Written contributions from delegations

Comments from the Belgian delegation

Written BE comments on 'Rolling review' - EMA Fee regulation proposal

Annex 1, point 2

2. Scientific opinions and assessments prior to potential submission of an application for a marketing authorisation

2.1. A fee of EUR 549 800 shall apply to any of the following:

(a) an opinion on a medicinal product for compassionate use pursuant to Article 83 of Regulation (EC) No 726/2004;

(b) a **rolling review of** ~~an assessment on an on-going basis of~~ data packages of particulars and documents submitted to the Agency by a prospective applicant prior to a formal submission of an application for a marketing authorisation falling within the scope of Regulation (EC) No 726/2004.

That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR 153 000 for the rapporteur and EUR 143 300 for the co-rapporteur.

2.2. In the event of multiple submissions of data packages submitted by the same prospective applicant for the same product, the fee set out in point 2.1 (b) shall only be charged once.

2.3. The amounts set out in point 2.1 shall be **charged and payed on top of** ~~deducted from~~ the respective fee and ~~from~~ the remuneration to competent authorities of the Member States payable for a marketing authorisation application for the same product, where such application is submitted by the same applicant.

Argumentation

In annex 1 point 2.1.(b) a fee and renumeration are foreseen for 'an assessment on an ongoing basis', which, as the commission confirmed, is equivalent to a rolling review. The issue however is that in the current proposal, there is no fee or renumeration for such a rolling review in when it is followed by a market authorization application:

- Point 2.3 of annex 1 states the amounts of the fees and renumerations for the rolling review will be deducted from the respective fee and renumeration to NCAs for a marketing authorization application for the same product. This de facto means in case after a rolling review a marketing authorization application is submitted, the rolling review will be free of charge.

  In concrete terms this means the following: the rolling review fee for a company is €549800; when the company applies for a market authorization after this rolling review, the company will only pay the difference amount between the rolling review fee and the market application fee. In case of a market application for a new product with new active substance (3.1) which costs 684900 euros, the company pays a fee of (684900 minus 549800 euros) the residual amount of 135100 euro. The total fee for the company is always the market application fee. This seems to suggest an incentive through a fee waiver. Why is this incentive not covered by the EMA budget like the other reductions?

- The text seems to suggest that the same applies to renumerations for NCAs. In our reading the NCAs will not be renumerated for a rolling review in case the rolling review is followed by a market authorization application.

  In concrete terms, this means the following: the renumerations for a rolling review are 153000 euro and 143300 euro for the respective rapporteurs. The renumerations for a market authorization application (3.1) are 217300 euro and 189300 euro for the respective rapporteurs. When a market authorization application follows a rolling review, the renumeration for the respective rapporteurs will be (217300 euro minus 153000 euro) and (189300 euro minus 143300 euro). The total renumeration for the respective rapporteurs for a rolling review and a marketing authorization application for that same product will always be the market authorization application renumeration. This is very troublesome, as rolling reviews are very labour, time and expert intensive. It is not sustainable to not have this work renumerated.

Both the fee charged and the renumeration paid to an NCA for a rolling review should be charged and paid on top of the respective fee and renumeration for a marketing authorization application for the same product.

We also want to call for coherence with the upcoming pharma review, more specifically in the regulation art. 6§2, a “phased review for medicinal products that are likely to offer an exceptional therapeutic advancement in the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the Union with major contribution to patient care” is mentioned. Does this refer the concept of rolling review? And if so, is the this the procedure that the commission means to refer to in the fee regulation proposal?

Comments from the French delegation

Objet : commentaires des autorités françaises sur le compromis proposé par la présidence suédoise relatif à la proposition de règlement sur les redevances dues à l'Agence européenne des médicaments (annexes), suite à la réunion du groupe de travail « Produits pharmaceutiques et dispositifs médicaux » du 27 avril 2023.

Ref : ST 8423/23.

