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From: Presidency

To: Delegations

Subject: Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC
Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006
- *Exchange of views*

Delegations will find in Annex the Articles related to the governance of the European Medicines Agency, to be discussed at the meetings of the Working Party on Pharmaceuticals and Medical Devices on 28-29 October 2024.

REGULATION

Chapter XI

European Medicines Agency

Section 1

Tasks of the Agency

Article 135

Establishment

The functioning of the European Medicines Agency established by Regulation (EC) No 726/2004 (the ‘Agency’) shall continue in accordance with the present Regulation.

The Agency shall be responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products for human use and of veterinary medicinal products.

Article 136

Legal status

1. The Agency shall have legal personality.
2. In each of the Member States, the Agency shall enjoy the most extensive legal capacity accorded to legal persons under their laws. It may, in particular, acquire or dispose of movable and immovable property, and be party to legal proceedings.
3. The Agency shall be represented by an Executive Director.

Article 137

Seat

The seat of the Agency shall be established in Amsterdam, the Netherlands.

Article 138

Objectives and tasks of the Agency

1. The Agency shall provide the Member States and the institutions of the Union with the best possible scientific opinion on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human use, veterinary medicinal products, which is referred to it in accordance with the Union legal acts relating to medicinal products for human use or veterinary medicinal products.

The Agency, acting particularly through its Committees, shall carry out the following tasks:

- (a) coordinating the scientific evaluation of the quality, safety and efficacy of medicinal products for human use, which are subject to Union marketing authorisation procedures;
- (b) coordinating the scientific evaluation of the quality, safety and efficacy of veterinary medicinal products, which are subject to Union marketing authorisation procedures in accordance with Regulation (EU) 2019/6 and the performance of other tasks set out in Regulation (EU) 2019/6 and Regulation (EC) 470/2009;
- (c) transmitting on request and making publicly available assessment reports, summaries of product characteristics, labels and package leaflets for the medicinal products for human use;
- (d) coordinating the monitoring of medicinal products for human use which have been authorised in the Union and providing advice on the measures necessary to ensure the safe and effective use of those products, in particular by coordinating the evaluation and implementation of pharmacovigilance obligations and systems and the monitoring of such implementation;
- (e) ensuring the collation and dissemination of information on suspected adverse reactions to medicinal products for human use authorised in the Union by means of databases that are permanently accessible to all Member States;

- (f) assisting Member States with the rapid communication of information on pharmacovigilance concerns relating to medicinal products for human use to healthcare professionals and coordinating the safety announcements of the competent authorities of the Member States;
- (g) distributing appropriate information on pharmacovigilance concerns relating to medicinal products for human use to the general public, in particular by setting up and maintaining a European medicines web-portal;
- (h) coordinating, as regards medicinal products for human use and veterinary medicinal products, the verification of compliance with the principles of good manufacturing practice, good laboratory practice, good clinical practice, good pharmacovigilance practice and, as regards medicinal products for human use, the verification of compliance with pharmacovigilance obligations;
- (i) ensuring the secretariat of the Joint Audit Programme referred to in Article 54;
- (j) upon request, providing technical and scientific support in order to improve cooperation between the Union, its Member States, international organisations and third countries on scientific and technical issues relating to the evaluation and monitoring of medicinal products for human use and of veterinary medicinal products, in particular in the framework of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use and the Veterinary International Conference on Harmonization;
- (k) coordinating as referred to in Article 53 a structured cooperation on inspections in third countries between Member States, the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe, the World Health Organization or trusted international authorities, by means of international inspection programmes;
- (l) conducting inspections with Member States to verify the compliance with the principles of good manufacturing practice, including issuing GMP certificates and good clinical practice at the request of the Supervisory Authority referred to in Article 50(2) whenever additional capacity is needed to carry out inspection of Union interest including in response of public health emergencies;
- (m) recording the status of marketing authorisations for medicinal products for human use granted in accordance with Union marketing authorisation procedures;

