the labelling and package leaflet. The assessment report and the documentation listed in the Article 28 shall be forwarded to all Member States and the applicant.**	Au point 3, les autorités françaises constatent que la **procédure impose des délais intermédiaires qui ne permettent pas à l'Etat membre de référence de conduire la procédure de manière à permettre à chacun de s'exprimer**. Le déroulement de cette procédure est d'ores et déjà aménagé par le groupe de coordination et il convient, dans le cadre du **délai global de 210 jours, de lui laisser le soin d'établir le calendrier opérationnel.**

4. Within 90 days after receipt of the documents referred to in paragraph 3, Member States shall examine the assessment report, the summary of the product characteristics, the labelling and the package leaflet and inform the reference Member State of whether they have no objections to the assessment report, summary of product characteristics, labelling and package leaflet.	**4. The concerned member states shall examine the assessment report, the summary of the product characteristics and forward their observations to the reference member state**	Au point 4, les autorités françaises proposent le remplacement par une **rédaction plus générale**
5. Where all Member States agree, the reference Member State shall record the agreement, close the procedure and inform the applicant and the Member States accordingly. Each Member State from the list referred to in paragraph 2 shall grant a marketing authorisation in conformity with the approved assessment report, summary of the product characteristics, labelling and package leaflet within 30 days of the receipt	**5. Where the outcome of the assessment is favourable, the reference Member State shall record the agreement, close the procedure and inform the applicant and the Member States accordingly. Each Member State from the list referred to in paragraph 2 shall notify a decision in accordance with the Article 31 accompanied by the documentation listed in the Article 28. The decision should be notify within 30**	Au point 5, la possibilité qu'une évaluation débouche sur un refus doit être prise en compte.

of the information regarding the agreement from the reference Member State	**days of the receipt translation by the applicant of the summary of the product characteristics, labelling and package leaflet in the concern language if needed. Where the outcome of the assessment is unfavourable, the reference Member State shall close the procedure and inform the applicant and the Member States accordingly. Each Member State from the list referred to in paragraph 2 shall notify a decision in accordance with the Article 32**	
6. If at any stage of the procedure a Member State concerned invokes the reasons referred to in Article 113(1) for prohibiting the veterinary medicinal product it shall no longer be considered as a Member State where the applicant seeks to obtain a marketing authorisation. However, a Member State having invoked those reasons may subsequently recognise the marketing authorisation in accordance with Article 57.		

7. Competent authorities shall make the assessment report publicly available, after deleting any commercially confidential information.		
SECTION 4 **MUTUAL RECOGNITION OF MARKETING AUTHORISATIONS GRANTED BY NATIONAL AUTHORITIES**		
Article 47 *Scope of mutual recognition marketing authorisations*		
A national marketing authorisation for a veterinary medicinal product shall be recognised by other Member States in accordance with the procedure laid down in Article 48.		

Article 48 *Procedure for mutual recognition marketing authorisation*		
Les autorités françaises ne veulent pas qu'un même MV fasse l'objet de deux procédures concomitantes. Si plusieurs procédures ont été déposées, seule la première doit être prise en compte		
1. Applications for mutual recognition of marketing authorisations shall be submitted to the Member State that granted the first national marketing authorisation ("reference Member State").	1. Applications for mutual recognition of marketing authorisations shall be submitted to the Member State that granted the first national marketing authorisation ("reference Member State"). **The application shall list Member States where the applicant seeks to obtain a marketing authorisation ('Member States concerned'). The applicant shall submit an identical dossier in all Member States.**	Le dispositif ne paraît pas cohérent, car seul l'EM de référence reçoit une demande de reconnaissance mutuelle (RM) alors qu'il a déjà une AMM nationale pour ce produit. Les EM concernés ne reçoivent ni dossier ni aucune information alors qu'une demande de RM est faite pour leur pays. Pour cette raison, se pose la question : comment les États membres concernés seront-ils informés ? La liste des EM concernés est manquante, comme au point 2 de l'article 46 sur la procédure décentralisée. Les AF demandent qu'un dossier identique soit soumis dans tous les États membres dans lesquels une demande de reconnaissance mutuelle est déposée.

2. A minimum of 6 months shall elapse between the decision granting the first national marketing authorisation and the submission of the application for mutual recognition of the national marketing authorisation.		Quelle est la motivation pour imposer un délai de 6 mois entre la première AMM nationale et le dépôt d'une procédure décentralisée (DCP), qui n'existait pas dans la 2001/82 CE ?
3. An application for mutual recognition of a marketing authorisation shall be accompanied by the following: a) an information about the Member States where the applicant seeks to obtain recognition of the marketing authorisation; b) copies of marketing authorisations granted for the veterinary medicinal product in other Member States; c) an information about the Member States in which an application for a marketing authorisation submitted by the applicant for the same veterinary medicinal product is		3.c) : les autorités françaises ne veulent pas qu'un même médicament vétérinaire fasse l'objet de 2 procédures concomitantes. Si plusieurs procédures ont été déposées, seule la première doit être prise en compte.

under examination; d) a summary of the product characteristics proposed by the applicant; (e) the text to appear in the labelling and package leaflet; (f) information on refusals to grant a marketing authorisation in the Union or in a Member State or in a third country and the reasons for the refusal.		20. 3 f), cette information sur les autorisations sollicitées ailleurs et notamment en pays-tiers n'apparaît qu'en RM et en centralisée : pourquoi cette disposition ne s'applique pas à la DCP ?

4. Within 90 days of receipt of a valid application, the reference Member State shall prepare an updated assessment report for the veterinary medicinal product. The updated assessment report together with the approved summary of the product characteristics and the text to appear in the labelling and package leaflet shall be forwarded to all Member States and the applicant, together with the list of Member States where the applicant seeks to obtain recognition of the marketing authorisation ('concerned Member States').		
5. Within 90 days after receipt of the documents referred to in paragraph 3, Member States shall examine the assessment report, the summary of the product characteristics, the labelling and the package leaflet and inform the reference Member State of whether it has no objections to the assessment report, summary of product characteristics, labelling and package leaflet.		

6. Where all Member States agree, the reference Member State shall record the agreement, close the procedure and inform the applicant and the Member States accordingly. Each Member State referred to in paragraph 3 shall **grant a marketing authorisation in conformity with the approved assessment report, summary of the product characteristics, labelling and package leaflet within 30 days of the receipt of the information regarding the agreement from the reference Member State.**	6.Where all Member States agree, the reference Member State shall record the agreement, close the procedure and inform the applicant and the Member States accordingly. Each Member State referred to in paragraph 3 shall **notify a decision in accordance with the articles 31 or 32. marketing authorisation. The decision should be notified in conformity with the approved assessment report, summary of the product characteristics, labelling and package leaflet within 30 days of the receipt translation by the applicant of the summary of the product characteristics, labelling and package leaflet in the concern language.**	Les autorités françaises souhaitent que le délai de 30 jours court après la réception de l'ensemble des éléments traduits, car les délais de transmission des traductions peuvent être longs.

7. If at any stage of the procedure a concerned Member State invokes the reasons referred to in Article 113(1) for prohibiting the veterinary medicinal product, it shall no longer be considered as a Member State where the applicant seeks to obtain a marketing authorisation. However, a Member State having invoked those reasons may subsequently recognise the marketing authorisation in accordance with Article 57.		
8. Competent authorities shall make the assessment report publicly available, after deleting any commercially confidential information.		21. Cette disposition qui clôt les procédures est présente dans toutes les procédures. Il serait donc pertinent de prévoir un article commun de clôture des procédures dans lequel serait expressément indiquée la possibilité de refus. Les autorités françaises suggèrent de **compléter l'article 28 qui serait intitulé : « Outcome of the evaluation and closure of the**

		procedure » et d'y faire figurer la disposition figurant au point 8.
SECTION 5 **COORDINATION GROUP REVIEW AND SCIENTIFIC RE-EXAMINATION**		
Article 49 *Coordination group review procedure*		
L'article 49 décrit les conditions de réexamen des dossiers en cas d'absence de consensus entre les membres du groupe de coordination pour la reconnaissance mutuelle et les procédures décentralisées des médicaments à usage *vétérinaire* (*CMDv*) et définit des règles d'adoption à la majorité des suffrages. Le groupe de coordination devient ainsi un groupe de gestionnaires du risque adoptant des décisions contraignantes pour les EM qui doivent ensuite adopter des décisions nationales en conséquence. En ce qui concerne l'aspect juridique, les autorités françaises s'interrogent en premier lieu sur la légalité de cette mesure. Elles estiment que cela va à l'encontre du traité de fonctionnement de l'Union européenne notamment en son article 288 qui prévoit que les actes juridiques contraignants pour les EM (règlement, directive ou décision) sont adoptés par des institutions européennes (le Parlement, le Conseil ou la Commission). Or le CMDv n'est pas une institution établie par le traité ni une de ses instances. En second lieu, en ce qui concerne l'aspect politique, si une telle mesure était jugée légale, le fait que les décisions soient adoptées à la majorité simple de l'ensemble des EM n'est pas acceptable par les autorités françaises, car le vote à la majorité simple ne peut s'appliquer pour ce type de décision selon le Traité sur l'Union européenne (TUE et notamment article 16.3). Ce vote ne respectant pas les règles de vote à la majorité		

qualifiée prenant en compte le poids des divers EM, nous aurions ainsi des AMM en procédure centralisée adoptée à la majorité qualifiée et des AMM en DCP et RM adoptées à la majorité simple. De plus les chances de faire valoir son opposition apparaissent extrêmement réduites du fait que tous les EM doivent voter y compris ceux qui ne sont pas concernés par le produit.

En ce qui concerne l'aspect scientifique, le rapporteur désigné pour le réexamen sera un des États membres en désaccord. Ce rapporteur, ne disposant pas du dossier va remettre dans le nouveau rapport ses objections toujours sans avoir accès au dossier, ce nouveau rapport n'apportera donc rien de plus que le rapport d'évaluation. Aucune des divergences soulevées ne pourra être analysée scientifiquement et il est à prévoir que les États membres ne changent pas d'avis.

Outre la charge de travail très lourde des agences avec les procédures dans lesquelles elles sont directement impliquées, les disparités régionales en termes d'espèces, de pathologies, de préoccupations sociétales entraîneront des incompréhensions. Le vote ne sera absolument pas le reflet d'une évaluation scientifique.
Le CMDv n'est pas un comité d'expertise et ne peut se substituer au CVMP.

Si la Commission ne souhaite pas que les dossiers en cas de désaccord soient arbitrés au niveau du CVMP par référé comme le prévoit la réglementation actuelle, les autorités françaises proposent que, suite au réexamen d'un avis si le consensus n'est toujours pas trouvé, l'avis du CMDv soit :

- transmis à l'agence selon la procédure de saisine dans l'intérêt de l'Union décrite à l'article 84 lorsque des intérêts de santé publique, santé animale ou de l'environnement sont en jeux ou ;
- transmis à la Commission dans les autres cas pour adoption par voie d'exécution via le comité permanent du médicament vétérinaire selon les principes de la majorité qualifiée.(art 283.3 du TFUE).

1. If a Member State raises, within the time period referred to in Article 46(4) or Article 48(5) its objections to the assessment report, proposed summary of product characteristics or proposed labelling and package leaflet, a detailed statement of the reasons shall be provided to the reference Member State, the other Member States and the applicant. The points of disagreement shall be referred without delay to the coordination group for mutual recognition and decentralised procedures set up by Article 142('the coordination group') by the reference Member State.		
2. Within the coordination group, a rapporteur shall be appointed in order to prepare a second assessment report for the veterinary medicinal product.		

3. The second assessment report shall be presented by the rapporteur to the coordination group within the period of 90 days. **Upon presentation of the second assessment report, the coordination group shall adopt an opinion by a majority of the votes cast by the members of the coordination group represented at the meeting.**	3.The second assessment report shall be presented by the rapporteur to the coordination group within a period of 90 days.	Les autorités françaises proposent d'écrire ainsi les points 3 et 6 de l'article 49 reprenant le principe de l'adoption par acte d'exécution de la procédure centralisée (art 40 points 6 à 11) :
4. In the event of an opinion in favour of granting a marketing authorisation, the reference Member State shall record the agreement of Member States, close the procedure and inform Member States and the applicant accordingly.		
5. Each Member State concerned shall grant a marketing authorisation in conformity with the agreement within 30 days of receipt of the information regarding the agreement from the reference Member State.		

6. In the event of an unfavourable opinion, **the marketing authorisation shall be refused by each Member State concerned within 30 days of acknowledgement of the agreement**. **The scientific conclusions and grounds for revocation of the marketing authorisation shall be annexed to the unfavourable opinion**.	**6.** In the event of an unfavourable opinion, **the rapporteur shall inform the Agency of his concern for purposes of the application of the procedure laid down in Article 85 when the interests of the Union are at stake. In other cases, the opinion shall be forwarded to the Commission without delay.** **The Commission may request any information from the rapporteur concerning the substance of his opinion. The rapporteur shall forward his outline reply to the Commission within 90 days of receiving its request.** **Within 15 days of receipt of the opinion, the Commission shall prepare a draft of the decision associated with the procedure.** **If the draft decision proposes that marketing authorisation be granted, the**	(9) Le groupe de coordination ne peut avoir la légitimité pour intervenir comme groupe décisionnaire. Ses propositions doivent être renvoyées à la procédure de comitologie impliquant le comité permanent prévu à l'article 145. La décision doit, en effet, être de niveau communautaire et contraignante pour les États membres.

	draft shall include or refer to the documents listed in Article 28. **Where the draft decision proposes that marketing authorisation be refused, the grounds for refusal shall be stated in accordance with Article 32.** **Where the draft decision does not accord with the rapporteur's opinion, the Commission shall attach detailed explanations of the grounds for these differences.** **The draft decision shall be forwarded to Member States and the applicant.** **The Commission may, by means of implementing acts, take a final decision on the granting of a marketing authorisation under the decentralised or mutual recognition procedure. Those implementing**	

	acts shall be adopted in accordance with the examination procedure referred to in Article 145(2). **The Agency shall forward to the applicant the documents provided for by Article 28.** **The Agency shall make the opinion publicly available, after deleting any commercially confidential information.**	

Article 50 *Request for scientific re-examination*		Article 50 Demande de réexamen scientifique
Pourquoi seuls les demandeurs peuvent bénéficier d'un recours auprès du CVMP de l'agence et pas les autorités compétentes ? En tout état de cause, les AF s'opposent à ce que le réexamen par le CVMP soit limité aux seules questions soulevées par le demandeur dans son recours tel que mentionné au point 3 de cet article. Enfin les autorités françaises demandent à ce que la décision finale soit adoptée par voie d'exécution de la Commission comme cela se pratique aujourd'hui pour les référés et non par un vote à majorité simple au CMDv.		
1. Within 15 days after receipt of the assessment report referred to in Article 46(3) or in Article 48(4) the applicant may provide written notice to the Agency requesting a re-examination of the assessment report. In that case the applicant shall forward to the Agency detailed grounds for the request within 60 days of receipt of the assessment report. The application shall be accompanied by proof of payment of the fee payable to the Agency for the re-examination.		