Le niveau des montants des redevances des médicaments vétérinaires tel qu'il ressortait de la proposition de la Commission suscitait déjà une vive inquiétude des autorités françaises sur la capacité du secteur à supporter ces coûts. Or, le compromis de la présidence suédoise, discuté lors du groupe pharmaceutique du 27 avril dernier, propose de relever encore ces montants de 20%.

Les autorités françaises identifient un risque fort de déstabilisation de ce secteur industriel très spécifique en raison du niveau trop élevé des redevances. Cela pourrait avoir des conséquences sur l'innovation et la disponibilité des médicaments vétérinaires, avec de possibles répercussions sur la santé animale, la santé humaine et le bien-être général.
Dans ce contexte, une augmentation de 13 %, limitée aux seuls effets de l'inflation, est le niveau maximal que les autorités françaises seraient prêtes à accepter. Les autorités françaises réitèrent par ailleurs leur proposition de prévoir une révision rapide, après la publication du règlement, des montants de ces redevances sur la base de coûts objectivés par les autorités nationales compétentes (ANC).

The level of fees for veterinary medicinal products, as set out in the Commission's first proposal, already raised serious concerns on the part of the French authorities about the sector's ability to bear these costs. The Swedish Presidency's compromise, discussed at the Pharmaceutical Group meeting on 27th of April, proposes to increase these amounts by a further 20%.

The French authorities identify a high risk of destabilization of this very specific industrial sector if the fees are too high. The difficulties of the industry could have serious consequences on innovation and on the availability of veterinary medicines, with possible consequences on animal health, but also on human health and general well-being.
In this context, a 13% increase of the fees (impact of inflation) would be the maximum level that the French authorities could accept. The French authorities also underline their proposal to examine and evaluate these fees on a cost basis, based on data collected by the NCAs (national competent authorities), as soon as possible after the publication of the Regulation

Comments from the German delegation

DE comments on the proposal for a regulation on fees and charges payable to the European Medicines Agency

The comments are preliminary. We also refer to our written comments submitted on 10 and 17 February, 1 and 27 March and 5 and 24 April. The wording is based on the revised compromise text proposed by the Presidency on 20 April.

DE changes are marked **underlined and bold**. Deletions are marked in ~~strikethrough~~.

I. Annex I

2. Scientific opinions and assessments prior to potential submission of an application for a marketing authorisation

2.1.(b) Rolling Review:

In the Commission proposal, there is no fee or remuneration for a rolling review when it is followed by a market authorization application. This is not sustainable, as the rolling review process produces significant additional workload for the competent authorities. We support the proposal made by Belgium, which was supported by other Member States in the last Council Working Party, for an additional remuneration.

An additional remuneration is needed that takes into account the extensive work, time investment and level of expertise required in rolling reviews. Both the fee and the remuneration for a rolling review should be charged and paid on top of the respective fee and remuneration for a marketing authorisation application for the same product.

II. Annex 5

2. Applications relating to core dossier medicinal products to be used in a human pandemic situation

[…]

2.2. In addition to the deferral provided for in point 2.1, for regulatory activities within the framework of the submission of a core dossier for a pandemic [influenza]* vaccine and the follow-up submission of a pandemic variation, a fee reduction of 100 % shall apply in the following cases:

(a) pre-submission activities pursuant to section 3 of Annex IV;
(b) scientific advice pursuant to section 1 of Annex I;
(c) extension of marketing authorisation pursuant to section 4 of Annex I;

(d) major type-II variation pursuant to section 5 of Annex I;
~~(e) annual fee pursuant to section 1 of Annex III.~~

Those reductions shall apply until the human pandemic situation is duly recognised.

~~2.3. Where reductions apply pursuant to point 2.2, no remuneration shall be paid to the national competent authorities for the annual fees referred to in point 2.2(e).~~

Rationale:
The annual fee should not be waived, as it is not related to pandemic preparedness. We therefore propose to delete point 2.2(e) in the list as well as point 2.3

*remark on the scope of point 2.2: It remains to be seen whether the concept of pandemic preparedness vaccines will become established for other pandemic vaccines in the future. It would have to be examined whether the pandemic influenza vaccines should only be cited as examples.