- (n) creating a database on medicinal products for human use, to be accessible to the general public, and ensuring that it is updated, and managed independently of pharmaceutical companies; the database is to facilitate the search for information already authorised for package leaflets; it is to include a section on medicinal products for human use authorised for the treatment of children; the information provided to the general public is to be worded in an appropriate and comprehensible manner;
- (o) assisting the Union and its Member States in the provision of information to health-care professionals and the general public about medicinal products for human use and about veterinary medicinal products evaluated by the Agency;
- (p) providing scientific advice to undertakings or, as relevant, not-for-profit entities on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products for human use;
- (q) supporting, through enhanced scientific and regulatory advice, the development of medicinal products which are of major interest from the point of view of public health, including antimicrobial resistance, and in particular from the viewpoint of therapeutic innovation (priority medicines);
- (r) checking that the conditions laid down in Union legal acts on medicinal products for human use and on veterinary medicinal products and in the marketing authorisations are met in the case of parallel distribution of medicinal products for human use and on veterinary medicinal products authorised in accordance with this Regulation or, as applicable, Regulation (EU) 2019/6;
- (s) drawing up, at the Commission's request, any other scientific opinion concerning the evaluation of medicinal products for human use and of veterinary medicinal products or the starting materials used in the manufacture of medicinal products for human use;
- (t) with a view to the protection of public health, compiling scientific information concerning pathogenic agents which might be used in biological warfare, including the existence of vaccines and other medicinal products for human use and other veterinary medicinal products available to prevent or treat the effects of such agents;

- (u) coordinating the supervision of the quality of medicinal products for human use and of veterinary medicinal products placed on the market by requesting testing of compliance with their authorised specifications to the European Directorate for the Quality of Medicines and Healthcare that coordinates with the Official Medicines Control Laboratory or by a laboratory that a Member State has designated for that purpose. The Agency and the European Directorate for the Quality of Medicines and Healthcare shall enter into a written contract for the provision of services to the Agency under this subparagraph;
- (v) forwarding annually to the budgetary authority aggregated information on procedures for medicinal products for human use and veterinary medicinal products;
- (w) taking decisions as referred to in Article 6(5) of [revised Directive 2001/83/EC];
- (x) contributing to the joint reporting with the European Food Safety Authority and European Centre for Disease Prevention and Control on the sales and use of antimicrobials in human and veterinary medicine as well as on the situation as regards antimicrobial resistance in the Union based on contributions received by Member States, taking into account the reporting requirements and periodicity in Article 57 of Regulation (EU) 2019/6. Such joint reporting shall be carried out at least every three years;
- (y) adopting a decision granting, refusing or transferring an orphan designation;
- (z) adopting decisions on paediatric investigation plans, waivers and deferrals in relation to medicinal products;
- (za) providing regulatory support and scientific advice for the development of orphan and paediatric medicinal products;
- (zb) coordinating assessment of and certifying quality master files for medicinal products for human use as well as, where necessary, coordinating inspections of manufacturers applying for or holding a certificate for a quality master file;
- (zc) establishing a mechanism of consultation of authorities or bodies active along the life cycle of medicinal products for human use for exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency;
- (zd) developing coherent scientific assessment methodologies in the fields falling within its mission;

- (ze) cooperating with EU decentralised agencies and other scientific authorities and bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, the European Centre for Disease Prevention and Control and the European Environment Agency as regards the scientific assessment of relevant substances, exchange of data and information and development of coherent scientific methodologies, including replacing, reducing or refining animal testing, taking into account the specificities of the assessment of medicinal products;
- (zf) coordinating the monitoring and management of critical shortages of medicinal products included in the list referred to in Article 123(1);
- (zg) coordinating the identification and management of the Union list of critical medicinal products referred to in Article 131;
- (zh) supporting the working party referred to in Article 121(1), point (c), and the MSSG in their tasks in relation to critical shortages and critical medicines;
- (zi) providing regulatory support and scientific advice for, and facilitate the development, validation and regulatory uptake of new-approach methodologies that replace the use of animals in testing;
- (zj) facilitating joint non-clinical studies between applicants and holders to avoid unnecessary duplication of tests using live animals;
- (zk) facilitating data sharing of results from non-clinical studies on live animals;
- (zl) drawing up scientific guidelines to facilitate the implementation of the definitions established in this Regulation and in [revised Directive 2001/83], and for the environmental risk assessment of medicinal products for human use, in consultation with the Commission and the Member States.