2. Within 120 days of receipt of the grounds for the request, the Committee for Medicinal Products for Veterinary Use set up by Article 139 ('the Committee') shall re-examine the assessment report. The reasons for the conclusion reached shall be annexed to the opinion.			
3. **The re-examination procedure shall deal only with the points of the assessment report identified by the applicant in the written notice.**	**3. The committee shall define the scope of the examination, taking into account the information supplied by the applicant.**	(10)	Le champ du ré-examen doit être défini par le comité des médicaments à usage vétérinaire (CVMP), seul légitime à rendre un avis scientifique en la matière.
4. Within 15 days of its adoption, the Agency shall forward the opinion of the Committee to the **coordination group**, together with a report describing the assessment of the veterinary medicinal product by the Committee and stating the reasons for its conclusions. Those documents shall be forwarded **to the Commission**, to Member States and to the applicant for	4. Within 15 days of its adoption, the Agency shall forward the opinion of the Committee to the **Commission**, together with a report describing the assessment of the veterinary medicinal product by the Committee and stating the reasons for its conclusions. Those documents shall be forwarded **to Member States** and to the applicant for information purposes.	(11)	

information purposes.		
5. Upon presentation of the Agency's opinion, the coordination group shall act by the majority of the votes cast by its members represented at the meeting. The reference Member State shall record the agreement, close the procedure and inform the applicant. Article 49 shall apply accordingly. Where the decision is not in accordance with the opinion of the Agency, the coordination group shall annex a detailed explanation of the reasons for the differences.	**5. Within 15 days of receipt of the opinion, the Commission shall prepare a draft of the decision associated with the procedure.** **If the draft decision proposes that marketing authorisation be granted, the draft shall include or refer to the documents listed in Article 28.** **Where the draft decision proposes that marketing authorisation be refused, the grounds for refusal shall be stated in accordance with Article 32.** **Where the draft decision does not accord with the committee's opinion, the Commission shall attach detailed explanations of the grounds for these differences.** **The Commission may, by means of implementing acts, take a final decision on the granting of a marketing authorisation under the decentralised or mutual**	*22.* Au point 5, les autorités françaises proposent de reprendre la procédure d'adoption par acte d'exécution telle que décrite pour la procédure centralisée aux points 7 à 11 de l'article 40 :

	recognition procedure. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2). The Agency shall forward to the applicant the documents provided for by Article 28. The Agency shall make the opinion publicly available, after deleting any commercially confidential information.	
CHAPTER IV ***POST MARKETING AUTHORISATION MEASURES***		
Section 1 **Union product database**		
Article 51 *Union Database of veterinary medicinal product database*		
1. A Union database on veterinary medicinal products ('product database') shall be set up and maintained by the Agency.		

2. The product database shall contain information on: (a) veterinary medicinal products authorised within the Union by the Commission and by the competent authorities, together with their summaries of product characteristics, **package leaflets** and lists of sites where each product is manufactured; (b) homeopathic veterinary medicinal products registered within the Union by the Commission and by the competent authorities, together with their package leaflet and lists of sites where each product is manufactured; (c) veterinary medicinal products allowed to be used in a Member State in accordance with Articles 119 and 120.	2. The product database shall contain information on: (a) veterinary medicinal products authorised within the Union by the Commission and by the competent authorities, together with their summaries of product characteristics and lists of sites where each product is manufactured. (b) homeopathic veterinary medicinal products registered within the Union by the Commission and by the competent authorities, together with their package leaflet and lists of sites where each product is manufactured; (c) veterinary medicinal products allowed to be used in a Member State in accordance with Articles 119 and 120.	- 2.a), les AF demandent la suppression de la référence aux notices : les RCP sont déjà prévus dans les informations à inclure dans la base de données. Or les informations contenues dans les notices doivent être conformes aux RCP : il n'y a donc pas d'intérêt à les ajouter.

	3. The Agency shall, in collaboration with Member States and the Commission, draw up the functional specifications for the product database.	- Les AF proposent que le paragraphe 7 soit déplacé pour apparaître avant le paragraphe 3. En effet, il expose comment sont définies les spécifications fonctionnelles de la base de données sur les médicaments, c'est donc une étape préalable à la définition des formats prévue à l'article 3. -
3. Within 12 months from the date of the entry into force of this Regulation, the Agency shall make public a format for electronic submissions of information on marketing authorisations of veterinary medicinal products granted by the competent authorities.	**4.** Within 12 months from the date of the entry into force of this Regulation, the Agency shall make public a format for electronic submissions of information on marketing authorisations of veterinary medicinal products granted by the competent authorities.	Modification de la numérotation
4. The competent authorities shall submit information on marketing authorisations granted by them to the product database, using the format referred to in paragraph 3.	**5.** The competent authorities shall submit information on marketing authorisations granted by them to the product database, using the format referred to in paragraph 3.	

5. The Agency shall submit information on marketing authorisations granted by the Commission to the product database, using the format referred to in paragraph 3.	**6.** The Agency shall submit information on marketing authorisations granted by the Commission to the product database, using the format referred to in paragraph 3.	
6. Within 12 months from the date of application of this Regulation, the competent authorities shall submit electronically information on all veterinary medicinal products authorised in their Member State before the date of application of this Regulation to the Agency, using the format referred to in paragraph 3.	**7.** Within 12 months from the date of application of this Regulation, the competent authorities shall submit electronically information on all veterinary medicinal products authorised in their Member State before the date of application of this Regulation to the Agency, using the format referred to in paragraph 3.	
7. The Agency shall, in collaboration with Member States and the Commission, draw up the functional specifications for the product database.		- Les AF proposent que le paragraphe 7 soit déplacé pour apparaître avant le paragraphe 3. En effet, il expose comment sont définies les spécifications fonctionnelles de la base de données sur les médicaments, c'est donc une étape préalable à la définition des formats prévue à l'article 3.

8. The Commission shall ensure that information reported to the product database is collected, collated and made accessible and that the information is shared.		*(12)* .
Article 52 *Access to the product database*		
The competent authorities, the Agency and the Commission shall have full access to the information in the product database.		Les AF demandent des précisions sur la signification de « **accès sans restriction » (full access)** et demandent notamment s'il s'agit d'un accès en lecture uniquement (les AF sont favorables à un accès en lecture seule).
2. Marketing authorisation holders shall have full access to the information in the product database concerning their own marketing authorisations.		

3. The general public shall have access to information in the product database as regards the list of the authorised veterinary medicinal products, their summaries of product characteristics and package leaflets.		.
SECTION 2 **Placing on the market**		
Article 53 *Placing on the market*		
En lien avec la notion de « mise sur le marché » (« placing on the market ») définie au point 27 de l'article 4, les AF s'interrogent : - les informations sur les Etats membres dans lesquels le médicament vétérinaire est commercialisé seront-elles disponibles ? - comment s'articule la notion de « mise sur le marché » à celle de l' « AMM globale » : la mise sur le marché d'une forme pharmaceutique ou d'une présentation vaut-elle pour toutes les autres ?		
1. Marketing authorisation holders shall record in the product database the dates when their authorised veterinary medicinal products are placed on the market in a Member State.	1. Marketing authorisation holders shall record in the product database the dates when their authorised veterinary medicinal products are placed on the market in a Member State, **taking into account the various presentations authorised.**	Au paragraphe 1, les AF proposent de préciser que **l'information du titulaire de la date de la commercialisation effective du médicament vétérinaire prend en compte les différentes présentations autorisées** (rédaction existante à l'article 27 bis de la directive 2001/82/CE)

2. Generic veterinary medicinal products shall not be placed on the market until the period of the protection of technical documentation for the reference veterinary medicinal product as set out in Articles 34 and 35 has elapsed.		
Article 54 *Collection of data on the sales and use of antimicrobial veterinary medicinal products*		
Au point 1, les AF s'interrogent sur la prise en compte des données sur les ventes transfrontalières : comment seront-elles distinguées ? Comment seront-elles comptabilisées ?		
1. Member States shall collect relevant and comparable data on the volume of sales and the use of veterinary antimicrobial medicinal products.		
2. Member States shall send data on the volume of sales and the use of veterinary antimicrobial medicinal products to the Agency. The Agency shall analyse the data and publish an annual report.		

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to establish detailed rules on the methods of gathering data on the use of antimicrobials and the method of transfer of these data to the Agency.		
4. The Commission may, by means of implementing acts, set up the format and the requirements for the data to be collected in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).		

Article 55 *Responsibilities of the marketing authorisation holders*		*Article 55* *Responsabilités des titulaires d'autorisations de mise sur le marché*
1. In respect of the manufacturing process and control methods stated in the application for a marketing authorisation for the veterinary medicinal product and in order to take account of scientific and technical progress, the marketing authorisation holders shall ensure that any changes that may be required to enable that veterinary medicinal product to be manufactured and verified by means of generally accepted scientific methods are introduced. The introduction of such changes shall be subject to the procedures laid down in Section 4 of this Chapter.		

2. Competent authorities may require marketing authorisation holders to provide them with sufficient quantities of the veterinary medicinal products to enable controls to be made on the identification of the presence of residues of the veterinary medicinal products in question.	2. Competent authorities may require marketing authorisation holders to provide them with sufficient quantities of the veterinary medicinal products to enable controls to be made on **the products placed on the market and** on the identification of the presence of residues of the veterinary medicinal products in question.	Au point 2, les AF proposent que soient **élargis les motifs de demande d'échantillons** car prévoir cette demande pour le seul contrôle des résidus est trop restrictif : il conviendrait de l'étendre afin de pouvoir effectuer des contrôles des médicaments vétérinaires sur le marché (contrôle analytique mais aussi de notice et d'étiquetage, ainsi que les contrôles aléatoires basés sur des analyses de risque …).
3. Upon request of a competent authority, the marketing authorisation holder shall provide technical expertise to facilitate the implementation of the analytical method for detecting residues of the veterinary medicinal products in the national reference laboratory designated under Council Directive 96/23/EC .		

4. In order to permit continuous assessment of the benefit-risk balance, a competent authority or the Agency may at any time ask the marketing authorisation holder to forward data demonstrating that the benefit-risk balance remains favourable.	**4. The marketing authorisation holder shall without delay send the competent authority or the Commission any prohibition or restriction imposed by a competent authority and of any other new information which might**	- Les AF proposent d'inverser les paragraphes 4 et 5 pour définir en premier les responsabilités des titulaires d'AMM. - L**e terme « informe » n'est pas assez contraignant** : il conviendrait que le titulaire de l'AMM envoie toute interdiction/restriction qui lui serait imposée. Quid des termes « autorité compétente » : recouvrent-ils aussi les autorités de pays-tiers?
5. The marketing authorisation holder shall without delay inform the competent authority or the Commission of any prohibition or restriction imposed by a competent authority and of any other new information which might influence the assessment of the benefits and risks of the veterinary medicinal product concerned.	**5. In order to permit continuous assessment of the benefit-risk balance, a competent authority or the Agency may at any time ask the marketing authorisation holder to forward data demonstrating that the benefit-risk balance remains favourable.**	

6. Upon request from a competent authority, the Commission or the Agency, the marketing authorisation holder shall provide the competent authority, the Commission or the Agency with all data in his possession relating to the volume of sales.		Ce point 6 est **en lien avec la pharmacovigilance :** si la disparition des PSURs devait être appliquée, alors il conviendrait de modifier cette disposition pour ne pas la limiter aux seules données de volumes de ventes (données espèces à intégrer).
	7. The holder of a marketing authorisation for a veterinary medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that veterinary medicinal product to persons who are permitted to conduct retail of veterinary medicinal products in accordance with article 107 so that the needs of patients in the Member State in question are covered. **8. The marketing authorisation holder shall**	Les AF proposent d'ajouter deux paragraphes 7 et 8 pour : - indiquer que le **titulaire de l'autorisation de mise sur le marché d'un médicament doit assurer**, dans la limite de sa responsabilité, **un approvisionnement approprié et continu du médicament** pour les personnes autorisées à exercer des activités de commerce de détail, de manière à couvrir les besoins en santé animale de l'État membre concerné. - **Indiquer que le titulaire de**

	be obliged to notify the Member States concerned forthwith of any action taken by the holder to suspend the marketing of a veterinary medicinal product or to request the withdrawal of a marketing authorisation, together with the reasons for such action.	**l'autorisation de mise sur le marché est tenu de notifier immédiatement aux États membres concernés toute action qu'il a engagée pour suspendre la commercialisation** du médicament ou pour solliciter le retrait de l'autorisation de mise sur le marché, en indiquant les raisons de cette action.
Article 56 *National helpdesks for small and medium-sized enterprises*		*Article 56* *Services nationaux d'assistance réglementaire aux petites et moyennes entreprises*
Les AF sont réservées sur cette disposition : - que signifient exactement les termes **« national help desk »** car chaque EM a déjà aujourd'hui des systèmes ou modes de communication/concertation avec les titulaires d'AMM' ? cela relève-t-il du niveau d'un règlement? - **si cette disposition devait être maintenue, pourquoi la restreindre aux SME** ? En effet, il existe également un besoin d'assistance pour les grandes entreprises. - cette disposition ne crée-t-elle pas une charge administrative supplémentaire pour les autorités compétentes ?		

1. In order to help **small and medium-sized** enterprises to comply with the requirements of this Regulation, Member States shall establish national helpdesks. .		
2. National helpdesks shall provide advice to applicants, marketing authorisation holders, manufacturers, importers and any other interested parties **which are small or medium-sized enterprises** on their responsibilities and obligations under this Regulation and on applications for the authorisation of veterinary medicinal products		

	Section 2 bis (new) **Imports, parallel imports and parallel distribution**	
	Article 56a (new) **Parallel Import authorisation and parallel distribution authorisation** **1. An authorisation shall be required for the following actions:** **a) the parallel importation of veterinary medicinal products by a manufacturer or distributor authorised in a Member State, independently of the holder of the marketing authorisation. The imported veterinary medicinal product and the national reference medicinal product shall have:** **(i) the same qualitative and quantitative composition in terms of active substances and excipients, and the same pharmaceutical form;**	La jurisprudence communautaire a reconnu la possibilité aux entreprises de commercialiser un médicament vétérinaire autorisé dans un autre Etat membre dès lors qu'il est identique à un médicament vétérinaire autorisé dans le pays. Il convient de transposer cet acquis de la jurisprudence dans ce projet de règlement en qualifiant cette activité d'importation parallèle ou de distribution parallèle et de définir un dispositif d'encadrement de cette activité dans l'Union Européenne. (13) Les AF proposent un dispositif permettant d'encadrer et d'harmoniser l'importation parallèle et la distribution parallèle dans les Etats membres de l'Union Européenne.