III. Annex 6

Annex VI
Performance Information

The following information shall relate to each calendar year:

[…]

(6) number of working hours spent by the rapporteur and the co-rapporteurs or roles considered as equivalent for the purposes of this regulation as referred to in the Annexes to this regulation, and experts contracted for the procedures of the expert panels on medical devices per **type of** procedure~~s~~ on the basis of the information provided to the Agency by the national competent authorities concerned. The **types of** procedures to be included shall be decided by the Management Board based on a proposal by the Agency.

Rationale:
We are concerned that gathering the information per individual procedure will be too burdensome and will unnecessarily take up resources at the competent authorities. We therefore propose to focus the performance information on the types of procedures.

Comments from the Greek delegation[1]

[1] Supported by Croatia and Slovenia

The Greek delegation avails the opportunity to express its appreciation to the Swedish Presidency for its hard work and this compromise proposal with the revised annexes of the EMA fees Regulation. We believe that this compromise is in the right direction aiming to better reflect the role of the NCAs. In this context, please find below our comments and additions:

ANNEX I

Fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use

5. Major variation of type II to the terms of a marketing authorisation in accordance with Commission Regulation (EC) No 1234/2008

5.1. A fee of EUR ~~99 800~~ **175 300** shall apply to an application for a major variation of type II as defined in Article 2(3) of Regulation (EC) No 1234/2008 ('major variation of type II') for an addition of a new therapeutic indication or modification of an approved indication. The remuneration shall be EUR ~~29 400~~**64 400** for the rapporteur and EUR ~~29 400~~**64 400** for the co-rapporteur.

5.2. A fee of EUR ~~13 000~~**17 100** shall apply to an application for a major variation of type II not covered by point 5.1. The remuneration shall be EUR ~~6 800~~**10 100** for the rapporteur.

5.3. For each application for a major variation of type II that is grouped in a single application pursuant to Article 7 of Regulation (EC) No 1234/2008, the corresponding fee shall be charged as set out in points 5.1 and 5.2. Remuneration shall be paid in accordance with those points.

5.4. Where a work-sharing application pursuant to Article 20 of Regulation (EC) No 1234/2008 includes more than one centrally authorised product, the fees and remuneration specified in points 5.1 and 5.2 of this Annex shall apply to each variation of the first centrally authorised product, whereas a charge of EUR ~~800~~ **900** shall apply to each variation of the second and subsequent centrally authorised product included in the application.

6. Variation of type IB to the terms of a marketing authorisation in accordance with Commission Regulation (EC) No 1234/2008

6.1. A fee of EUR 2 000 shall apply to an application for a minor variation of type IB as defined in Article 2 (5) of Regulation (EC) No 1234/2008 ('minor variation of type IB'). The remuneration shall be EUR 500 for the rapporteur.

7. Renewal to the terms of a marketing authorisation in accordance with Commission Regulation (EC) No 726/2004

7.1. A fee of EUR 2 000 shall apply to an application for a renewal as defined in Article 14 (1-3) of Regulation (EC) No. 726/2004 ('renewal of a marketing authorization application'). The remuneration shall be EUR 500 for the rapporteur.

8. Annual assessment to the terms of a marketing authorisation under exceptional circumstances in accordance with Commission Regulation (EC) No 726/2004

8.1. A fee of EUR 2 000 shall apply to an application for an annual assessment as defined in Article 14(8) of Regulation (EC) No. 726/2004 and Part II.6 of the Annex I to Directive 2001/83/EC ('annual assessment of a marketing authorization under exceptional circumstances'). The remuneration shall be EUR 500 for the rapporteur.

14. Paediatric applications in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council[2]

14.1. A fee of EUR ~~31 700~~**36 400** shall apply to an application for agreement of a paediatric investigation plan requested pursuant to Article 15 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR ~~6 700~~**8 000** for the rapporteur and 2 600 for the Peer Reviewer.