2. The database provided for in paragraph 1, point (n), shall include all medicinal products for human use authorised in the Union together with the summaries of product characteristics, the package leaflet and the information shown on the labelling. Where relevant, it shall include the electronic links to the dedicated webpages where the marketing authorisation holders have reported the information pursuant to Article 40(4), point (b), and Article 57 of [revised Directive 2001/83/EC].

For the purposes of the database, the Agency shall set up and maintain a list of all medicinal products for human use authorised in the Union. To this effect:

- (a) the Agency shall make public a format for the electronic submission of information on medicinal products for human use;
- (b) marketing authorisation holders shall electronically submit to the Agency information on all medicinal products for human use authorised in the Union and shall inform the Agency of any new or varied marketing authorisations granted in the Union, using the format referred to in point (a).

Where appropriate, the database shall also include references to clinical trials currently being carried out or already completed, contained in the clinical trials database provided for in Article 81 of Regulation (EU) No 536/2014.

Article 139

Coherence of scientific opinions with other Union bodies

1. The Agency shall take the necessary and appropriate measures to monitor and identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other Union bodies and agencies carrying out similar tasks in relation to issues of common concern.
2. Where the Agency identifies a potential source of divergence, it shall contact the body or agency in question to ensure that all relevant scientific or technical information is shared and in order to identify potentially contentious scientific or technical issues.
3. Where a substantive divergence over scientific or technical issues is identified and the body concerned is a Union Agency or a scientific committee, the Agency and the body concerned shall cooperate to resolve the divergence, and inform the Commission without undue delay.

4. The Commission may ask the Agency to conduct an assessment as regards specifically the use of the substance concerned in medicinal products. The Agency shall make public its assessment stating clearly the reasons for its specific scientific conclusions.
5. To enable coherence between scientific opinions and to avoid duplication of tests, the Agency shall make arrangements with other bodies or agencies established under Union law for cooperation on scientific assessments and methodologies. The Agency shall also make arrangements for the exchange of data and information on relevant substances with the Commission, Member States' authorities and other Union Agencies, in particular for environmental risk assessments, non-clinical studies and maximum residue limits.

These arrangements shall seek to ensure that exchanges of data and information are made available in electronic formats and shall protect the commercially confidential nature of the information exchanged and be without prejudice to the provisions on regulatory protection.

Article 140

Scientific opinions in the context of international collaboration

1. The Agency may give a scientific opinion, in particular in the context of cooperation with the World Health Organization, for the evaluation of certain medicinal products for human use intended for markets outside the Union. For this purpose, an application shall be submitted to the Agency in accordance with the provisions of Article 6. Such application may be submitted and assessed together with a marketing authorisation application or any subsequent variation for the EU. The Agency may, after consulting the World Health Organization, and as appropriate other relevant organisations, draw up a scientific opinion in accordance with Articles 6, 10 and 12. The provisions of Article 13 shall not apply.
2. The Agency shall establish specific procedural rules for the implementation of paragraph 1, as well as for the provision of scientific advice.

Article 141

International regulatory cooperation

1. In so far as is necessary in order to achieve the objectives set out in this Regulation, and without prejudice to the respective competences of the Member States and the institutions of the Union, the Agency may cooperate with the competent authorities of third countries and/or with international organisations.