	(ii) the same therapeutic effects and the same target species. **The national reference medicinal product and the veterinary medicinal product imported in parallel must have been harmonised under Article 69 or 70, or authorised in accordance with Articles 46 and 48;** **b) the parallel distribution of veterinary medicinal products by a distributor independently of the holder of the marketing authorisation.** **2. Applications for authorisation for these activities shall be submitted to the national authority responsible for parallel authorization, and to the Agency for parallel distribution authorisation.** **The competent authorities and the Agency**	*(14)*

	shall register the authorisation of parallel importation or parallel distribution that they have granted in the database on veterinary medicinal products established under Article 51. **3. The veterinary medicinal product imported in parallel or distributed in parallel shall be marketed in the packaging and with labelling in the language stipulated by each Member State of importation or distribution.** **4. a)Parallel import authorisation applications shall be submitted to the competent authority of the Member State of the importer.** **These authorisations shall be granted for a period of five years.** **Any change in the information submitted in order to obtain authorisation shall be notified to the competent authority, which**	

	shall accordingly alter the initial authorisation if necessary. **A parallel import authorization application shall, at the minimum, contain the following information:** **(a) the name of the veterinary medicinal product, its strength and its pharmaceutical form;** **(b) details of the imported veterinary medicinal product and of the medicinal product authorised in the Member State of importation, and details of the nature of the relabelling;** **(c) the name or company name of the applicant;** **(d) the name or company name or logo of the holder of the marketing authorization or the number of the marketing authorisation of the reference product and of the imported product;**	

	(e) details of the manufacturing site where the veterinary medicinal products are to be relabelled; **(f) the name of the qualified person responsible for pharmacovigilance;** **(g) a declaration that the applicant is independent of the holder of the marketing authorisation.** **4.b Parallel distribution authorisation applications shall be submitted to the Agency.** **These authorisations shall be granted for a period of five years.** **Any change in the information submitted in order to obtain authorisation shall be notified to the Agency, which shall accordingly alter the initial authorization if necessary.** **The application shall contain information**	

	concerning: **(a) the name or company name of the applicant, of the manufacturer involved in relabelling, and the parallel distributor;** **(b) the name of the qualified person responsible for pharmacovigilance;** **(c) the Member State of origin and destination.** **4. The competent authority or the Agency may suspend or withdraw parallel import or parallel distribution authorisations if the provisions of Article 56a and of paragraphs 1, 2 and 3 of this article are no longer complied with or if the product presents a risk to human or animal health or the environment.**	

SECTION 3 **SUBSEQUENT RECOGNITION IN THE MUTUAL RECOGNITION AND DECENTRALISED MARKETING AUTHORISATION PROCEDURES**		
Les autorités françaises sont opposées à la procédure de reconnaissance mutuelle subséquente telle que proposée par la Commission (administrative repeat use) car elle est de nature administrative. Chaque nouvel Etat membre concerné devrait avoir la possibilité de conduire une évaluation au moment où l'AMM est demandée sur son territoire		
Article 57 *Subsequent recognition of marketing authorisations by other Member States*		
1. After completion of a mutual recognition procedure laid down in Article 48 or a decentralised procedure laid down in Article 46, the marketing authorisation holder may submit an application for a marketing authorisation for a veterinary medicinal product to additional Member States. The application shall include the following: a) a list of **all decisions granting marketing authorisations** concerning this	1. After completion of a mutual recognition procedure laid down in Article 48 or a decentralised procedure laid down in Article 46, the marketing authorisation holder may submit an application for a marketing authorisation for a veterinary medicinal product to additional Member States. The application shall include the following: a) a list of **members states where a**	a) il convient de faire référence à la liste des EM car il n'y a pas d'intérêt à avoir toutes les décisions dans les différentes langues

veterinary medicinal product; b) a list of variations introduced since the first marketing authorisation in the Union was granted; c) a summary report on pharmacovigilance data.	**marketing authorisation was granted** concerning this veterinary medicinal product; b) a list of variations introduced since the first marketing authorisation in the Union was granted **or refused**; c) a summary report on pharmacovigilance data. **d) information about any suspension or withdrawal in any members states or third countries** **e) all the data referred to in article 7 accompanied with the assessment report.** **1 bis. The assessment of a subsequent recognition of a marketing authorization is conducted in accordance with the procedure laid down in article 48.**	nationales ; b)il convient d'étendre la liste des modifications - ajout des points d) et e) : il convient de **prévoir les informations sur les suspensions et retraits** (EM et pays-tiers) ainsi que **toutes les données indiquées à l'article 7** (données à fournir lors de la demande) avec le rapport d'évaluation - **ajout d'un point 1 bis prévoyant la procédure d'évaluation**

2. The additional Member State shall adopt a decision granting a marketing authorisation in conformity with the assessment report referred to in Articles 46(3) and 48(4) or, where appropriate, an updated assessment report, summary of the product characteristics, labelling and package leaflet within 30 days of receipt of the documents listed in paragraph 1.	The additional Member State shall adopt a decision granting a marketing authorisation in conformity with the assessment report referred to in Articles 46(3) and 48(4) or, where appropriate, an updated **and approved** assessment report, summary of the product characteristics, labelling and package leaflet within 30 days of receipt of the documents listed in paragraph 1.	Il convient de préciser que les rapports d'évaluation, les RCP, l'étiquetage et la notice **sont actualisés *et approuvés.***
3. Paragraphs 1 and 2 shall not apply to veterinary medicinal products that have been authorised through a mutual recognition or decentralised procedure before the date of the application of this Regulation.		
4. Recognition of marketing authorisations for those veterinary medicinal products shall be granted in accordance with the procedure laid down in Article 48.		

SECTION 4 **CHANGES TO MARKETING AUTHORISATIONS**		
Article 58 *Variations to the terms of a marketing authorisation*		
1. Variation to the terms of a marketing authorisation means a change to the terms of the marketing authorisation for a veterinary medicinal product as referred to in Article 31 (‘variation’).		
2. The Commission shall, by means of implementing acts, establish a list of variations to the terms of a marketing authorisation for a veterinary medicinal product requiring **assessment** (‘variations requiring assessment’). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145-2.	2. The Commission shall, by means of implementing acts, establish a list of variations to the terms of a marketing authorisation for a veterinary medicinal product **that do not require an** assessment (‘variations **not** requiring assessment’). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	Aux points 2 et 3 a, les AF proposent que le raisonnement porté par la disposition soit inversé : pour des **raisons de sécurité**, il convient de **lister les modifications qui ne feront <u>pas</u> l’objet d’une évaluation** car il n’est pas possible d’établir une liste positive de tous les cas de modifications de manière exhaustive.

3. The Commission shall take account of the following criteria when adopting those implementing acts: a) **the need for a scientific assessment of changes in order to determine the** risk to public health, animal health or the environment; b) whether changes have **an** impact on the safety and efficacy of the veterinary medicinal product; c) whether changes imply a **significant** alteration to the summary of product characteristics.	3. The Commission shall take account of the following criteria when adopting those implementing acts: a) **the variations that do not lead to a** risk to public health, animal health or the environment; b) whether changes have **no** impact on the safety and efficacy of the veterinary medicinal product; c) whether changes imply a **minor** alteration to the summary of product characteristics.	Au point 3-c), les AF demandent, en cohérence avec la demande au point 2, de **ne lister que les modifications ne nécessitant pas d'évaluation**, qu'il soit tenu compte des modifications mineures et non pas des modifications importantes. .
Article 59 *Consequential changes to product information*		
Where a variation entails consequential changes to the summary of the product characteristics, the labelling or the package leaflet, those changes shall be considered as part of that variation for the purposes of the examination of the application for a variation.		.

Article 60 *Variations to the terms of a marketing authorisation that do not require assessment*		
1. Where a variation does not appear in the list established in accordance with Article 58(2), the marketing authorisation holder shall record the change in the product database within **12 months** following the implementation of the variation.	1. Where a variation does not appear in the list established in accordance with Article 58(2), the marketing authorisation holder shall record the change in the product database within **1 month** following the implementation of the variation.	Le **délai de 12 mois est trop long** ; les AF proposent un délai de 1 mois pour l'enregistrement dans la base.
2. If necessary, competent authorities or, where the veterinary medicinal product is authorised under the centralised marketing authorisation procedure, the Commission shall amend the decision granting a marketing authorisation in accordance with the change.	**2.** Competent authorities or, where the veterinary medicinal product is authorised under the centralised marketing authorisation procedure, the Commission shall amend the decision granting a marketing authorisation in accordance with the change.	Les AF souhaitent supprimer les termes "si nécessaire". En effet, **seules les autorités compétentes sont garantes des décisions d'AMM (et non les titulaires)** : à la suite des déclarations de modifications, elles prennent les décisions d'autorisation et de mise à jour de la base.

Article 61 *Application for variations requiring assessment*		
Les AF françaises expriment leur préoccupation quant au rôle de l'Etat membre rapporteur (RMS) mais surtout celui des Etats membres concernés (CMS) tel qu'il apparait à la lecture des articles 61 à 66. En effet, **<u>seul</u> le RMS reçoit le contenu des demandes de modifications des AMM, les CMS étant destinataires uniquement de la liste des AMM concernées. Ainsi, le RMS pourra évaluer, accepter ou refuser la demande, sans que les autres Etats membres n'interviennent** puisqu'ils n'ont à leur disposition ni le dossier, ni le rapport. La seule possibilité pour les autres EM d'intervenir est dans le cadre d'un worksharing. Il faut également noter qu'il n'est pas certain que le RMS ait à disposition le dossier initial. C'est pourquoi les autorités françaises demandent que les articles 61 à 66 soient révisés afin de donner plus de lisibilité sur le rôle du RMS et des CMS et dans le cas de l'article 61, que soit précisé le fait que la totalité des données relatives à la modification soit fournie.		
1. Marketing authorisation holder shall submit an application for a variation requiring assessment to a competent authority or to the Agency.		
2. The application referred to in paragraph 1 shall contain: a) a description of the variation; b) reference to marketing authorisations affected by the application;	2. The application referred to in paragraph 1 shall contain: a) a description of the variation; **a) bis : the full set of data required by the article 7 for this variation**; b) reference to marketing authorisations	

c) where the variation leads to other variations to the terms of the same marketing authorisation, a description of those other variations; d) where the variation concerns marketing authorisations granted under the mutual recognition or decentralised procedures, a list of Member States which granted those marketing authorisations.	affected by the application; c) where the variation leads to other variations to the terms of the same marketing authorisation, a description of those other variations; d) where the variation concerns marketing authorisations granted under the mutual recognition or decentralised procedures, a list of Member States which granted those marketing authorisations.	

Article 62 *Groups of variations*		
When applying for several variations to the terms of the same marketing authorisation, a marketing authorisation holder may submit one application for all variations.	When applying for several variations to the terms of the same marketing autorisation **as referred to in point c) of the article 61(2),** a marketing authorisation holder may submit one application for all variations. **When applying for several not consequential variations to the terms of the same marketing authorisation, a marketing authorization holder shall submit one individual application for each variation.**	Les AF proposent que cet article fasse référence au point c de l'article 61(2) et prévoit le cas des modifications non liées aux termes d'une même autorisation de mise sur le marché.
Article 63 *Worksharing procedure*		
1. When applying for variations to the terms of several marketing authorisations held by the same marketing authorisation holder and granted by different competent authorities and/or the Commission, the marketing authorisation holder shall submit an application to all competent authorities	1. When applying for variations to the terms of several marketing authorisations held by the same marketing authorisation holder and granted by different competent authorities and/or the Commission, the marketing authorisation holder shall submit an **identical** application to all competent authorities	Les AF demandent que la procédure de répartition des tâches ne puisse s'appliquer que si le titulaire d'AMM atteste que la partie de l'AMM concernée par les modifications est identique dans tous les EM.

concerned and the Agency.	concerned and the Agency. **Marketing authorization holder shall attest that the part of the marketing authorisations concerned by the variations is identical in all the members states concerned before a worksharing procedure could apply.**	
2. Where one of the marketing authorisations referred to in paragraph 1 is a centralised marketing authorisation, the Agency shall assess the application in accordance with the procedure laid down in Article 64.		
3. Where none of the marketing authorisations referred to in paragraph 1 is a centralised marketing authorisation, the coordination group shall assign a competent authority among those having granted the marketing authorisations to assess the application in accordance with the procedure laid down in Article 64.		

Article 64 *Procedure for variations requiring assessment*		
1. If a variation application fulfils the requirements laid down in Article 61, the competent **authority** or the Agency**, or a competent authority assigned in accordance with Article 63(3)** shall acknowledge receipt of a complete application.	1. If a variation application fulfils the requirements laid down in Article 61, competent **authorities** or the Agency, shall acknowledge receipt of a complete application.	Les demandes de modifications requérant une évaluation doivent être déposées dans **<u>tous</u>** les Etats membres : aussi, les paragraphes 1 et 2 doivent faire référence aux **autorités compétentes (au pluriel).** Les AF s'interrogent sur le sens des termes « délai raisonnable » utilisés au paragraphe 2 et proposent de supprimer cette notion qui n'est pas clairement définie. Les AF proposent que les délais d'évaluation soient définis par actes d'exécution (car ils doivent rester de l'initiative des EM).
2. If the application is incomplete, **the competent authority** or the Agency**, or a competent authority assigned in accordance with Article 63(3)** shall require the applicant to complete the application **within a reasonable deadline.**	2. If the application is incomplete, competent **authorities** or the Agency, shall require the applicant to complete the application	

3. The competent authority or the Agency, or a competent authority assigned in accordance with Article 63(3) shall assess the application and prepare an opinion on the variation **within 60 days following the receipt of a valid application.** However, where it is necessary having regard to the urgency of the matter, the opinion shall be adopted without delay.	3. The competent authority or the Agency, or a competent authority assigned in accordance with Article 63(3) shall assess the application and prepare an opinion on the variation. **The commission shall, by mean of implementing acts, establish delays for the assessment of variations.** However, where it is necessary having regard to the urgency of the matter, the opinion shall be adopted without delay. **These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**	Elles s'interrogeront sur les termes **« urgence » et « sans tarder »** utilisés au paragraphe 3.
4. Within the period referred to in paragraph 3, the competent authority or the Agency may require the applicant to provide supplementary information **within a set time limit.** The procedure shall be suspended until the supplementary information has been provided.	4. Within the period referred to in paragraph 3, the competent authority or the Agency may require the applicant to provide supplementary information. The procedure shall be suspended until the supplementary information has been provided. **The commission shall, by mean of implementing acts, establish these delays. In case the**	Au paragraphe 4, les AF proposent que soit **prévu le refus de la variation si le délai est écoulé sans réponse.**

	supplementary information is not provided within the set time limit, competent authorities and/or the agency shall refuse the application. **These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**	
5. The opinion shall be forwarded to the applicant.	5. The opinion shall be forwarded to the applicant **and all the concerned competent authorities**.	. Au paragraphe 5, les AF proposent que **les autorités compétentes concernées reçoivent l'avis.**
6. Where the opinion is prepared by the Agency, the opinion shall be forwarded to the Commission. Where the Agency assesses the application in accordance with Article 63(2), the opinion shall be forwarded to the Commission and all competent authorities concerned.		

7. Where the opinion is prepared by a competent authority assigned in accordance with Article 63(3), the opinion shall be forwarded to all competent authorities concerned.		
8. Within 15 days of receipt of the opinion, the applicant may submit a written request to the Agency or the competent authority for a re-examination of the opinion. Detailed grounds for requesting a re-examination shall be stated in the request or be forwarded to the Agency or to the competent authority within 60 days of receipt of the opinion.		
9. Within 60 days of receipt of the grounds for the request, the Agency or the competent authority shall re-examine the points of the opinion identified in the request for re-examination by the applicant and adopt a re-examined opinion. The reasons for the conclusions reached shall be annexed to the opinion.		

Article 65 *Measures to close the procedures for variations requiring assessment*		.
Les AF alertent sur un point concernant la responsabilité : la proposition doit préciser **l'absence de responsabilité des EM car si ces derniers n'évaluent plus, ils ne peuvent être tenus responsables dans le cas où un problème en lien avec la modification verrait jour ultérieurement**		
1. Within 30 days of the completion of the procedure laid down in Article 64(6) and (7) a competent **authority** or the Commission shall amend the marketing authorisation or reject the variation and inform the applicant of the grounds for the rejection. In case of centralised marketing authorisation, the Commission shall, by means of implementing acts, take a final decision amending the marketing authorisation or rejecting the variation. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	1. Within 30 days of the completion of the procedure laid down in Article 64(6) tand (7) competent **authorities** or the Commission shall amend the marketing authorisation or reject the variation and inform the applicant of the grounds for the rejection. In case of centralised marketing authorisation, the Commission shall, by means of implementing acts, take a final decision amending the marketing authorisation or rejecting the variation. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	Les demandes de modifications requérant une évaluation doivent être déposées dans tous les Etats membres : aussi, les paragraphes 1 doit faire référence aux autorités compétentes (au pluriel).

2. Where the draft decision is not in accordance with the opinion of the Agency, the Commission shall annex a detailed explanation of the reasons for not following the opinion of the Agency.		
3. The competent authority or the Agency shall notify the marketing authorisation holder of the amended marketing authorisation **without delay.**	3. The competent authority or the Agency shall notify the marketing authorization holder of the amended marketing authorisation **within a delay of 30 days after the receipt of a translation by applicant of the summary of the product characteristic, labeling, and package leaflet in the concerned language if needed.**	Les AF proposent d'appliquer le **même délai de 30 jours que celui applicable aux décisions d'AMM** (cf. article 46.5 et 48.6 : propositions rédactionnelles identiques)
4. The product database shall be updated accordingly.	4.The product database shall be updated accordingly.**by competent authorities if necessary**	Les AF proposent de préciser **la responsabilité de la mise à jour de la base de données** (i.e. celle de l'autorité compétente).