14.2. A fee of EUR ~~17 600~~**20 400** shall apply to an application for a modification of an agreed paediatric investigation plan pursuant to Article 22 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR ~~6 400~~**7 700** for the rapporteur and 2 500 for the Peer Reviewer.

14.3. A fee of EUR ~~12 000~~**13 700** shall apply to an application for a product-specific waiver pursuant to Article 13 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR ~~1 800~~**2 200** for the rapporteur and 700 for the Peer Reviewer.

14.4. A fee of EUR ~~8 000~~**9 100** shall apply to a request for compliance check with the paediatric investigation plan pursuant to Article 23 of Regulation (EC) No 1901/2006. Such fee shall be waived in full. The remuneration shall be EUR ~~1 000~~**1 200** for the rapporteur and 400 for the Peer Reviewer.

2 Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

Comments from the Netherlands delegation[3]

[3] Supported by Croatia on the PRAC rapporteurship comments

The Hague, 04-04-2023

<u>Comments from the Netherlands</u> on the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council (COM(2022) 721 final)

The comments below are in response to the revised Presidency compromise text (8423/23) as discussed during the CWP of 27 April 2023.

First of all, the Netherlands wishes to thank the Presidency again for their substantial work in incorporating the input of the Member States for the targeted approach into the legislative proposal. The Presidency has taken into account many of the proposals put forward by the Member States.

The Netherlands has a few remaining comments. The comments included below were already made during previous CWPs, most recently the CWP of 27 April.

1. Annex I – fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use

<u>Point 2.1(b): "rolling review"</u>

The Netherlands does not agree with the fee and remuneration amounts proposed. The amounts proposed equal the amounts for a marketing authorisation application pursuant to Art. 8(3) - known active substance as proposed under point 3.2 of this annex. **Instead, at the very minimum, the fee and remuneration amounts for point 2.1(b) should be equal to those proposed for a marketing authorisation application pursuant to Art. 8(3) – new active substance under point 3.1 of this annex.** In other words, the amounts for point 2.1(b) should be corrected as follows:

*2.1. A fee of EUR ~~643 200~~ **<u>803 700</u>** shall apply to any of the following:*

(a) an opinion on a medicinal product for compassionate use pursuant to Article 83 of Regulation (EC) No 726/2004;

(b) an assessment on an on-going basis of data packages of particulars and documents submitted to the Agency by a prospective applicant prior to a formal submission of an application for a marketing authorisation falling within the scope of Regulation (EC) No 726/2004.

*That fee shall cover all strengths, all pharmaceutical forms and all presentations submitted in the same application. The remuneration shall be EUR ~~183 600~~ **<u>260 800</u>** for the rapporteur and EUR ~~172 000~~ **<u>227 200</u>** for the co-rapporteur.*

If this is not corrected, this means that companies who had their product containing a **new** active substance **fully** assessed through the rolling review but subsequently chose **NOT** to submit a marketing authorisation application pay a lower fee (i.e. €643 200) than companies whose product were "only" assessed (and subsequently approved or not) via the regular marketing authorisation application procedure (€803 700). The difference in payable amount is €160k, whereas the work involved for NCAs and EMA is the same or actually, as pointed out below, significantly more. The reason for this discrepancy is the fact that: **(1)** the fee for a rolling review under point 2.1(b) equals the fee under point 3.2 of this annex for an Article 8(3) - known active substance application fee and **(2)** the amount in point 2.1(b) is to be deducted from the fee under point 3 where such application is submitted by the same applicant. Hence, the proposals under points 2.1(b) and 2.3 combined lead to an unfair and non-cost-based fee system.

In addition, although the rules for the eligibility for the rolling review are not within the scope of the proposed EMA fee regulation, we wish to point out that these provisions lead to a perverse incentive for companies to choose the rolling review instead of a regular marketing authorisation application. This comments is even more important now that the Commission has proposed, as part of the revision of the general pharmaceutical legislation, to extend the scope of the rolling review beyond public health crisis-related products.