To this end, the Agency may, subject to prior approval by the Commission, establish working arrangements with the authorities of third countries and international organisations, with regard to:

- (a) the exchange of information, including non-public information, where relevant jointly with the Commission;
- (b) sharing of scientific resources and expertise, with a view to facilitating collaboration, while maintaining independent assessment in full compliance with the provisions of this Regulation and [revised Directive 2001/83/EC] and under conditions determined beforehand by the Management Board, in agreement with the Commission;
- (c) the participation in certain aspects of the Agency's work, under conditions determined beforehand by the Management Board, in agreement with the Commission.

These arrangements shall not create legal obligations incumbent on the Union and its Member States.

2. The Agency shall ensure that it is not seen as representing the Union position to an outside audience or as committing the Union to international cooperation.
3. The Commission may, in agreement with the Management Board and the relevant committee, invite representatives of international organisations with an interest in the harmonisation of technical requirements applicable to medicinal products for human use and to veterinary medicinal products to participate as observers in the work of the Agency. The conditions for participation shall be determined in advance by the Commission.

Section 2

Structure and operation

Article 142

Administrative and management structure

The Agency shall comprise:

- (a) a Management Board, which shall exercise the functions set out in Articles 143, 144 and 154.
- (b) an Executive Director, who shall exercise the responsibilities set out in Article 145;
- (c) a Deputy Executive Director who shall exercise the responsibilities set out in Article 145(7);
- (d) the Committee for Medicinal Products for Human Use;
- (e) the Pharmacovigilance Risk Assessment Committee;
- (f) the Committee for Veterinary Medicinal Products set up pursuant to Article 139(1) of Regulation (EU) 2019/6;
- (g) the Herbal Medicinal Products working group set up pursuant to Article 141 of [revised Directive 2001/83/EC];
- (h) the Emergency task force set up pursuant to Article 15 of Regulation (EU) 2022/123;
- (i) the MSSG set up pursuant to Article 3 of Regulation (EU) 2022/123;
- (j) the Medical Device Shortages Steering Group, set up pursuant to Article 21 of Regulation (EU) 2022/123;
- (k) the inspection working group;
- (l) a Secretariat, which shall provide technical, scientific and administrative support to all bodies of the Agency and ensure appropriate coordination between them, and which shall provide technical and administrative support for the coordination group referred to in Article 37 of [revised Directive 2001/83/EC] and ensure appropriate coordination between it and the Committees. It shall also undertake the work required of the Agency under the procedures for the assessment and preparations of decisions for paediatric investigation plans, waivers, deferrals or orphan designations.

Article 143
Management Board

1. The Management Board shall be composed of one representative from each Member State, two representatives of the Commission and two representatives of the European Parliament, all with voting rights.

In addition, two representatives of patients' organisations, one representative of doctors' organisations and one representative of veterinarians' organisations, all with voting rights, shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission which includes appreciably more names than there are posts to be filled. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant background documents. As quickly as possible, and at the latest within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint these representatives to the Management Board.

The members of the Management Board shall be appointed in such a way as to guarantee the highest levels of specialist qualifications, a broad spectrum of relevant expertise and the broadest possible geographic spread within the European Union.

2. Members of the Management Board and their alternates shall be appointed on the basis of their knowledge, recognised experience and commitment in the field of medicinal products for human or veterinary use, taking into account relevant managerial, administrative and budgetary expertise [which are to be used to further the objectives of this Regulation].

All parties represented in the Management Board shall make efforts to limit turnover of their representatives, in order to ensure continuity of the work of the Management Board. All parties shall aim to achieve a balanced representation between men and women on the Management Board.

3. Each Member State and the Commission shall appoint their members of the Management Board as well as an alternate who will replace the member in their absence and vote on their behalf.
4. The term of office for members and their alternates shall be four years. That term shall be extendable.
5. The Management Board shall elect a chairperson and a Deputy chairperson from among its members.

The chairperson and the Deputy chairperson shall be elected by a majority of two-thirds of the members of the Management Board with voting rights.