Article 66 *Coordination group review*		
Where the opinion is prepared by a competent authority **assigned in accordance with Article 63(3),** each competent authority concerned shall amend the marketing authorisation granted by it or reject the variation in line with the opinion prepared by the competent authority **assigned in accordance with Article 63(3).** However, if a competent authority does not agree with the opinion, the coordination group review procedure laid down in Article 49 shall apply.	Where the opinion is prepared by a competent authority each competent authority concerned shall amend the marketing authorisation granted by it or reject the variation in line with the opinion prepared by the competent authority. However, if a competent authority does not agree with the opinion, the coordination group review procedure laid down in Article 49 shall apply.	Les AF proposent que le **champ de cette disposition soit élargie** (non uniquement applicable aux procédures de répartition des tâches) afin de laisser la **possibilité aux EM concernés d'exprimer leur désaccord.**

Article 67 *Implementation of variations requiring assessment*		
Les AF s'interrogent sur la position de cet article dans le règlement : ne devrait-il pas se situer en amont à l'article 58 ?		
1. A marketing authorisation holder may implement a variation requiring assessment only after **a** competent **authority** or the Commission has amended the decision granting the marketing authorisation in accordance with that variation and the holder has been notified thereof.	1. A marketing authorisation holder may implement a variation requiring assessment only after **competent authorities** or the Commission has amended the decision granting the marketing authorisation in accordance with that variation and the holder has been notified thereof.	Les demandes de modifications requérant une évaluation doivent être déposées dans tous les Etats membres : aussi, les paragraphes 1 doit faire référence aux autorités compétentes (au pluriel).
2. Where requested by a competent authority or the Agency, a marketing authorisation holder shall supply without delay any information related to a variation to the terms of a marketing authorisation.	2. Where requested by a competent authority or the Agency, a marketing authorisation holder shall supply without delay any information related to a variation to the terms of a marketing authorisation.	

	3. Where it appears necessary in line with the articles 69, 70 or 85, a competent authority or the European commission may bring all necessary changes of a marketing authorization.	Les AF proposent une disposition supplémentaire **permettant aux autorités compétentes (ou à l'Agence) d'effectuer des modifications d'office** après une procédure de référé ou d'harmonisation.
SECTION 5 **HARMONISATION OF THE SUMMARIES OF THE PRODUCT CHARACTERISTICS FOR NATIONALLY AUTHORISED PRODUCTS**		
Article 68 *Preparatory phase of the harmonisation exercise*		
Les AF proposent que soient prévues des **dispositions supplémentaires pour les médicaments immunologiques** : l'harmonisation doit être restreinte au même titulaire et aux mêmes souches. Les AF soulèvent également un problème : il est **nécessaire de prévoir l'harmonisation uniquement pour le même produit autorisé dans plusieurs pays**, or seuls les titulaires sont en mesure de l'indiquer aux autorités compétentes concernées. Aussi, il convient de créer une obligation d'harmonisation pour les titulaires et leur demander de fournir les données nécessaires pour étayer une harmonisation sur les espèces, les indications et les temps d'attente.		

1. A harmonised summary of product characteristics shall be prepared in accordance with the procedure laid down in Article 69 for veterinary medicinal products, other than homeopathic veterinary medicinal products, which have the same qualitative and quantitative composition of their active substances and the same pharmaceutical form and for which national marketing authorisations have been granted in different Member States **before 1 January 2004** (‘similar products’).	1. A harmonised summary of product characteristics shall be prepared in accordance with the procedure laid down in Article 69 for veterinary medicinal products, other than homeopathic veterinary medicinal products, which have the same qualitative and quantitative composition of their active substances and the same pharmaceutical form and for which national marketing authorisations have been granted in different Member States (‘similar products’).	La référence à la date limite du 1 janvier 2004 n’est pas pertinente. En effet, il existe plus d’hétérogénéité depuis 2004 du fait des AMM génériques.
2. For the purposes of determining qualitative and quantitative composition of the active substances, different salts, esters, ethers, isomers, mixtures of isomers, complexes and derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy.		

Article 69 *Procedure for harmonisation of the summaries of products characteristics*		
Les AF soulignent que les autorités compétentes devront **consacrer des moyens très importants (pour la traduction des RCP). En pratique, la charge de travail ne pourra être répartie de façon homogène entre les différents Etats membres**. Aussi, il conviendrait de demander aux titulaires d'AMM de déposer une liste de toutes les AMM concernées accompagnée d'une proposition de RCP traduite.		
1. By 12 months after the date of application of this Regulation for OP to insert the actual date] competent authorities shall provide the coordination group with lists of all products for which national marketing authorisations have been granted before 1 January 2004.		
2. The coordination group shall establish groups of similar products. For each of the groups of similar products, the coordination group shall appoint one member to act as a rapporteur.	2. The coordination group shall establish groups of similar products. For each of the groups of similar products, the coordination group shall appoint one member to act as a rapporteur.	Les AF proposent l'ajout de l'alinéa suivant (en lien avec **l'obligation**

	On request, the marketing authorisation holders shall provide any information regarding all the marketing authorisations concerned.	**d'harmonisation pour les titulaires** évoquée plus haut à l'article 68) :
3. Within 120 days of his appointment, the rapporteur shall present the coordination group a report regarding possible harmonisation of summaries of product characteristics for the similar veterinary medicinal products in the group and propose a harmonised summary of products characteristics.		
23. 4. Harmonised summaries of product characteristics for veterinary medicinal products shall contain all of the following information: a) all species mentioned in the marketing authorisations granted by Member States in respect of the similar products in the group;	24. 4. Harmonised summaries of product characteristics for veterinary medicinal products shall contain all of the following information: a) all species mentioned in the marketing authorisations granted by Member States in respect of the similar products in the group;	Au point 4, les AF s'interrogent : quelle sera la marge de manœuvre des EM dans lesquels des espèces ou indications auront fait l'objet d'un refus ou d'une suppression de l'AMM ? Pourront-elles être réintroduites via cette harmonisation et sous quelles conditions ?

b) all therapeutic indications mentioned in the marketing authorisations granted by Member States in respect of the similar products in the group; c) the **shortest** withdrawal period of those stated in the summaries of the product characteristics.	b) all therapeutic indications **and dosages** mentioned in the marketing authorisations granted by Member States in respect of the similar products in the group, **except for indications regarding the prophylactic use of antimicrobials;** c) the **longest** withdrawal period of those stated in the summaries of the product characteristics. **d) any possible warnings or restrictions in use** **e) in the case of antimicrobials, the summary of products characteristics shall contain an educational warning message promoting the prudent and responsible use to avoid unnecessary risks of selection pressure.**	b) les AF proposent que les **RCP mentionnent les dosages** et les précautions ou restrictions d'utilisation. De plus, **toute indication thérapeutique d'usage préventif dans les conditions d'utilisation des médicaments antimicrobiens doit être interdite lors de l'harmonisation des médicaments.** c), les AF soulignent que **seul le temps d'attente (TA) le plus long est acceptable** pour des raisons de protection de la santé des consommateurs. Au e), les AF proposent l'introduction d'un message d'éducation sanitaire pour les RCP d'antibiotiques.

5. Upon presentation of a report, the coordination group shall act by a majority of the votes cast by the members of the coordination group represented at the meeting. The rapporteur shall record the agreement, close the procedure and inform Member States and the marketing authorisation holders accordingly.		*(15)*
6. In the event of an opinion in favour of adopting a harmonised summary of the product characteristics, each Member State shall vary a marketing authorisation in conformity with the agreement within 30 days of receipt of the information regarding the agreement from the rapporteur.		
7. In the event of an unfavourable opinion, the procedure referred to in Article 49 shall apply.		Les AF s'interrogent sur l'intérêt de renouveler une procédure de vote au sein du groupe de coordination.

Article 70 *Harmonisation of summary of products characteristics following reassessment*		
1. By way of derogation from Article 69, the Committee may recommend to the Commission groups of similar veterinary medicinal products for which a scientific reassessment is necessary before a harmonised summary of the product characteristics is prepared.		
2. The Commission shall, by means of implementing acts, adopt decisions on groups of product for which a reassessment is necessary. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).	2. The Commission shall, by means of implementing acts, adopt decisions on groups of product for which a reassessment is necessary. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2). **Antimicrobial veterinary medicinal**	(16) Les anciens produits présentent un risque accru de développement d'antibiorésistance lors de leur

	products shall be one of these groups and the reassessment of antimicrobial veterinary medicinal products shall be finished within five years of entry into force of this Regulation. **In the case of antimicrobials, the summary of products characteristics shall contain an educational warning message promoting the prudent and responsible use to avoid unnecessary risks of selection pressure.**	utilisation. En conséquence, **l'harmonisation des RCP des médicaments antimicrobiens doit être prioritaire.** Les AF proposent l'introduction d'un message d'éducation sanitaire pour les RCP d'antibiotiques.
3. By way of derogation from Article 69, veterinary medicinal products authorised before 20 July 2000 as well as veterinary medicinal products authorised after that date but which **were identified as potentially harmful to the environment in the course of the environmental risk assessment** shall be reassessed before a harmonised summary of the product characteristics is prepared.	3. By way of derogation from Article 69, veterinary medicinal products authorised before 20 July 2000 as well as veterinary medicinal products authorised after that date but which **present a risk assessment for the environment** shall be reassessed before a harmonised summary of the product characteristics is prepared.	Les AF s'interrogent sur le choix de la **date butoir du 20 juillet 2000**. En effet, il convient de rappeler que cette date correspond à l'entrée en vigueur de la ligne directrice VICH phase I sur l'ERA (environnemental risk assessment) mais qu'auparavant des lignes directrices du CVMP s'appliquaient et qu'en 2005 la LD VICH phase II a été publiée.

4. For the purposes of paragraphs 1 and 3, the procedure for a Union interest referral in accordance with Articles 84 to 87 shall apply accordingly.		
	Article 70bis (new) **Outcome of the harmonisation of summary of products characteristics processing**	
	1. After products authorised nationally have been harmonized, marketing authorisations shall be registered under a mutual recognition procedure. Further variations shall apply to all the harmonized products. 2. **Where a reference veterinary medicinal product has been varied during the harmonisation process, the products referring to it shall be varied in the same way.**	Les AF proposent **l'ajout d'un article supplémentaire afin de prévoir la suite de l'harmonisation** : il est nécessaire que toutes les AMM soient enregistrées en procédure de reconnaissance pour les évolutions ultérieures afin de maintenir l'harmonisation. Il est également nécessaire de prévoir la modification subséquente de toutes les autorisations retenant ce médicament comme produit de référence.

Article 71 *Position of marketing authorisation holder*		
Upon request from the coordination group or the Agency, holders of the marketing authorisations for products included in a group of similar products identified for a harmonisation of the summaries of the product characteristics shall submit information concerning their products		

Section 6 **Pharmacovigilance**	*TITLE VII* ***PHARMACOVIGILANCE***	**Section 6** **Pharmacovigilance**

En préambule :

- les AF souhaitent modifier la définition de la phamacovigilance (PV) mentionnée à l'article 4 point 21 afin de reprendre la définition de l'organisation mondiale de la santé (OMS), à savoir :

"Pharmacovigilance is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem"

- Les AF s'interrogent sur le sujet de l'environnement et de la pharmacovigilance.: en effet, les autorités françaises estiment que le traitement du risque environnemental est essentiel, et qu'une approche holistique est nécessaire pour prendre en compte tous les effets (effets faibles doses, effets cocktails, etc.) Il leur semble nécessaire de demander qu'une réflexion soit engagée sur la possibilité de mettre en place et d'exploiter d'autres outils.
- les AF souhaitent faire appliquer le système de pharmacovigilance aux produits enregistres (médicaments homéopathiques)

Article 72 *Pharmacovigilance system of the marketing authorisation holder*	*Article 72* *Pharmacovigilance system of the marketing authorisation holder* ***and the registration holder***	
1. Marketing authorisation holders shall elaborate and maintain a system for collecting information on the risks of veterinary medicinal products as regards animal health, public health and the environment enabling them to fulfil their pharmacovigilance responsibilities listed in Articles 73, 76 and 77 **('pharmacovigilance system').**	« Marketing authorisation holders **and registration holders** shall elaborate and maintain a system for collecting information on the risks of veterinary medicinal products as regards animal health, public health and the environment enabling them to fulfil their pharmacovigilance responsibilities listed in Articles 73, 76,77, **77bis and 81** ».	Le paragraphe 1 fait référence aux responsabilités qui incombent aux titulaires d'autorisation de mise sur le marché (AMM) en matière de pharmacovigilance et renvoient ainsi aux articles 73, 76 et 77. Les autorités françaises considèrent que les responsabilités décrites dans ces articles ne sont pas suffisantes, il est notamment écrit que les titulaires des AMM créent et gèrent un système de collecte d'informations ce qui semble trop vague, et elles souhaitent introduire des obligations nouvelles, en créant : **- Une « autorisation unique du système de pharmacovigilance »** pour encadrer le concept de « dossier permanent ». Elle

		reposera sur les informations décrites dans ce dossier. Ces informations seront évaluées au préalable par les États membres mais indépendamment des procédures d'autorisation des médicaments. *Chaque titulaire devra désigner une personne qualifiée et la structure lui permettant de respecter ses obligations en matière de pharmacovigilance*. L'autorisation délivrée à chaque dossier permanent sera reconnue dans toute l'Union, comme pour les autorisations de fabrication et de distribution en gros. Elle sera enregistrée dans une base de données européenne pour être portée à la connaissance de tous les États membres. **– Obligations concernant les effets indésirables (EI) notifiés :** les titulaires d'AMM doivent détecter mais aussi évaluer. Les résultats de ce suivi et de cette évaluation doivent être consignés dans la base de données

		de pharmacovigilance et communiqués à l'autorité compétente (AC) et à l'agence.
2. Competent authorities and the Agency shall supervise the pharmacovigilance systems of marketing authorisation holders.	2.Competent authorities and the Agency shall supervise the pharmacovigilance systems of marketing authorisation holders **and registration holders by means of authorisation and inspection of their « pharmacovigilance system» as defined in Article 77.**	Les autorités françaises souhaitent clarifier et préciser la notion de supervision par les autorités compétentes qui peut se faire au moyen d'une autorisation mais aussi par le biais des inspections. Elles proposent la modification suivante
Article 73 *Union pharmacovigilance system*		
1. Member States, the Commission, the Agency and marketing authorisation holders shall collaborate in setting up and maintaining a system to monitor the safety of authorised veterinary medicinal products, enabling them to fulfil their responsibilities as listed in Articles 77 and 79 ('Union pharmacovigilance system').	Member States, the Commission, the Agency and marketing authorisation **and registration** holders shall collaborate in setting up and maintaining a system to monitor the safety **and efficacy** of authorised **or registered** veterinary medicinal products, enabling them to fulfill their responsibilities as listed in Articles 77 and 79 ('Union pharmacovigilance system')	1. Le contrôle de l'efficacité des médicaments vétérinaires doit être pris en compte dans la base de données, par souci de cohérence avec le point b) du paragraphe 2 La pharmacovigilance doit également s'appliquer aux médicaments homéopathiques enregistrés.