We further comment that no cost and time data have been collected for the rolling review. The Dutch Medicines Evaluation Board has calculated that their costs for a rolling review are substantially higher than for a regular application for a marketing authorisation. There are several reasons for that, one being that the underlying data are often of lower quality which takes more time to assess. Another being that the assessment reports have to be updated more often. We therefore see the need to reassess the fee and remuneration amounts under point 2.1(b) via the cost-monitoring system and special report under Article 10 of the proposed regulation once more experience has been gained with the rolling review (i.e., once more time and cost data are available relevant to the rolling review).

Point 5: Type II variations

The Presidency proposal is in line with the input from the Member States for the targeted approach. The Netherlands therefore supports the proposal. The Netherlands however wishes to comment on the Commission's response to the Presidency proposal in the CWP of 27 April. The Commission indicated that they did not agree with the amounts proposed for Type II variations as the approach chosen would not be cost-based. First, the Netherlands wishes to underline that the data used for the calculations for the Commission proposal are in fact no longer cost-based, because hours spent and hourly rates have increased since 2016/2017. Simply correcting the amounts for inflation will therefore not lead to cost-based amounts. Second, the data provided via the targeted approach clearly stated **actual numbers for current average hours spent and current hourly rates**, which is the starting point for a cost-based approach.

To reiterate what was provided via the targeted approach (supplemented with additional calculations for costs not corrected for inflation rate or general adjustment and costs corrected for inflation):

Type of variation	Role	Current average		Costs (hours x rate) Note: These amounts do not include the proposed general adjustment of 20% or an adjustment for 13% inflation rate	Costs (hours x rate), including a correction for 13% inflation rate	Costs (hours x rate), including a general adjustment of 20%	Initial Commission proposal, corrected for an inflation rate of 13%
		Hours spent	Rate (these amounts EXCLUDE the general adjustment of 20% that was proposed via the targeted approach)				
Point 5.1 **Add. indication**	**Rapp**	347	154.75 EUR	**53 689 EUR**	**60 669 EUR**	**64 400 EUR**	**33 222 EUR**
	Co-Rapp	347	154.75 EUR	**53 689 EUR**	**60 669 EUR**	**64 400 EUR**	**33 222 EUR**
Point 5.2 **Quality and Safety**	**Rapp**	58	145	**8 410 EUR**	**9 503 EUR**	**10 100 EUR**	**7 684 EUR**

Following a cost-based approach means using for the calculations of fee and remuneration amounts **current** average time spent and **current** hourly rates. This means that the figures provided above should be included into the formula used for the calculation of fee and remuneration amounts, instead of those collected years ago for the EMA MBDG exercise. If new actual data on hours spent and hourly rates are not accepted for unclear reasons, then not only will remuneration amounts for variations not cover incurred costs, which is against the cost-based principle of this regulation, but this will also create serious concerns for the future application of the cost-monitoring system.

Further, in regards Type II other, although it appears that adjusting the initial Commission proposal for 13% inflation would yield an amount that is not too far from the costs calculated for the targeted approach, it needs to be pointed out that Type II other variations occur with a high frequency. The seemingly small deficit for every Type II other variation therefore adds up to a significant deficit for the rapporteur on an annual basis. Type II extension/modification of indication on the other hand occur at a low frequency, but the deficit that would be created if current hourly rates and current hours spent are not taken into consideration is clearly large. Please keep in mind that rapporteurs have no choice in whether or not to take on Type II variations and NCAs therefore cannot control the financial consequences following from Type II variations.