The Deputy chairperson shall automatically replace the chairperson if they are prevented from attending to their duties.

The term of office of the chairperson and the deputy chairperson shall be four years. The term of office may be renewed once. If however, their membership of the Management Board ends at any time during their term of office, their term of office shall automatically expire on that date.

6. Without prejudice to paragraph 5 and Article 144, points (e) and (g), the Management Board shall take decisions by absolute majority of its members with voting rights.
7. The Management Board shall adopt its rules of procedure.
8. The Management Board may invite the chairpersons of the scientific committees to attend its meetings, but they shall not have the right to vote.
9. The Management Board may invite any person whose opinion may be of interest to attend its meetings as an observer.

10. The Management Board shall approve the annual work programme of the Agency programme and forward it to the European Parliament, the Council, the Commission and the Member States.
11. The Management Board shall adopt the annual report on the Agency's activities and forward it by 15 June at the latest to the European Parliament, the Council, the Commission, the European Economic and Social Committee, the Court of Auditors and the Member States.

Article 144

Tasks of the Management Board

The Management Board shall:

- (a) give the general orientations for the Agency's activities;
- (b) adopt an opinion on the rules of procedures of the Committee for Medicinal Products for Human Use (Article 148) and the Committee for Veterinary Medicinal Products (Article 139 of Regulation (EU) 2019/6);
- (c) adopt procedures for the performance of scientific services regarding medicinal products for human use (Article 152);
- (d) appoint the Executive Director, and where relevant extend their term of office or remove them from office, in accordance with Article 145;
- (e) adopt yearly the Agency's draft single programming document before its submission to the Commission for its opinion, and the Agency's single programming document by a majority of two-thirds of members entitled to vote and in accordance with Article 154;
- (f) assess and adopt a consolidated annual activity report on the Agency's activities and send it by 1 July each year to the European Parliament, the Council, the Commission and the Court of Auditors. The consolidated annual activity report shall be made public;
- (g) adopt the annual budget of the Agency by a majority of two-thirds of the members entitled to vote and in accordance with Article 154;
- (h) adopt the financial rules applicable to the Agency in accordance with Article 155;

- (i) exercise, with respect to the staff of the Agency, the powers conferred by Regulation No 31 by the Council of the European Economic Community, and Regulation No 11 and by the Council of the European Atomic Energy Community ('Staff Regulations' and 'Conditions of Employment of Other Servants')¹ on the Appointing Authority and on the Authority Empowered to Conclude a Contract of Employment ('the appointing authority powers');
- (j) adopt implementing rules for giving effect to the Staff Regulations and the Conditions of Employment of Other Servants in accordance with Article 110 of the Staff Regulations;
- (k) develop contacts with stakeholders and stipulate the conditions applicable as mentioned in Article 163;
- (l) adopt an anti-fraud strategy, proportionate to risks of fraud taking into account the costs and benefits of the measures to be implemented;
- (m) ensure adequate follow-up to findings and recommendations stemming from the internal or external audit reports and evaluations, as well as from investigations of the European Anti-fraud Office ('OLAF') and the European Public Prosecutor's Office ('EPPO');
- (n) adopt rules to ensure the availability to the public of information concerning the authorisation or supervision of medicinal products for human use as mentioned in Article 166;
- (o) adopt an efficiency gains and synergies strategy;
- (p) adopt a strategy for cooperation with third countries or international organisations;
- (q) adopt a strategy for the organisational management and internal control systems.

The Management Board shall adopt, in accordance with Article 110 of the Staff Regulations, a decision based on Article 2(1) of the Staff Regulations and on Article 6 of the Conditions of Employment of Other Servants, delegating relevant appointing authority powers to the Executive Director and defining the conditions under which that delegation of powers can be suspended. The Executive Director shall be authorised to sub-delegate those powers.