2. Competent authorities, the Agency and marketing authorisation holders shall make available to healthcare professionals and animal **holders** different means of reporting to them the following events whether or not the event is considered to be product-related ('adverse events'): a) any response in an animal **to a veterinary or human medicinal product, that is noxious and unintended;**	2. Competent authorities, the Agency, marketing authorisation holders **and registration holders** shall make available to healthcare professionals and animal **keepers** different means of reporting to them the following events whether or not the event is considered to be product-related ('adverse events'): **a)** any response in an animal, **that is unfavorable and unintended and that occurs following administration of a veterinary medicinal product in accordance or not with the summary of product characteristics;**	Les AF demandent : - le remplacement de la notion de propriétaire des animaux par celle de détenteur d'animaux ; en effet, les termes « holders keepers owners » sont employés indifféremment dans la proposition de texte. Or, en français, les notions de détenteur, de propriétaire et de gardien ont des significations différentes. Les autorités françaises demandent si les trois termes regroupent les mêmes notions en langue anglaise et demanderont qu'un seul terme soit retenu afin d'éviter toute confusion dans les différentes traductions, à savoir « keeper » ; - l'utilisation de la définition de l'événement indésirable retenue par le comité de coopération internationale sur l'harmonisation des exigences techniques pour l'enregistrement des médicaments vétérinaires (VICH) ;

b) any observation of a lack of efficacy of a veterinary medicinal product following administration to an animal in accordance with the summary of product characteristics; c) any environmental incidents observed following administration of a veterinary medicinal product to an animal; **d) any infringements of withdrawal period following administration to an animal of a veterinary or human medicinal product;** **e)** any noxious response in humans to a veterinary medicinal product; **f) any finding of an active substance in a produce of a food-producing animal exceeding the levels of residues established in accordance with Regulation (EC) No**	b) any observation of a lack of efficacy of a veterinary medicinal product following administration to an animal in accordance with the summary of product characteristics; c) any environmental incidents observed following administration of a veterinary medicinal product to an animal; **d) deleted** **e)** any noxious response in humans to a veterinary medicinal product; **f) deleted**	- le déplacement de la mention des médicaments à usage humain du point a) vers la fin du paragraphe 2, puisque, pour ceux-ci, la notion de respect du résumé des caractéristiques du produit (RCP) est sans objet ; - le rapprochement du périmètre des effets indésirables sur celui qui découle de la définition du VICH, d'où la suppression des points d) et f) du paragraphe 2. De manière plus précise, le dispositif de pharmacovigilance n'est pas approprié pour détecter les problèmes liés aux résidus de médicaments vétérinaires. La nouveauté introduite ne paraît pas pertinente, car elle mélange la surveillance des médicaments et le non respect de la réglementation. S'agissant en particulier des effets indésirables qui

470/2009.	**g) any response in an animal, that is unfavorable and unintended and that occurs after use of a human medicinal product.**	découlent du non respect du temps d'attente, les autorités françaises se demandent quelle action éventuelle sur l'AMM du médicament pourra être menée .
Article 74 *Union pharmacovigilance database*	Article 74 Union pharmacovigilance **and pharmacovigilance systems** database	Pour les autorités françaises, **les masters files**, qui décrivent les systèmes de pharmacovigilance mis en place par les titulaires, **doivent être soumis à autorisation**. Une base de données sera donc nécessaire pour disposer des informations relatives à ces autorisations. D'où : - modification de l'intitulé de l'article 74
1. The Agency shall establish and maintain a Union database on pharmacovigilance of veterinary medicinal products (the "pharmacovigilance database").		

	1 bis "The Agency shall establish and maintain a Union database on pharmacovigilance system (the "pharmacovigilance system database"). This database shall include the pharmacovigilance system master files submitted by the marketing authorisation holders or the registration holders and information on their authorisation or refusal, and on outcome of their inspections."	- insertion d'un paragraphe 1 bis
2. The Agency shall, in collaboration with the Member States and the Commission, draw up the functional specifications for the pharmacovigilance database.	**2.** The Agency shall, in collaboration with the Member States and the Commission, draw up the functional specifications for the pharmacovigilance database **and the pharmacovigilance system database.**	- modification des articles 2 et 3
3. The Agency shall ensure that information reported to the pharmacovigilance database is uploaded and made accessible in accordance with Article 75.	**3.** The Agency shall ensure that information reported to the pharmacovigilance database **and to the pharmacovigilance system database** is uploaded and made accessible in accordance with Article 75**.**	

Article 75 *Access to the pharmacovigilance database*	Article 75 Access to the pharmacovigilance **and pharmacovigilance systems** database	Pour tenir compte de la **mise en place d'une base de données sur les systèmes de pharmacovigilance,** sont modifiés : - l'intitulé de l'article 75
1. The competent authorities shall have full access to the pharmacovigilance database.	"The competent authorities shall have full access to the pharmacovigilance database **and to the pharmacovigilance system database."**	- et le paragraphe 1 est modifié.
2. Marketing authorisation holders shall have access to the pharmacovigilance database to the extent necessary for them to comply with their pharmacovigilance responsibilities as specified in Article 77.	2. Marketing authorisation holders **and registration holders** shall have access to the pharmacovigilance database to the extent necessary for them to comply with their pharmacovigilance responsibilities as specified in Article 77.	
3. The general public shall have access to the pharmacovigilance database only as regards the following information: a) the **number** of adverse events reported each year, broken down by product, animal species and type of adverse event;	3. The general public shall have access to the pharmacovigilance database only as regards the following information: a) the **incidence** of adverse events reported each year, broken down by product, animal species and type of adverse event;	Au paragraphe 3, **le public et les vétérinaires ne doivent avoir accès qu'à des données validées.** Donc, en ce qui concerne la détection de signal, il faut prévoir l'accès aux résultats de la détection mais pas aux données en cours d'évaluation. C'est pourquoi il est

b)information on **the process and** outcome of the signal management referred to in Article 81 for veterinary medicinal products and groups of products.	b) information on the outcome of the signal management referred to in Article 81 for veterinary medicinal products and groups of products.	proposé de supprimer les termes « information on process ». En tout état de cause, l'interprétation de telles données sans calcul de l'incidence sera sujette à mésinterprétation. Les AF proposent le remplacement du terme « number » par « incidence ».
	4. Health professionals shall have access to the pharmacovigilance database as regards the following information: **a) the incidence of adverse events reported each year, broken down by product, animal species and type of adverse event;** **b) previous declarations made concerning the same product and the number of cases per species in the previous six months;** **c) information on the results of the signal detection system for veterinary medicinal products and groups of products.**	(17) Les professionnels de santé animale, les vétérinaires en particuliers, doivent être plus étroitement associés au fonctionnement de la base de données de pharmacovigilance et doivent pouvoir être mieux informés des suites données à leurs signalements afin que ceux-ci soient réellement utiles.

Article 76 *Adverse events reporting*		
1. Competent authorities shall record in the pharmacovigilance database all adverse events which were reported to them by healthcare professionals and animal holders and that occurred in the territory of their Member State, within 30 days following the receipt of the adverse event report.	25. 1. Competent authorities shall record in the pharmacovigilance database all adverse events which were reported to them by healthcare professionals and animal holders and that occurred in the territory of their Member State**, as well as the result of their evaluation,** within 30 days following the receipt of the adverse event report.	Les autorités françaises font observer que la **base de données doit contenir <u>des cas évalués</u> par les autorités compétentes** nationales ou par les titulaires des autorisations de mises sur le marché.
2. Marketing authorisation holders shall record in the pharmacovigilance database all adverse events which were reported to them by healthcare professionals and animal holders and that occurred within the Union or in a third country with regard to their authorised veterinary medicinal products, within 30 days following the receipt of the	2. Marketing authorisation holders **and registration holders** shall record in the pharmacovigilance database all adverse events which were reported to them by healthcare professionals and animal holders and that occurred within the Union or in a third country with regard to their authorised veterinary medicinal products **or registered**	

adverse event report.	**veterinary medicinal products**, **as well as the result of their evaluation,** within 30 days following the receipt of the adverse event report. 26.	
3. Competent authorities may, **on their own initiative or on request from the Agency, request the marketing authorisation holder** to collect specific pharmacovigilance data**,** in particular regarding the use of a veterinary medicinal product in specified animal species, in the context of public and animal health, safety of the persons administering the product, and the protection of the environment. The authority shall state in detail the reasons for the request and inform other competent authorities and the Agency thereof.	3. Competent authorities **or the Agency** may request the marketing authorisation holder **or the registration holder** to collect specific pharmacovigilance data **and to carry out post-authorisation safety studies,** in particular regarding the use of a veterinary medicinal product in specified animal species, in the context of public and animal health, safety of the persons administering the product. The authority shall state in detail the reasons for the request and inform other competent authorities and the Agency thereof.	3 et 4 : les autorités françaises s'interrogent sur la proposition actuelle : - qui **laisse supposer que dans le cas d'une AMM centralisée, les autorités nationales compétentes interviennent sur demande de l'agence européenne pour demander à leur tour des informations aux titulaires** ; - qui introduit une **ambiguïté sur les**

4. Within 15 days after receipt of the request referred to in paragraph 3, the marketing authorisation holder may give written notice to the competent authority that he wishes a re-examination of the request **to collect additional specific pharmacovigilance data.**	4. Within 15 days after receipt of the request referred to in paragraph 3, the marketing authorisation holder **or the registration holder** may give written notice to the competent authority that he wishes a re-examination of the request to collect additional specific pharamcovigilance data **and to carry out post-authorisation safety studies**	**termes « recueil de données spécifiques ».** S'il s'agit d'une simple transmission de données déjà collectées, les autorités françaises ne sont pas favorables au fait de demander l'avis du titulaire, ce qui de plus serait en contradiction apparente avec le point e) de l'article 78. Par contre, s'il s'agit de données nouvelles à collecter (réalisation d'études de sécurité post-AMM) la procédure envisagée peut se comprendre.
5. Within 60 days following the receipt of the written notice, the competent authority shall re-examine the request and provide the marketing authorisation holder with its decision.	5. Within 60 days following the receipt of the written notice, the competent authority shall re-examine the request and provide the marketing authorisation holder **or the registration holder** with its decision.	

Article 77 *Pharmacovigilance responsibilities of the marketing authorisation holder*	Article 77 Pharmacovigilance responsibilities of the marketing authorisation holder **and the registration holder**	
Alors que le projet de texte fait reposer l'essentiel des responsabilités en pharmacovigilance sur les autorités compétentes (AC), les modifications proposées visent en premier lieu à **impliquer davantage les titulaires d'AMM dans la surveillance de leurs médicaments et à donner plus de moyens de contrôle aux autorités compétentes)** : - en précisant le rôle d'évaluation des effets indésirables des titulaires d'AMM ; - en rendant obligatoire la transmission des résultats de cette activité d'évaluation aux autorités compétentes. c) En ce qui concerne les dossiers permanents du système de pharmacovigilance, les inspections a posteriori semblent insuffisantes, c'est pourquoi les autorités françaises préconisent une autorisation du système de pharmacovigilance de chaque titulaire par une autorité compétente, préalable à l'octroi d'AMM, ainsi qu'un suivi des modifications de ces dossiers après l'autorisation.		

1**.** The marketing authorisation holder shall be responsible for the pharmacovigilance of the products for which he holds a marketing authorisation.	1.The marketing authorisation holder **or the registration holder** shall be responsible for the pharmacovigilance of the products for which he holds a marketing authorization **or registration**. **He shall comply with principles and guidelines on good pharmacovigilance practices.**	1. - Les autorités françaises proposent **d'introduire et de rendre opposable au niveau du règlement la base essentielle des exigences en matière de pharmacovigilance des médicaments vétérinaires,** à savoir le respect des bonnes pratiques de pharmacovigilance des médicaments vétérinaires. Ce sont des exigences qui relèvent de la responsabilité du titulaire de l'AMM et qui servent de base à l'inspection par les autorités compétentes (AC) Elles permettent d'assurer un niveau de surveillance post-AMM harmonisé des médicaments vétérinaires au sein de l'Union européenne, garant ainsi de leur sécurité

	1bis. The marketing authorisation holder or the registration holder shall submit to the concerned competent authorities, for each product he owns : **(a) - the evaluation of each adverse event that occurred within the European Union and that was brought to his attention, within the timeframe defined in article 76,** **(b) - the benefit-risk scientific assessment, with the periodicity defined at the time of granting of the marketing authorization or registration,** **(c) - the analysis conducted in the context of signal management process, as defined in Article 81.** **The benefit-risk scientific assessment as referred to in (b) takes into account at least the following information :**	- Le **nombre de déclarations n'est pas un critère suffisant pour évaluer un risque lié à l'utilisation d'un médicament**. Il faut **également prendre en compte le nombre d'animaux traités au travers du nombre d'unités vendues par période et par pays**. En conséquence, notamment dans le cadre du traitement des signaux, les autorités compétentes auront besoin de ces données. La disparition des PSURs va conduire les différentes autorités à demander ces données de vente au cas par cas aux titulaires ce qui, *in fine,* parait contraire à l'objectif de simplification administrative affiché par la Commission pour les titulaires comme pour les autorités. **d)** De plus, les PSURs contiennent d'autres informations importantes

	- **Adverse event reports that occurred in the European union or in a third country,** - **Literature data,** - **Sales data,** - **Results of related clinical trials.** **The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to specify the minimal frequency to be applied for the scientific evaluation of the benefit-risk assessment for each group of veterinary medicinal products as referred to in article 81.** **The Commission shall by means of implementing acts define guidelines of good pharmacovigilance practices for veterinary medicinal products. Those implementing acts shall be adopted in accordance with examination procedure referred to in**	telles que les données de la littérature, les cas des essais cliniques, une évaluation bénéfice/risque par le titulaire, et une conclusion sur l'adéquation ou pas du RCP avec les données observées. Les autorités françaises considèrent qu'il est **nécessaire qu'une évaluation scientifique du rapport bénéfice/risque soit réalisée régulièrement par les titulaires et que celle-ci soit transmise aux autorités compétentes nationales pour toute nouvelle autorisation** Les autorités françaises proposent de **réintroduire des rapports de sécurité en adaptant leur contenu et leur fréquence en fonction du profil de risque du produit, pour répondre à l'objectif de simplification**

	article 145(2). -	**administrative, tout en respectant l'objectif de sécurité sanitaire.** Ainsi, il est proposé de demander au titulaire de l'AMM d'envoyer à l'autorité compétente une évaluation scientifique du rapport bénéfice-risque » selon une périodicité qui sera fixée lors de l'octroi de l'AMM, sur la base d'une analyse de risque qui sera fonction de la nature du produit. **Au niveau européen**, cette analyse conduira à **regrouper les médicaments de manière à harmoniser les calendriers de dépôt des évaluations scientifiques du rapport bénéfice-risque** ainsi que la mise en œuvre du processus de détection de signal prévu à l'article 81. Les périodicités minimales d'évaluation seront définies au niveau européen.