Point 6.7: Pharmacovigilance referral

The Netherlands does not agree with the remuneration amount proposed. The hourly rate used for the calculation of the referral fees is too low. The proposed fees are based on an hourly rate of €38,50 / hour. There are probably only very few NCAs that can work for this rate. A more realistic hourly rate would be €120 / hour (this hourly rate does not include a correction for inflation or the proposed general adjustment). If you apply this more realistic hourly rate to the average number of hours used for calculating the fee, i.e. about 590 hours, then the amount for remuneration has to be substantially higher than proposed here.

Pharmacovigilance referrals are important in regards patient safety. A remuneration amount that is significantly lower than costs incurred by NCAs may lead to rapporteurs trying to avoid starting a referral if they can.

Further, we propose only a single remuneration amount for pharmacovigilance referrals, contrary to the Commission proposal, as in our view this would cover NCAs' costs regardless of the number of active substances or combination of active substances and the number of MAHs.

2. Annex I and III – PRAC rapporteurship

The Netherlands is of the opinion that the PRAC rapporteur should receive a share in the remuneration for initial marketing authorisation applications (point of Annex I) and annual fee (point of Annex III). More specific:

- Annual fee: The proposed share in the annual fee for the PRAC rapporteur is based on PRAC rapporteur activities such as signal assessments as well as assessment of the RMP for variations. To cover these costs, the PRAC rapporteur is to receive 10% of the proposed remuneration amount of the CHMP rapporteur **PLUS** 10% of the proposed remuneration amount of the CHMP co-rapporteur. This means that both CHMP rapporteurs receive 90% of the remuneration amounts initially proposed for these roles. These percentages are based on medium hours and hourly rates per relevant activity.
- Applications for marketing authorisation: The proposed share in the procedural fees for the PRAC rapporteur is based on costs incurred by the PRAC rapporteur for assessment of the RMP and the pharmacovigilance plan. To cover these costs, the PRAC rapporteur is to receive 5% of the proposed remuneration amount of the CHMP rapporteur **PLUS** 5% of the proposed remuneration amount of the CHMP co-rapporteur. This means that both CHMP rapporteurs receive 95% of the remuneration amounts initially proposed for these roles. These percentages are based on medium hours and hourly rates per relevant activity.

For detailed calculations, we refer to our contribution for the targeted approach.

The Netherlands has therefore made a proposal for redistribution of certain CHMP (co-)rapporteurs' remuneration amounts to also compensate the PRAC rapporteur role. This proposal does not lead to amendment of the fee to be paid by industry or to amendment of the fee share for EMA, it only leads to amended remuneration amounts for the CHMP (co-)rapporteur and new remuneration amounts for the PRAC rapporteur (i.e., the amounts for the CHMP rapporteurs are partially re-distributed to the PRAC rapporteur).

The proposal only relates to the PRAC rapporteur, because the PRAC co-rapporteur generally has a limited role. In addition, the redistribution of the share for NCAs, instead of a top-up (which would make total fees and total remuneration amounts higher), is considered sufficient to generally cover NCAs' costs. Reason is that for legacy products, the NCA that is CHMP rapporteur is also the PRAC rapporteur, meaning that the relevant NCA already receives a share of the CAP annual fee and procedural fee for marketing authorisation applications. For new products (i.e., products for which the marketing authorisation was applied for after the application of the new pharmacovigilance legislation), however, the NCA that acts as PRAC rapporteur is not the same as the NCAs that act as CHMP rapporteurs.

The underlying rationale for this proposal is that the hours spent by the PRAC rapporteur on initial applications, variations and additional activities (as collected for the evaluation of the fee system) have been contributed by the Commission to the CHMP rapporteurs' hours. The PRAC rapporteur is however not the same NCA as those acting as CHMP (co-)rapporteur, which means they are not financially compensated for their important work. For instance, the PRAC rapporteur is responsible for the assessment of the RMP and Pharmacovigilance plan for initial applications and certain Type II variations and for signal detection (additional activity), but they do not receive a share of the relevant procedural and annual fee paid by companies.