Where exceptional circumstances so require, the Management Board may, by way of a decision, temporarily suspend the delegation of the appointing authority powers to the Executive Director and those sub-delegated by the latter and exercise them itself or delegate them to one of its members or to a staff member other than the Executive Director.

¹ Regulation No 31 (EEC), 11 (EAEC) by the Council of the European Economic Community and by the Council of the European Atomic Energy Community, laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community (OJ 45, 14.6.1962, p. 1385).

Article 145
Executive Director

1. The Executive Director shall be engaged as a temporary agent of the Agency under Article 2, point (a), of the Conditions of Employment of Other Servants.
2. The Executive Director shall be appointed by the Management Board from a list of candidates proposed by the Commission following an open and transparent selection procedure.

For the purpose of concluding the contract with the Executive Director, the Agency shall be represented by the Chairperson of the Management Board.

Before appointment, the candidate nominated by the Management Board shall be immediately invited to make a statement to the European Parliament and to answer any questions put by its Members.

3. The term of office of the Executive Director shall be five years. By the end of that period the Commission shall undertake an assessment that takes into account an evaluation of the Executive Director's performance and the Agency's future tasks and challenges.
4. The Management Board, acting on a proposal from the Commission that takes into account the assessment referred to in paragraph 3, may extend the term of office of the Executive Director once, for no more than five years.

An Executive Director whose term of office has been extended may not participate in another selection procedure for the same post at the end of the overall period.

5. The Executive Director may be removed from office only upon a decision of the Management Board acting on a proposal from the Commission.

6. The Management Board shall reach decisions on appointment, extension of the term of office or removal from office of the Executive Director on the basis of a two-thirds majority of its members with voting rights.
7. The Executive Director will be assisted by a Deputy Executive Director. If the Executive Director is absent or indisposed, the Deputy Executive Director shall take their place.
8. The Executive Director shall manage the Agency. The Executive Director shall be accountable to the Management Board. Without prejudice to the powers of the Commission and of the Management Board, the Executive Director shall be independent in the performance of their duties and shall neither seek nor take instructions from any government or from any other body.
9. The Executive Director shall report to the European Parliament on the performance of their tasks when invited to do so. The Council may invite the Executive Director to report on the performance of those tasks.
10. The Executive Director shall be the legal representative of the Agency. The Executive Director shall be responsible for:
 - (a) the day-to-day administration of the Agency;
 - (b) implementing decisions adopted by the Management Board;
 - (c) managing all the Agency resources necessary for conducting the activities of the Committees referred to in Article 142, including making available appropriate scientific and technical support to those Committees, and for making available appropriate technical support to the coordination group;
 - (d) ensuring that the time-limits laid down in Union legal acts for the adoption of opinions by the Agency are complied with;
 - (e) ensuring appropriate coordination between the Committees referred to in Article 142 and, where necessary, between those Committees and the coordination group or other working groups of the Agency;
 - (f) the preparation of the draft statement of estimates of the Agency's revenue and expenditure, and execution of its budget;

- (g) the preparation of the draft single programming document and the submission it to the Management Board after consulting the Commission;
- (h) implementing the single programming document and report to the Management Board on its implementation;
- (i) preparing the Agency's consolidated annual activity report on the Agency's activities and presenting it to the Management Board for assessment and adoption;
- (j) all staff matters;
- (k) providing the secretariat for the Management Board;
- (l) without prejudice to the competences of OLAF and EPPO, protecting the financial interests of the Union by applying preventive measures against fraud, corruption and any other illegal activities, by effective checks and, if irregularities are detected, by recovering amounts wrongly paid and, where appropriate, by imposing effective, proportionate and dissuasive administrative and financial penalties;
- (m) reporting, on the basis of key performance indicators agreed by the Management board, on the IT infrastructure developed by the Agency by means of implementation of legislation, in term of timing, budgetary compliance and quality.