2. Where the pharmacovigilance tasks have been contracted out by the marketing authorisation holder to a third party, those arrangements shall be set out in details in the pharmacovigilance system master file.	2. Where the pharmacovigilance tasks have been contracted out by the marketing authorisation holder **or the registration holder** to a third party, those arrangements shall be set out in details in the pharmacovigilance system master file.	
3. The marketing authorisation holder shall permanently have at his disposal one or more appropriately **qualified persons** responsible for pharmacovigilance. **Those persons** shall reside and operate in the Union. **Only one qualified person shall be designated by the marketing authorisation holder per pharmacovigilance system master file.**	3.The marketing authorisation holder **or the registration holder** shall permanently have at his disposal one appropriately qualified person responsible for pharmacovigilance. **This** person shall reside and operate in the Union.	3. Dans le but de permettre aux titulaires d'AMM de remplir leurs obligations en matière de pharmacovigilance dans les meilleures conditions possibles et pour faciliter le contrôle par les AC, il apparaît indispensable que chaque titulaire ne dispose que d'une seule personne responsable de la pharmacovigilance et donc d'un seul Dossier permanent du système de pharmacovigilance

4. Where the tasks of the qualified person responsible for pharmacovigilance listed in Article 78 have been contracted out to a third party, those arrangements shall be detailed in the **contract.**	4. Where the tasks of the qualified person responsible for pharmacovigilance listed in Article 78 have been contracted out to a third party, those arrangements shall be detailed in the **pharmacovigilance system masterfile.**	4. Les autorités françaises souhaitent que **les autorités compétentes soient informées des délégations de tâches en matière de pharmacovigilance.**
5. The marketing authorisation holder shall, based on pharmacovigilance data and where necessary, submit changes to the terms of a marketing authorisation in accordance with Article 61.	5. The marketing authorisation holder **or the registration holder** shall, based on pharmacovigilance data and where necessary, submit changes to the terms of a marketing authorisation in accordance with Article 61 **or the terms of the registration**. **The marketing authorisation holder or the registration holder shall, based on risk management measures decided by the Competent authorities or the Agency, submit changes to the terms of a marketing authorisation in accordance with Article 61, or the terms of the registration, in order to implement these measures.**	5. Il faut prévoir que les **titulaires déposeront des modifications d'AMM demandées par les AC, suite à l'évaluation des données de pharmacovigilance.**

6. The marketing authorisation holder shall not communicate information regarding adverse events to the general public in relation to the veterinary medicinal product without giving prior notification of his intention to the competent authority or authorities having granted the marketing authorisation or to the Agency where the marketing authorisation was granted in accordance with the centralised authorisation procedure. Where the marketing authorisation holder communicates such information to the general public, he shall ensure that it is presented objectively and is not misleading.	6. The marketing authorisation holder **or the registration holder** shall not communicate information regarding adverse events to **the veterinarians, to other health professionals and to** the general public in relation to the veterinary medicinal product without giving prior notification of his intention to the competent authority or authorities having granted the marketing authorization **or the registration,** or to the Agency where the marketing authorisation was granted in accordance with the centralised authorisation procedure. Where the marketing authorisation holder **or the registration holder** communicates such information **to the veterinarians, to other health professionals and** to the general public, he shall ensure that it is presented objectively and is not misleading.	6. En ce qui concerne la communication d'informations sur les événements indésirables, le **projet de texte n'évoque que la communication par les titulaires d'AMM vers le grand public**. Or, il apparaît important aux autorités françaises que **l'obligation de notification aux AC concerne également la communication vers les vétérinaires et les autres professionnels de santé.**

	<u>Article 77 bis</u> **<u>(Single pharmacovigilance master file)</u>**	Les AF proposent l'insertion d'un article 77 bis. Le système proposé dans le projet de règlement **dissocie le dossier permanent concernant le système de pharmacovigilance de la procédure d'autorisation des médicaments sans en tirer les conséquences en matière de soumission préalable aux États membres et d'évolution ultérieure de ces dossiers.** En effet, **seules les inspections et les contrôles a posteriori sont explicitement prévus par ce projet.**
	The organisation of pharmacovigilance activities conducted by marketing authorisation holders or registration holders shall be described in a unique pharmacovigilance system masterfile, which is subject to authorization by Member States. Member States shall lay down procedures for granting a	L'ajout de cet article propose **d'encadrer le concept du dossier permanent en créant une autorisation unique.** Cette autorisation reposera sur les informations décrites dans ce dossier qui seront évaluées au préalable par les États membres mais indépendamment des procédures d'autorisation des médicaments. Chaque titulaire devra désigner une personne

	pharmacovigilance system authorisation. The decisions arising from these procedures shall be valid throughout the Union. **The competent authority should inform on the outcome of the procedure within 90 days from the day on which the competent authority receives the complete application.** **The pharmacovigilance system masterfile is submitted to the competent authority where the qualified person resides.** **The competent authority shall notify its decision to the marketing authorization holder or the registration holder and upload this decision together with the pharmacovigilance system masterfile in the Pharmacovigilance system database.** **The marketing authorisation holder or the registration holder submits subsequent substantial modifications of his pharmacovigilance system masterfile.**	qualifiée et l'infrastructure lui permettant de respecter ses obligations en matière de pharmacovigilance. L'autorisation qui sera délivrée à chaque dossier permanent sera portée à la connaissance de l'ensemble des États membres par l'enregistrement dans une base de données européenne et sera reconnue dans toute l'Union, comme pour les autorisations de fabrication et de distribution en gros. Les modifications substantielles ultérieures apportées à ces dossiers seront également évaluées par les États membres comme c'est le cas actuellement dans le cadre du règlement variation. Comme pour les fabricants et les distributeurs, le non-respect des obligations incombant au titulaire et à sa personne qualifiée pourra être sanctionné par une suspension ou un retrait de cette autorisation.

Article 78 *Qualified Person Responsible for Pharmacovigilance*		
Qualified persons responsible for pharmacovigilance as referred to in Article 77(3) shall carry out the following tasks: a) **elaborating** and maintaining **a detailed description** of the pharmacovigilance system used by the marketing authorisation holder with respect to the veterinary medicinal product for which the authorisation has been granted ('pharmacovigilance system master file') for all products under their responsibility;	Qualified persons responsible for pharmacovigilance as referred to in Article 77(3) shall carry out the following tasks: a) **Achieving** and maintaining **the authorisation** of the pharmacovigilance system used by the marketing authorisation holder **or the registration holder** with respect to the veterinary medicinal product for which the authorisation **or the registration** has been granted ('pharmacovigilance system master file') for all products under their responsibility;	Cette modification est une mise en cohérence avec ce qui est proposé à l'article 77 bis.

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b) allocating reference numbers to the pharmacovigilance system master file and communicating the reference number of the pharmacovigilance master file of each product to the product database;		b)Suppression de ce point, car à partir du moment où les **systèmes de pharmacovigilance sont autorisés et qu'il y a un seul dossier permanent par titulaire, cette mesure devient caduque.**
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c) notifying the competent authorities and the Agency of the place where the qualified person operates and where the pharmacovigilance system master file is accessible in the Union;		c)suppression de ce point puisque dans la proposition française, **cette exigence est insérée dans l'article 77 bis.**
	b) establishing and maintaining a system	
d) establishing and maintaining a system which ensures that all adverse events which are brought to the attention of the marketing authorisation holder are collected and	which ensures that all adverse events which are brought to the attention of the marketing authorisation holder **or the registration holder** are collected and recorded in order to	Nouvelle numérotation

recorded in order to be accessible at least at one site in the Union;	be accessible at least at one site in the Union;	
e) preparing the adverse event reports referred to in Article 76;	**c)** Preparing and **evaluating** the adverse event reports referred to in Article 76.	Cette modification est une **mise en cohérence** avec le paragraphe 1bis de l'article 77, proposé par les autorités françaises.
f) ensuring that collected adverse event reports are recorded in the pharmacovigilance database;	**d)** ensuring that collected adverse event reports are recorded in the pharmacovigilance database and **transmitted through the database to the competent authority in whose territory the event occurred**	Cette modification vise à décrire **l'alimentation de la base européenne et la transmission en parallèle des déclarations vers l'autorité nationale compétente concernée**.

g) ensuring that any request from the competent authorities or the Agency for the provision of additional information necessary for the evaluation of the benefit-risk balance of a veterinary medicinal product is answered fully and promptly, including providing information about the volume of sales or prescriptions of the veterinary medicinal product concerned;	**e)** ensuring that any request from the competent authorities or the Agency for the provision of additional information necessary for the evaluation of the benefit-risk balance of a veterinary medicinal product is answered fully and promptly, including providing information about the volume of sales or prescriptions of the veterinary medicinal product concerned; **f) Providing competent authorities or the Agency with the periodical benefit-risk balance assessment per product, taking into account at least pharmacovigilance data, literature data, clinical trials data and exposure data, with a periodicity defined at the time of granting of the marketing authorization**	Les autorités françaises s'interrogent sur **l'utilisation possible, en pharmacovigilance du nombre de prescriptions**. Ne s'agit-il pas plutôt d'une estimation du nombre d'animaux exposés qui est une donnée indispensable ? Ajout de 2 nouveaux paragraphes pour mise en cohérence avec ce qui est proposé à l'article 77 :

	g) Providing competent authorities or the Agency with the analysis conducted in the context of signal management process per product as defined in Article 81	
h) providing competent authorities or the Agency with any other information relevant to detecting a change to the benefit-risk balance of a veterinary medicinal product, including appropriate information on post-marketing surveillance studies; i) evaluating by means of the pharmacovigilance system all information, considering options for risk minimisation and prevention and taking appropriate measures if necessary;	h) providing competent authorities or the Agency with any other information relevant to detecting a change to the benefit-risk balance of a veterinary medicinal product, including appropriate information on post-marketing surveillance studies; i) evaluating by means of the pharmacovigilance system all information, considering options for risk minimisation and prevention and taking appropriate measures if necessary;	

j) monitoring the pharmacovigilance system and ensuring that if needed, an appropriate corrective action plan is prepared and implemented;	j) monitoring the pharmacovigilance system and ensuring that if needed, an appropriate corrective action plan is prepared and implemented, **and the corresponding modification of the pharmacovigilance system masterfile is submitted;**	
k) ensuring that all personnel involved in the performance of pharmacovigilance activities receives continued training;	k)ensuring that all personnel involved in the performance of pharmacovigilance activities receives continued training;	
l) communicating any regulatory measure that is taken in a third country and is based on pharmacovigilance data to the competent authorities and the Agency within 15 days of receipt of such information.	l) communicating any regulatory measure that is taken in a third country and is based on pharmacovigilance data to the competent authorities and the Agency within 15 days of receipt of such information.	

Article 79 *Pharmacovigilance responsibilities of the competent authorities **and** the Agency*	Article 79 Pharmacovigilance responsibilities of the competent authorities**, the** Agency**, the veterinarians and other healthcare professionals**	
1. Competent authorities shall evaluate all adverse events reported to them by healthcare professionals and animal holders, manage risks and take the measures referred to in Articles 130 to 135 concerning marketing authorisations where necessary.	1. Competent authorities shall evaluate all adverse events reported to them by healthcare professionals and animal holders, manage risks and take the measures referred to in Articles 130 to 135 concerning marketing authorisations **or registrations** where necessary.	
2. Competent authorities shall take all appropriate measures to encourage the reporting of adverse events by healthcare professionals and animal holders.	2. Competent authorities shall take all appropriate measures to encourage the reporting of adverse events by **veterinarians and other** healthcare professionals and animal holders.	Les autorités françaises apportent une **précision** au paragraphe 2 et elles suggérent d'**harmoniser** les obligations de déclarations prévues au paragraphe 3

3. **Competent authorities may impose specific requirements on veterinarians and other healthcare professionals in respect of the reporting of adverse events.** The Agency and the competent authorities may organise meetings or a network for groups of veterinarians or other healthcare professionals, where there is a specific need for collecting, collating or analysing specific pharmacovigilance data.	3. **Veterinarians and other healthcare professionals shall report adverse events as listed in article 73.** The Agency and the competent authorities may organise meetings or a network for groups of veterinarians or other healthcare professionals, where there is a specific need for collecting, collating or analysing specific pharmacovigilance data.	
4. Competent authorities and the Agency shall provide the general public, veterinarians and other healthcare professionals with all important information on adverse events relating to the use of a veterinary medicinal product in a timely manner electronically or through other publicly available means of communication.		

5. Competent authorities shall verify by means of inspections referred to in Article 125 that **marketing autorisation holders** comply with the requirements relating to pharmacovigilance laid down in this Section.	5. Competent authorities shall verify by means of inspections referred to in Article 125 that marketing autorisation holders **and registration holders** comply with the requirements relating to pharmacovigilance laid down in this Section.	
6. **The Agency shall evaluate the adverse events to the centrally authorised veterinary medicinal products, manage risks and recommend measures to the Commission.** The Commission shall take the measures referred to in Articles 130 to 135 concerning marketing authorisations where necessary.	6. **Following advice of the pharmacovigilance working party the Agency shall manage risks and recommend measures to the Commission for the centrally authorised veterinary medicinal products.** The Commission shall take the measures referred to in Articles 130 to 135 concerning marketing authorisations where necessary.	Les autorités françaises ne sont pas favorables à cette rédaction qui attribue un **nouveau rôle d'évaluation à l'agence européenne du médicament** (EMA) qui n'existe pas dans les autres chapitres et qui **risque de dupliquer le travail déjà accompli par les autorités compétentes nationales**. Il leur apparait souhaitable que l'EMA garde un rôle de coordination.

Article 80 *Delegation of tasks by competent authority*		
1. A competent authority may delegate any of the tasks entrusted to it as referred to in Article 79 to a competent authority in another Member State subject to the written agreement of the latter.		
2. The delegating competent authority shall inform the Commission, the Agency and other Member States of the delegation in writing. The delegating competent authority and the Agency shall make that information public.		

Article 81 *Signal management process*		
1. Competent authorities and the Agency shall cooperate in monitoring the data in the pharmacovigilance database to determine whether there is any change to the benefit-risk balance of veterinary medicinal products with a view to detecting risks to animal health, public health and protection of the environment (‘signal management process’).	1.Competent authorities and the Agency shall cooperate in monitoring the data in the pharmacovigilance database to determine whether there is any change to the benefit-risk balance of veterinary medicinal products with a view to detecting risks to animal health and public health, and protection of the environnment and protection of the environnement (‘signal management process’). **This monitoring should also take into account the periodical benefit-risk balance assessment per product provided by marketing authorisation holders and registration holders.** **Marketing authorisation holders and registration holders shall monitor and**	Au paragraphe 1, les autorités françaises : - proposent une référence aux PSURs qu’elles ont souhaité réintroduire à l’article 77 1 bis ; - rappellent que les titulaires d’autorisation de mise sur le marché doivent également mettre en œuvre une détection de signal, comme indiqué dans la proposition d’article 77 1bis, sur ses produits et informer les AC nationales des problèmes détectés

	evaluate the data in the pharmacovigilance database related to the products for which they own a marketing authorization and communicate the results of this monitoring and evaluation to the Competent authorities and the Agency.	
2. **Competent authorities and the Agency** shall establish groups of veterinary medicinal products for which signal management process can be combined with a view of detecting risks to animal health, public health and protection of the environment.	2. A **pharmacovigilance working party** shall establish groups of veterinary medicinal products for which signal management process can be combined with a view of detecting risks to animal health, public health and protection of the environment.	l) Selon la lecture des autorités françaises de la proposition de la Commission, les groupes de produits concerneraient tous les médicaments, quelle que soit leur procédure d'autorisation. Puis en fonction des procédures, les discussions se feraient dans 2 groupes différents, le groupe de coordination pour la reconnaissance mutuelle et les procédures décentralisées pour les médicaments vétérinaires (CMDv) ou le comité pour les médicaments à usage vétérinaires (CVMP).é des

		médi Les autorités françaises considèrent **qu'une approche harmonisée au niveau européen en matière de pharmacovigilance serait facilitée si l'ensemble des sujets (en lien avec la pharmacovigilance) et des médicaments du même groupe, quelle que soit leur procédure d'AMM** (centralisée, en reconnaissance mutuelle ou décentralisée) **étaient discutés dans une seule et même instance.**
3. **The Agency and the coordination group** shall agree on sharing of the monitoring of data on groups of veterinary medicinal products recorded in the pharmacovigilance database. For each group of veterinary medicinal products a competent authority **or the Agency** shall be appointed as responsible for the monitoring thereof ('lead authority').	3. **A pharmacovigilance working party** shall agree on sharing of the monitoring of data on groups of veterinary medicinal products recorded in the pharmacovigilance database. For each group of veterinary medicinal products a competent authority shall be appointed as responsible for the monitoring thereof ('lead authority').	Les AF rappellent que **l'EMA doit garder un rôle de coordination.**

4. The results of the signal management process shall be agreed upon by the **competent authorities and, where appropriate, the Agency.** The lead authority shall record the results in the pharmacovigilance database.	4.The results of the signal management process shall be agreed upon by **the pharmacovigilance working party**, **which proposes appropriate risk management measures if necessary to the Agency and to the coordination group.** The lead authority shall record the results in the pharmacovigilance database.	les autorités françaises indiquent que pour **finaliser le processsus de détection de signal**, il leur semble nécessaire de **renvoyer vers le CMDv et vers le CVMP** la mise en œuvre des mesures de gestion de risques qui doivent s'appliquer aux AMM.
SECTION 7 **RE-EXAMINATION OF A MARKETING AUTHORISATION FOR A LIMITED MARKET AND IN EXCEPTIONAL CIRCUMSTANCES**		
En préambule, les autorités françaises rappellent la proposition **d'AMM délivrée sous conditions** qu'elles ont formulée précédemment. Elles considèrent nécessaire de **prévoir dans la procédure d'octroi des AMM décrite à l'article 31 1bis la possibilité de soumettre l'AMM à certaines obligations spécifiques,** pour autoriser un médicament vétérinaire même si le dossier n'est pas complet. L'AMM doit pouvoir être accompagnée de conditions contraignantes pour le titulaire, lorsque cela est rendu nécessaire, comme dans le cas des plans de gestion de risque, de la surveillance de la résistance aux antimicrobiens et de la protection de l'environnement.		