This makes the PRAC rapporteur role unattractive, which is problematic as it is an important role in regards guaranteeing patient safety. Already now it is hard to appoint PRAC rapporteurs. If there's no financial compensation for PRAC raps this means that NCAs will have to cross subsidize from other activities, which is against the objective of this regulation. And then there is the issue that smaller NCAs that may not have funds from CHMP rapporteur fees are not able to get involved more because they can't afford to take on the role of PRAC rapporteur.

This comment is especially relevant, now that in future CHMP and PRAC may be the only scientific committees within the EMA, as is proposed by the Commission for the revision of the pharmaceutical basic acts.

3. Annex II – fees, charges and remuneration for assessment procedures and services relating to medicinal products for veterinary use +
Annex III – annual fees for veterinary products

The Netherlands would like to place a cautionary comment. The veterinary sector, because of the specifics of its market, is vulnerable. The initial Commission proposal already meant an increase in veterinary fees, although the exact impact on annual costs for the sector will only be known once more experience has been gained with the new veterinary regulation. We are concerned about the potential impact any further increase in proposed fees and remuneration amounts could have on the veterinary sector. For the Netherlands, at least for now, the initial Commission proposal would be acceptable, which is also why we didn't request any of the procedures to be included in the targeted approach. In our view, in the fairly near future, the cost-monitoring system provided for in Article 10 could then be used to recalculate the fees and remuneration amounts based on actual costs incurred by EMA and NCAs once more experience has been gained with the new veterinary regulation.

4. Annex III – annual fees

Cyprus, Latvia, Malta and Slovenia requested in their written comments from 10 February the pharmacovigilance annual fee to be waived in full for medicinal products authorised in EU Member States with a population of around 3 million or less. In the Council Working Party of 20 February, the Presidency explained that they, together with the Commission, are looking for a technical solution maintaining the status quo. The Netherlands sympathises with the reasons underlying this proposal. However, more in-depth analysis on budgetary consequences and the number of products impacted are needed before we can take a position on this matter. We therefore kindly await the Presidency/Commission proposal for this technical solution.

5. Annex IV – other fees

Point 1: inspection

The Presidency proposal is based on the input provided by the Member States via the targeted approach. The proposal is based on a single fee per inspected site (GMP/GCP). This is different from the current approach where, via the Implementing rules, different fee levels can be calculated per site depending on the complexity of the inspection. If the approach is followed of a more simplified fee system where there is only a single fee per site, then the amount proposed by the Presidency (which is higher than the amount proposed by the Commission) is necessary to cover all types of inspections (simple and complex).

However, considering inspections are complex activities, we agree with the Commission's comment made during the CWP of 27 April that a more granular approach is to be favoured. This is also of importance for the sustainability of the EU inspectorate network. In addition, a single fee may lead to a perverse stimulus to focus on easy (i.e. lower-cost) inspections.

We therefore propose to maintain the granular approach as is currently applicable, which gives the option to charge per product or additional activity or additional team for GMP/GCP inspections. In regards PMF inspections it is of importance that the fee is calculated on a per site basis as there can be multiple sites in a single PMF, and this should be reflected in the fee. Such a granular approach can be based on the current approach detailed in the Implementing Rules and adopted by the EMA Management Board via the Working Arrangements in Article 8 of the new regulation.

Since also in future there will be simple inspections that will not attract "top-up fees", it is of essence that the basic fee included in the annex is sufficient to cover inspectorates' costs for simple inspections. Otherwise it will be unattractive to perform inspections that do not generate additional fees. The basic fee should be higher than the top-up fees. The Commission proposal for the basic fee is considered too low, but the time between the CWP of 27 April and now has appeared too short to calculate the exact average costs for a simple inspections. Please note that the calculations made for the targeted approach were based on average costs for all types of inspections (simple and more complex), so some adjustments are necessary.

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CONTRIBUTION

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (Attachés) Working Party on Pharmaceuticals and Medical Devices (EMA fees)
Subject:	EMA fees proposal - comments from delegations

Delegations will find attached comments from delegations on the annexes of the EMA fees proposal.