11. Each year the Executive Director shall submit a draft report covering the activities of the Agency in the previous year and a draft work programme for the coming year to the Management Board for approval, making a distinction between the Agency's activities concerning medicinal products for human use, those concerning herbal medicinal products and those concerning veterinary medicinal products.

The draft report covering the activities of the Agency in the previous year shall include information about the number of applications evaluated by the Agency, the time taken for completion of the evaluation, and the medicinal products for human use and veterinary medicinal products authorised, rejected or withdrawn.

Article 146

Scientific Committees – General provisions

1. The scientific committees shall be responsible for providing the scientific opinions or recommendations of the Agency, each within their own spheres of competence, and shall have the possibility, where necessary of organising public hearings.
2. The membership of the scientific committees shall be made public. When each appointment is published, the professional qualifications of each member shall be specified.
3. The Executive Director of the Agency or their representative and representatives of the Commission shall be entitled to attend all meetings of the scientific committees referred to in Article 142, working parties and scientific advisory groups and all other meetings convened by the Agency or its scientific committees.
4. Members of the scientific committees and experts responsible for evaluating medicinal products and nominated by Member States shall rely on the scientific evaluation and resources available to national competent authorities responsible for marketing authorisation, and on external experts proposed by Member States or selected by the Agency. Each competent national authority shall monitor the scientific level and independence of the evaluation carried out and facilitate the activities of nominated members of the Committees and experts. Member States shall refrain from giving those members and experts any instruction which is incompatible with their own individual tasks or with the tasks and responsibilities of the Agency.
5. The members of the scientific committees may be accompanied by experts in specific scientific or technical fields.
6. When preparing any opinion or recommendation, the scientific committees shall use their best endeavours to reach a scientific consensus. If such a consensus cannot be reached, the opinion shall consist of the position of the majority of members and divergent positions, with the grounds on which they are based.

7. The Committee for Medicinal Products for Human Use may, if they consider it appropriate, seek guidance on important questions of a general scientific or ethical nature.
8. The scientific committees and any working parties and scientific advisory groups established in accordance with this Article shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products for human use, in particular patient and consumer organisations and healthcare professionals' associations. For that purpose working groups of patient and consumer organisations and healthcare professionals' associations shall be established by the Agency. They shall ensure a fair representation of healthcare professionals, patients and consumers covering a wide range of experience and disease areas, including orphan, paediatric and geriatric diseases and advanced therapy medicinal products, and a broad geographical range.

Rapporteurs appointed by the scientific committees may, on an advisory basis, establish contacts with representatives of patient organisations and healthcare professionals' associations relevant to the therapeutic indication of the medicinal product for human use.

9. The Committee for Veterinary Medicinal Products shall operate in accordance with Regulation (EU) No 2019/6 and paragraphs 1, 2 and 3.

Article 147

Conflict of interest

1. Members of the Management Board, members of the committees, rapporteurs and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All indirect interests which could relate to this industry shall be entered in a register held by the Agency which is accessible to the public, on request, at the Agency's offices.

The Agency's code of conduct shall provide for the implementation of this Article with particular reference to the acceptance of gifts.

2. Members of the Management Board, members of the committees, rapporteurs and experts who participate in meetings or working groups of the Agency shall declare, at each meeting, any specific interests which could be considered to be prejudicial to their independence with respect to the items on the agenda. These declarations shall be made available to the public.

Article 148

Committee for Medicinal Products for Human Use activities

1. The Committee for Medicinal Products for Human Use shall be responsible for drawing up the opinion of the Agency on any matter concerning the admissibility of the files submitted in accordance with the centralised procedure, the granting, variation, suspension or revocation of an authorisation to place a medicinal product for human use on the market in accordance with the provisions of this Chapter, and pharmacovigilance. For the fulfilment of its pharmacovigilance tasks, including the approval of risk management systems and monitoring their effectiveness provided for under this Regulation, the Committee for Medicinal Products for Human Use shall rely on the scientific assessment and recommendations of the Pharmacovigilance Risk Assessment Committee referred to in Article 142, point (e).
2. In addition to their task of providing objective scientific opinions to the Union and Member States on the questions which are referred to them, the members of the Committee for Medicinal Products for Human Use shall ensure that there is appropriate coordination between the tasks of the Agency and the work of competent national authorities, including the consultative bodies concerned with the marketing authorisation.
3. The Committee for Medicinal Products for Human Use shall be composed of the following:
 - (a) one member and one alternate member appointed by each Member State, in accordance with paragraph 6;
 - (b) four members and one alternate members appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent healthcare professionals;
 - (c) four members and four alternate members appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent patient organisations.