Article 82 *Procedure for re-examination of a marketing authorisation for a limited market*		
Les autorités françaises considèrent que **les AMM marché limité et circonstances exceptionnelles doivent relever de cette catégorie d'AMM soumises à certaines obligations spécifiques**. Découlent de cette position, des propositions de modifications concernant les procédures de réexamen des AMM marché limité et AMM circonstances exceptionnelles.		
1. Before the expiry of the period of validity of 3 years, marketing authorisations for a limited market granted in accordance with Article 21 shall be re-examined on application from the marketing authorisation holder. After the initial re-examination, it shall be re-examined every 5 years.		
2. The application for a re-examination shall be submitted to the competent authority that granted the authorisation or to the Agency at least 6 months before the expiry of the limited market marketing authorisation and shall demonstrate that the veterinary medicinal product remains for use in a limited	27. 2.The application for a re-examination shall be submitted to the competent authority that granted the authorisation or to the Agency at least 6 months before the expiry of the limited market marketing authorisation and shall demonstrate	28. Les autorités françaises souhaitent que : • la demande de réexamen de l'AMM **marché limité réponde aux obligations spécifiques** imposées dans l'AMM ; • lorsque **le rapport bénéfice/risque est**

market and that the marketing authorisation holder complies, if applicable, with the conditions referred to in Article 21(1).	that the veterinary medicinal product remains for use in a limited market and that the marketing authorisation holder complies, if applicable, with the conditions referred to in Article 21(1**) and complies with certain specific obligations referred to in article 31 (1bis).**.	**jugé positif lors de l'évaluation de la demande de réexamen, l'autorité compétente ou la Commission procède à un renouvellement de l'autorisation de mise sur le marché pour cinq ans et réévalue,** le cas échéant, les obligations définies dans la première autorisation de mise sur le marché ; • **L'AC suspende ou retire l'autorisation** de mise sur le marché du médicament vétérinaire si le médicament vétérinaire n'est plus destiné à un marché limité ou si les conditions définies dans l'autorisation de mise sur le marché ne sont pas remplies.
3. When an application for re-examination has been submitted, the limited market marketing authorisation shall remain valid until a decision on the application has been adopted by the competent authority or the Commission.		
4. The competent authority or the Agency shall assess the application for a re-examination in order to ascertain whether the benefit-risk balance is positive.	4.The competent authority or the Agency shall assess the application for a re-examination in order to ascertain whether the benefit-risk balance is positive.	

5. The competent authority or the Commission may at any time grant a marketing authorisation valid for an unlimited period of time in respect of a veterinary medicinal product authorised for a limited market, provided that the holder of the marketing authorisation for a limited market submits the missing comprehensive **quality and** efficacy data referred to in Article 21(1).	5. The competent authority or the Commission may at any time grant a marketing authorisation valid for an unlimited period of time in respect of a veterinary medicinal product authorised for a limited market, provided that the holder of the marketing authorisation for a limited market submits the missing comprehensive **efficacy data referred to in Article 21(1).** **The competent authorities shall suspend or withdraw the marketing authorisation if at least one of** **the following conditions is fulfilled :** - **the veterinary medicinal products is no more intended for a limited market;** - **the conditions defined in the marketing authorisation are not complied.**	

Article 83 *Procedure for re-examination of a marketing authorisation in exceptional circumstances*		
1. Before the expiry of the period of validity of 1 year, marketing authorisations granted in accordance with Article 22 shall be re-examined on application from the marketing authorisation holder.		
2. The application for re-examination shall be submitted to the competent authority that granted the authorisation or the Agency at least 3 months before the expiry of the marketing authorisation.		
3. When an application for re-examination has been submitted, the marketing authorisation shall remain valid until a decision on the application has been adopted by the competent authority or the Commission.		

4. The competent authority or the Commission may at any time grant a marketing authorisation valid for an unlimited period of time, provided that the marketing authorisation holder submits the missing comprehensive safety and efficacy data referred to in Article 22(1).	**4. After this application of re-examination,** the competent authority or the Commission grant a marketing authorisation valid for an unlimited period of time, provided that the marketing authorisation holder submits the missing comprehensive safety and efficacy data referred to in Article 22(1). **If the marketing authorisation holder does not submit the missing comprehensive safety and efficacy data referred to in Article 22(1), the competent authority or the Commission may grant a marketing authorisation subject to certain specific obligations referred to in article 31(1bis). The competent authorities shall suspend or withdraw the marketing authorization if the conditions defined in the marketing authorisation are not complied.**	Les autorités françaises souhaitent que : • lorsque le titulaire de l'AMM circonstance exceptionnelle ne fournit pas les données manquantes en matière d'innocuité et d'efficacité lors de la demande de réexamen, l'autorité compétente ou la Commission puisse accorder une autorisation de mise sur le marché assortie des obligations spécifiques ; • l'AC suspende ou retire l'autorisation de mise sur le marché du médicament vétérinaire si les conditions définies dans l'autorisation de mise sur le marché ne sont pas remplies, à l'instar des modifications proposées pour la demande de réexamen de l'AMM marché limité.

SECTION 8 **UNION INTEREST REFERRAL**		
Article 84 Scope of the *Union interest referral*		
29. Les autorités françaises s'interrogent sur la **notion de « libre circulation** » dans le champ des référés. Comme il n'existe pas de libre circulation au sein de l'Union pour les médicaments vétérinaires, est-ce que ce terme implique que des référés pourraient être **initiés en cas d'importation ou d'importation parallèle** ? Les **activités d'importation et d'importation parallèle ne sont pas prises en compte dans le projet** tel que soumis, est-ce à travers ce point que les notions d'importation et d'importation parallèle sont prises en compte ?		
1. Where the interests of the Union are involved, and in particular the interests of public or animal health or of the environment related to the quality, safety or efficacy of veterinary medicinal products or the free movement of products within the Union, any Member State or the Commission may refer its concern to the Agency for the application of the procedure laid down in Article 85. The matter of concern shall be clearly identified.		

2. Upon request from the Agency, Member States and marketing authorisation holders shall forward to the Agency all available information relating to the Union interest referral.		.
3. Where the referral provided for in paragraph 1 concerns more than one veterinary medicinal product or a therapeutic class, the Agency may limit the procedure to specific parts of the terms of the marketing authorisation.		30. Au paragraphe 3, l'agence limite la procédure à certaines parties du dossier. Il conviendrait de bien préciser que cela ne peut être réalisé que dans le respect de la question qui doit être clairement identifiée en vertu du point 1.
Article 85 *Referral procedure*		
1. The Agency shall publish information about referrals made in accordance with Article 84 on its website. Interested parties shall be invited to provide comments.		

2. The Committee shall consider the referred matter and shall issue a reasoned opinion within 90 days of the date on which the matter was referred to it. That period may be extended by the Committee for a further period of up to 60 days, taking into account the views of the marketing authorisation holders concerned.		
3. Before issuing its opinion, the Committee shall provide the marketing authorisation holder with the opportunity to present explanations within a specified time limit. The Committee may suspend the time limit referred to in paragraph 2 to allow the marketing authorisation holder to prepare the explanations.		

4. In order to consider the matter, the Committee shall appoint one of its members to act as a rapporteur. The Committee may appoint independent experts to give advice on specific questions. When appointing such experts, the Committee shall define their tasks and specify the time limit for the completion of these tasks.		
5. If it considers it appropriate, the Committee may invite any other person to provide information relating to the matter before it.		
6. Within 15 days after its adoption, the Agency shall forward the final opinion of the Committee to Member States, the Commission and the marketing authorisation holder, together with an assessment report of the veterinary medicinal product and the reasons for its conclusions.		

Article 86 *Decision following the Union interest referral*		
1. Within 15 days after receipt of the opinion referred to in Article 85(6), the Commission shall prepare a draft decision. If the draft decision is not in accordance with the opinion of the Agency, the Commission shall also set out a detailed explanation of the reasons for the differences in an annex to the draft decision.		
2. The draft decision shall be forwarded to Member States.		

Article 87 *Commission decision following the referral*		Article 87 Décision de la Commission faisant suite à la saisine
1. The Commission shall, by means of implementing acts, take a final decision on the Union interest referral. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2). Unless otherwise stated in the referral notification in accordance with Article 84, the decision shall apply to all veterinary medicinal products subject to the marketing authorisation **that contain the active substance** concerned by the referral.	1.The Commission shall, by means of implementing acts, take a final decision on the Union interest referral. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2). Unless otherwise stated in the referral notification in accordance with Article 84, the decision shall apply to all veterinary medicinal products subject to the marketing authorisation concerned by the referral.	les autorités françaises considèrent que la **décision doit s'appliquer aux médicaments concernés par la saisine et non pas aux médicaments qui contiennent la même substance active**. En effet, tous les médicaments contenant la substance active ne sont pas obligatoirement concernés par la saisine, car celle-ci peut porter sur la forme pharmaceutique, la formulation ou les indications
2. Where the veterinary medicinal product has been authorised in accordance with the national, mutual recognition or decentralised procedures, the decision referred to in paragraph 1 shall be addressed to all Member States and communicated to the marketing authorisation holder for information.		

3. Member States shall take any necessary action with regard to the marketing authorisations for all veterinary medicinal products concerned to comply with the decision within 30 days of its notification, unless a different period is foreseen in the decision.	3.Member States shall take any necessary action with regard to the marketing authorisations for all veterinary medicinal products concerned to comply with the decision within 30 days of its notification, unless a different period is foreseen in the decision. **A competent authority or the Commission may bring all necessary changes of a marketing authorization.** **National marketing authorisations shall be transferred under a European procedure after the conclusion of the referral procedure. Further variations shall apply to all the harmonized products.**	Au paragraphe 3, les autorités françaises souhaitent que les **États membres** puissent **en fin de procédure de référé réaliser des modifications d'office des AMM**. Les autorités françaises avaient proposé que cette possibilité de modifier d'office des AMM soit introduite au point 67. De plus, les autorités françaises souhaitent que soit inscrite dans le texte, **l'obligation de transformer les AMM nationales qui ont été harmonisées dans les conclusions du référé**, en AMM selon une procédure de reconnaissance mutuelle de façon à ce que les modifications ultérieures d'AMM ne conduisent pas à une nouvelle dysharmonisation

4. In case of centrally authorised veterinary medicinal products a decision as referred to in paragraph 1 shall be addressed to the marketing authorisation holder.		

CHAPTER V **HOMEOPATHIC VETERINARY MEDICINAL PRODUCTS**
Ce chapitre traite du cas spécifique des enregistrements de médicaments homéopathiques par dérogation à la procédure d'AMM. Les autorités françaises demandent si **les médicaments homéopathiques peuvent bénéficier d'une AMM, notamment en cas de revendication d'indications thérapeutiques.** Les autorités françaises s'interrogent sur la sortie des médicaments vétérinaires homéopathiques enregistrés du champ de la pharmacovigilance : - la Commission peut-elle éclairer les États membres sur les **bases scientifiques de ce choix : « Quels sont les événements indésirables, actuellement notifiés sur ces produits ? Leur nombre et leur nature ? »**

Article 88 *Homeopathic veterinary medicinal products*		
1. By way of derogation from Article 5, homeopathic veterinary medicinal products that satisfy the requirements set out in Article 89 and are not immunological homeopathic veterinary medicinal products shall be registered in accordance with Article 90. 2. The competent authorities shall record homeopathic veterinary medicinal products registered by them in the database referred to in Article 51.		

Article 89 *Registration of homeopathic veterinary medicinal products*		
1. Homeopathic veterinary medicinal products that satisfy all of the following conditions shall be subject to a registration procedure: a) the medicinal product is administered by a route described in the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in Member States; b) there is a sufficient degree of dilution to guarantee the safety of the medicinal product; in particular, the medicinal product shall not contain more than one part per 10 000 of the mother tincture; c) no specific therapeutic indication appears on the labelling of the medicinal product or in any information relating thereto.		

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 146 in order to adapt paragraph 1(b) and (c) in the light of new scientific evidence.		
Article 90 *Requirements and procedure for registration of homeopathic veterinary medicinal products*		
1. The following documents shall be included in the application for a registration of a homeopathic veterinary medicinal product: a) scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered; b) a dossier describing how the homeopathic stock or stocks is/are obtained and controlled, and justifying its/their		

homeopathic nature, on the basis of an adequate bibliography; in the case of homeopathic veterinary medicinal products containing biological substances, a description of the measures taken to ensure the absence of pathogens; c) the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation; d) the manufacturing authorisation for the veterinary medicinal products concerned; e) copies of any registrations or authorisations obtained for the same veterinary medicinal products in other Member States; f) the text to appear on the outer packaging and immediate packaging of the veterinary		

medicinal products to be registered; g) data concerning the stability of the medicinal product; h) in the case of veterinary medicinal products intended for food-producing species, proposed withdrawal period together with all requisite justification; i) in the case of veterinary medicinal products intended for food-producing species and containing pharmacologically active substances that have not been included in Regulation (EU) N° 37/2010 for the animal species in question, a document certifying that a valid application for the establishment of maximum residue limits has been submitted to the Agency in accordance with Regulation (EC) No 470/2009.		

2. An application for registration may cover a series of medicinal products derived from the same homeopathic stock or stocks.		
3. In a decision concerning registration the competent authority shall determine the conditions under which the homeopathic veterinary medicinal product may be made available to end users in accordance with Article 29.		
4. The procedure of registering a homeopathic veterinary medicinal product shall be completed within 210 days after the submission of a valid application.		

Chapitre VI Manufacturing, import, and export		
Les AF regrettent l'absence de dispositions similaires à celles introduites dans la Directive 2011/62/UE instituant un code communautaire relatif aux médicaments à usage humain, en ce qui concerne la prévention de l'introduction dans la chaîne d'approvisionnement légale de médicaments falsifiés. Il conviendrait notamment d'introduire dans le règlement relatif aux médicaments vétérinaires : ▪ la définition du médicament falsifié ; ▪ des obligations en matière de dispositifs de sécurité et de traçabilité ; ▪ de nouvelles exigences concernant les matières premières et excipients ;		
Article 91 *Manufacturing authorisations*		
1. A manufacturing authorisation shall be required in order to carry out any of the following activities ('manufacturing'): a) to produce or import veterinary medicinal products; or b) to engage in any part of the process of producing a veterinary medicinal product or of bringing a veterinary medicinal product to its final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing it or any constituent of it for supply as part of that	A manufacturing authorisation shall be required in order to carry out any of the following activities ('manufacturing'): a) to produce or import **from third countries** veterinary medicinal products **including autogenous vaccines**; or b) to engage in any part of the process of producing a veterinary medicinal product **or autogenous vaccines** or of bringing a veterinary medicinal product to its final state, including engaging in the processing, assembling, packaging, labelling, storage,	- Au paragraphe 1, les AF demandent que la rédaction soit précisée sur deux points afin de bien faire mentionner que : - l'activité d'importation visée au point a concerne les pays tiers à l'UE ; - les produits visés au a) et b) concernent les MV y compris les autovaccins.

process.	sterilising, testing or releasing it or any constituent of it for supply as part of that process.	
2. Notwithstanding paragraph 1, a manufacturing authorisation shall not be required for preparation, dividing up, changes in packaging or presentation where these processes are carried out solely for retail in accordance with Articles 107 and 108.		- Au paragraphe 2, les AF demandent que le **terme « division** » (« dividing up » en anglais) **soit défini clairement auparavant, notamment dans le chapitre I à l'article 4 « définitions »**. En effet, bien qu'existant déjà actuellement dans la directive 2001/82/CE en vigueur (à l'article 44), ce terme « division » nécessite d'être mieux encadré afin d'harmoniser les conditions dans lesquelles est effectuée cette opération : - l'opération de « division » a-t-elle pour objectif unique de répondre à l'exigence de délivrer uniquement « la quantité requise pour le traitement »

		telle que visée à l'article 107 §2 et à l'article 110 §3 ? - quel type de déconditionnement est-visé ? Les AF proposent que cette opération soit limitée au déconditionnement secondaire de l'emballage extérieur. - quels étiquetages sont définis pour les produits issus de cette opération de division ? Les AF soulèvent que les exigences d'étiquetage et de notice des produits issus de cette opération doivent être clairement indiqués à la section 4 du chapitre II.
3. The competent authorities shall record the manufacturing authorisations granted by them in the database on manufacturing, import and wholesale distribution set up in accordance with Article 94.		

4. Manufacturing authorisations shall be valid throughout the Union.		
Article 92 *Requirements for **obtaining a** manufacturing authorisation*	*Article 92* *Requirements for **applications of** manufacturing authorisations*	Les AF demandent un changement du titre : « Exigences applicables *aux demandes* d'autorisation de fabrication » (*Requirements for applications of manufacturing authorisations)* et.
1. Applications for manufacturing authorisations shall be submitted to a competent authority in the Member State where the manufacturing site is located.		
2. An application for a manufacturing authorisation shall contain at least the following information: (a) veterinary medicinal products which are to be manufactured or imported; (b) pharmaceutical forms which are to be manufactured or imported;		

(c) details about the manufacturing site where the veterinary medicinal products are to be manufactured or tested; (d) statement to the effect that the applicant fulfils the requirements laid down in Article 98.		
Article 93 ***Granting of*** *application for manufacturing authorisations*	*Article 93* - *Application for manufacturing authorisations*	La disposition vise à encadrer les demandes d'autorisations de fabrication et non à décrire l'octroi de l'autorisation : il s'agit ici du stade d'instruction de la demande
1. **Before granting a** manufacturing authorisation, the competent authority shall carry out an inspection in accordance with Article 125 of the manufacturing site where the veterinary medicinal products are to be manufactured or tested.	- 1 **For assessing an application for** manufacturing authorisation, the competent authority shall carry out **an inquiry or** an inspection in accordance with Article 125 of the manufacturing site where the veterinary medicinal products are to be manufactured or tested	Le pré-requis d'inspection mentionné au paragraphe 1 doit être complété par la notion d'enquête comme indiqué dans la directive 2001/82 à l'article 46 (car l'inspection ne peut avoir lieu que si l'établissement de fabrication est déjà en fonctionnement).

2. An authorisation shall apply only to the manufacturing site, the veterinary medicinal products, and the pharmaceutical forms specified in the application.		
3. Member States shall lay down procedures for granting manufacturing authorisations. The procedures for **granting a** manufacturing authorisation shall not exceed 90 days from the day on which the competent authority receives the application.	3.Member States shall lay down procedures for granting manufacturing authorisations. The procedures for **assessing an application for** a manufacturing authorisation shall not exceed 90 days from the day on which the competent authority receives the application.	
4. The competent authority may require the applicant to submit further information in addition to that supplied in the application pursuant to Article 92. Where the competent authority exercises this right, the time limit referred to in paragraph 3 of this Article shall be suspended until the additional data required has been submitted.		

5. A manufacturing authorisation may be granted conditionally, subject to a requirement for the applicant to undertake actions or introduce specific procedures within a given time period. The manufacturing authorisation **may** be suspended if these requirements are not complied with.	5. A manufacturing authorisation may be granted conditionally, subject to a requirement for the applicant to undertake actions or introduce specific procedures within a given time period. The manufacturing authorisation **shall** be suspended if these requirements are not complied with	L'autorisation de fabrication conditionnelle ***doit*** (et non « peut ») être suspendue lorsque les exigences ne sont pas respectées.
Article 94 *Database on manufacturing authorisations*	*Article 94* *Database on manufacturing* ***and wholesale distribution*** *authorisations*	Le **titre est trop restrictif :** la base de données porte sur les autorisations de fabrication *et de distribution en gros*.
1. A Union database on manufacturing, import and wholesale distribution shall be set up and maintained by the Agency ('manufacturing and wholesale distribution database').		

2. The database shall include information on any manufacturing and wholesale distribution authorisations granted by competent authorities within the Union.	2.The database shall include information on any manufacturing and wholesale distribution authorisations granted by competent authorities within the Union. **When a manufacturing and wholesale distribution authorisation has been granted conditionally, it shall be mentioned.**	les AF proposent que les autorisations conditionnelles soient signalées dans la base de données
3. The Agency shall make public a format for electronic submissions of data to the database.		
. 4 Competent authorities shall record in the manufacturing and wholesale distribution database information on authorisations and certificates granted in accordance with Articles 93, 103 and 105 together with information on the veterinary medicinal products covered by the authorisations, using the format referred to in paragraph 3.		

5. The Agency shall, in collaboration with Member States and the Commission, draw up functional specifications for the manufacturing and wholesale distribution database.		
6. The Agency shall ensure that information reported to the database is collated and made accessible and that the information is shared.		
Article 95 *Access to the database on manufacturing authorisations*	*Article 95* *Access to the database on manufacturing* ***and wholesale distribution*** *authorisations*	De même qu'à l'article 94, les AF font remarquer que le **titre est trop restrictif :** la base de données porte sur les autorisations de fabrication *et de distribution en gros*.
1. The competent authorities shall have full access to the database set up in accordance with Article 94.		

2. Manufacturers and wholesalers shall have access to the database to the extent necessary for them to comply with their obligations.		Au paragraphe 2, les AF s'interrogent sur la portée des termes « dans la mesure nécessaire pour leur permettre de s'acquitter de leurs obligations » : les fabricants et distributeurs auront-ils accès à la saisie de données dans la base de données ou auront-ils uniquement la possibilité de la consulter ? Les AF souhaitent que les fabricants et les distributeurs en gros n'aient qu'un accès consultatif.
3. The general public shall have access to information in the database specifying the companies that have been granted manufacturing or wholesale distribution authorisations and the manufacturing sites and **products** concerned by these authorisations	3. The general public shall have access to information in the database specifying the companies that have been granted manufacturing or wholesale distribution authorisations and the manufacturing sites and **pharmaceutical forms** concerned by these authorisations	Au paragraphe 3, les AF souhaitent préciser le sens de « médicaments concernés ». Cela doit s'entendre comme« formes pharmaceutiques » comme indiquées dans l'autorisation d'ouverture et non les noms des spécialités (en lien avec la base de données des médicaments).

Article 96 *Changes to manufacturing authorisations on request*		
1. If the holder of a manufacturing authorisation requests a change in that manufacturing authorisation, the procedure for examining such a request shall not exceed 30 days from the day on which the competent authority receives the request. In exceptional cases, this period of time may be extended by the competent authority to 90 days. 2. The application shall contain description of the requested change and the authorised products affected by this change.	;	

3. Within the period referred to in paragraph 1, the competent authority may request the holder to provide supplementary information within a set time limit. The procedure shall be suspended until such time as the supplementary information has been provided. 4. The competent authority shall inform the holder of the outcome of the assessment and where appropriate, amend the manufacturing authorisation, and update, where appropriate, the manufacturing and wholesale distribution database.		

Article 97 *Manufacturing authorisation for import and export*		
1. The manufacturing authorisation shall also be required for imports from and exports to third countries. 2. The requirement referred to in paragraph 1 shall not apply to holders of a wholesale distribution authorisation referred to in Article 104.		
Article 98 *Obligations of the manufacturing authorisation holders*		
The holder of a manufacturing authorisation shall: a) have at his disposal suitable and sufficient premises, technical equipment and testing facilities for the manufacture, export or import of the veterinary medicinal products stated in the manufacturing authorisation;		

b) have at his disposal the services of at least one qualified person within the meaning of Article 100; c) enable the qualified person referred to in Article 100 to carry out his duties, particularly by placing at his disposal all the necessary technical equipment and testing facilities; d) inform the competent authority if the qualified person referred to in Article 100 is replaced; e) have at his disposal the services of staff complying with the legal requirements existing in the Member State concerned as regards both manufacture and controls; f) allow the representatives of the competent authority access to his premises at any time;		

	(f bis) comply with the principles and the guidelines on good manufacturing practice for medicinal products and use as starting materials only active substances which have been manufactured in accordance with the detailed guidelines on good manufacturing practice for starting materials	Les AF souhaitent que soit ajoutée l'obligation pour le titulaire d'une autorisation de fabrication de : - **respecter les principes et lignes directrices relatifs aux bonnes pratiques de fabrication des médicaments** et - De **n'utiliser en tant que matières premières que des substances actives qui ont été fabriquées conformément aux lignes directrices détaillées relatives aux bonnes pratiques de fabrication des matières premières;** En effet, cette obligation (qui existe actuellement à l'article 50 point f) de la directive 2001/82/CE) **permet d'assurer un niveau de qualité des médicaments vétérinaires harmonisé au sein de l'Union européenne garant ainsi de leur efficacité et innocuité.**

g) keep detailed records of all veterinary medicinal products supplied by him, including samples, in accordance with Article 99.		.Par ailleurs, les AF proposent qu'un article 102 bis soit créé pour que soient **définies par actes d'exécution les BPF de médicaments vétérinaires et de matières premières.**
Article 99 *Record keeping*		
The following information shall be recorded in respect of all veterinary medicinal products supplied by the holder of a manufacturing authorisation: a) date of the transaction, b) name of the veterinary medicinal product, c) quantity supplied, d) name and address of the recipient, e) batch number. 2. The records mentioned in paragraph 1 shall be available for inspection by competent authorities for a period of 3 years.		

Article 100 *Qualified person for manufacturing*		
1. The holder of a manufacturing authorisation shall have permanently and continuously at his disposal the services of at least one qualified person who fulfils the conditions laid down in this Article and is responsible, in particular, for carrying out the duties specified in Article 101.		
2. The qualified person shall **be in possession of a diploma, certificate or other evidence of appropriate qualification and shall have acquired sufficient experience in the field of manufacturing. The holder of the authorisation may himself assume the responsibility referred to in paragraph 1, if he personally fulfils those conditions as specified above.**	2. The qualified person shall **provide evidence that he has the knowledge required for the manufacture and control of veterinary medicinal products, in order to fulfill the obligations specified in Article 101, in particular:** **a) The qualified person shall be in possession of a diploma, certificate or other evidence of appropriate qualification of formal qualifications**	Il est nécessaire de définir précisément le socle minimal de la formation théorique de la personne qualifiée afin de ne pas créer des disparités de profil et de compétences au sein de l'Union européenne. Cette personne assure la responsabilité de la libération des lots et est donc garante de la bonne qualité, efficacité et innocuité des médicaments vétérinaires qu'elle libère. De même, il convient de préciser ce qui est attendu en termes

	awarded on completion of a university course of study, or a course recognized as equivalent by the Member State concerned, extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines: pharmacy, medicine, veterinary science, chemistry, pharmaceutical chemistry and technology, biology. **and,** **b) The qualified person shall have acquired sufficient experience over at least two years, in the field of manufacturing of veterinary medicinal products and active substances. The duration of practical experience may be reduced by one year where a university course lasts for at least five years**	d' « expérience suffisante » afin de définir la durée de cette expérience pratique et les activités que doit avoir exercées la personne qualifiée. La définition de ces connaissances et compétences permet de s'assurer de la bonne exécution des missions qui sont attribuées à la personne qualifiée (parmi lesquelles figure la libération des lots). Ces propositions sont en cohérence avec les dispositions qui existent actuellement dans la directive 2001/82/CE en vigueur (article 53).

	and by a year and a half where the course lasts for at least six years. **The holder of the authorisation may himself assume the responsibility referred to in paragraph 1, if he personally fulfills those conditions as specified above.**	
Article 101 *Batch release of veterinary medicinal products*		
1. Where veterinary medicinal products have been manufactured by the holder of a manufacturing authorisation, the qualified person for manufacturing shall ensure that each batch of the veterinary medicinal products has been manufactured and tested in compliance with the terms of the marketing authorisation. The qualified person for manufacturing shall prepare a report to this effect.		.

2. Where veterinary medicinal products have been imported from third countries, the qualified person for manufacturing shall ensure that each imported production batch has undergone in the Union a qualitative and a quantitative analysis of at least all the active substances, and all the other tests necessary to ensure the quality of the veterinary medicinal products in accordance with the requirements of the marketing authorisation.		
3. The reports signed by the qualified person as referred to in paragraph 1 shall be valid throughout the Union.		
4. The qualified person for manufacturing shall keep records in respect of each released production batch. These records shall be kept up to date as operations are carried out and shall remain at the disposal of the competent authority for a period of 5 years.		

5. Where veterinary medicinal products manufactured in the Union are imported into the Union from a third country, paragraph 1 shall apply. 6. Where veterinary medicinal products are imported from third countries with which the Union has made arrangements regarding application of standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 91/412/EEC and it is demonstrated that the tests referred to in paragraph 1 have been carried out in the exporting country, the competent authority in the Member State of importation may relieve the qualified person of the of responsibility for carrying out the tests referred to in paragraph 2.		

Article 102 *Competent authorities' measures*		
1. The competent authority shall ensure that the obligations of qualified persons referred to in Article 100 are fulfilled, either by means of appropriate administrative measures or by making such persons subject to a professional code of conduct. 2. The competent authority may temporarily suspend such persons upon the commencement of administrative or disciplinary proceedings against them for failure to fulfil their obligations.		
	Article 102 bis (new) **The Commission shall, by means of implementing acts, adopt the principles and guidelines of good manufacturing practice for veterinary medicinal products referred to in Article 98 (f bis). Detailed guidelines shall be published by the Commission and**	Les AF souhaitent que soient réintroduites les dispositions sur les BPF des médicaments vétérinaires et des matières premières (telles qu'elles existent actuellement aux articles 50 a et 51 de la directive 2001/82/CE en vigueur).

	revised as appropriate to take account of scientific and technical progress. **The principles of good manufacturing practice as regards the manufacturing of active substances for use as starting materials as referred to in Article 98 (f bis) shall be adopted in the form of detailed guidelines. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).**	Aussi, les AF proposent l'ajout d'un article 102 bis

Article 103 *Certificates of manufacturing authorisations*		
Upon request of the manufacturer or exporter of veterinary medicinal products, or of the authorities of an importing third country, the competent authority shall certify that the manufacturer: a) holds a manufacturing authorisation for the product in question, or b) possesses a certificate of good manufacturing practice as referred to in Article 127. When issuing such certificates, the competent authority shall attach the approved summary of the product characteristics or, in the absence thereof, an equivalent document, in case of veterinary medicinal products intended for export which are already authorised in	Upon request of the manufacturer or exporter of veterinary medicinal products, or of the authorities of an importing third country, the competent authority shall certify that the manufacturer: a) holds a manufacturing authorisation for the product in question, or b) possesses a certificate of good manufacturing practice as referred to in Article 127. When issuing such certificates, the competent authority shall attach the approved summary of the product characteristics or, in the absence thereof, an equivalent document, in case of veterinary medicinal products intended for export which are already authorised in	Il **manque une disposition pour prévoir le cas où le fabricant ne possède pas d'autorisation de mise sur le marché** : comme prévu à l'article 93 (3) de la directive 2001/82/CE, le fabricant doit fournir aux autorités compétentes, pour l'établissement du certificat, une déclaration expliquant les raisons pour lesquelles cette autorisation n'est pas disponible.

their territory.	their territory. **Where the manufacturer is not in possession of an authorization to place the product on the market, he shall provide the authorities responsible for establishing the certificate referred to in article 127 with a declaration explaining why such authorization is not available.**	