4. The Committee for Medicinal Products for Human Use may co-opt a maximum of five additional members chosen on the basis of their specific scientific competence. Those members shall be appointed for a term of three years, which may be renewed, and shall not have alternates.

With a view to the co-opting of such members, the Committee for Medicinal Products for Human Use shall identify the specific complementary scientific competence of the additional member or members. Co-opted members shall be chosen among experts nominated by Member States or the Agency.

5. The alternates shall represent and vote for the members in their absence and may also be appointed to act as rapporteurs in accordance with Article 152.

Members and alternates shall be chosen for their role and experience in the evaluation of medicinal products for human use as appropriate and shall represent the competent authorities of the Member States.

6. The members and alternate members of the Committee for Medicinal Products for Human Use shall be appointed on the basis of their relevant expertise in the assessment of medicinal products which should cover all types of medicinal products covered by [revised Directive 2001/83/EC] and this Regulation and which include medicinal products for rare and paediatric diseases, advance therapy medicinal products, biological and biotechnological products, in order to guarantee the highest levels of specialist qualifications and a broad spectrum of relevant expertise. The Member States shall cooperate in order to ensure that the final composition of the Committee for Medicinal Products for Human Use provides appropriate and balanced coverage of all scientific areas relevant to its tasks taking into account scientific developments and new types of medicinal products. For this purpose, Member States shall liaise with the Management Board and the Commission.

7. The members and alternate members of the Committee for Medicinal Products for Human Use shall be appointed for a term of three years, which may be renewed following the procedures referred to in paragraph 6. The Committee shall elect its chairperson and vice-chairperson from among its members for a term of 3 years, which may be prolonged once.
8. The Committee for Medicinal Products for Human Use shall establish its own rules of procedure.

These rules shall, in particular, lay down:

- (a) procedures for appointing and replacing the chairperson;
- (b) procedures relating to working parties and scientific advisory groups; and
- (c) a procedure for the urgent adoption of opinions, particularly in relation to the provisions of this Regulation on market surveillance and pharmacovigilance.

They shall enter into force after receiving a favourable opinion from the Commission and the Management Board.

Article 149

Pharmacovigilance Risk Assessment Committee activities

1. The mandate of the Pharmacovigilance Risk Assessment Committee shall cover all aspects of the risk management of the use of medicinal products for human use including the detection, assessment, minimisation and communication relating to the risk of adverse reactions, having due regard to the therapeutic effect of the medicinal product for human use, the design and evaluation of post-authorisation safety studies and pharmacovigilance audit.
2. The Pharmacovigilance Risk Assessment Committee shall be composed of the following:
 - (a) one member and one alternate member appointed by each Member State, in accordance with paragraph 3;
 - (b) six members appointed by the Commission, with a view to ensuring that the relevant expertise is available within the Committee, including clinical pharmacology and pharmacoepidemiology, on the basis of a public call for expressions of interest;

- (c) two members and two alternate members appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent healthcare professionals;
- (d) two members and two alternate members appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent patient organisations.

The alternate members shall represent and vote for the members in their absence. The alternate members referred to in point (a) may be appointed to act as rapporteurs in accordance with Article 152.

3. A Member State may delegate its tasks in the Pharmacovigilance Risk Assessment Committee to another Member State. Each Member State may represent no more than one other Member State.
4. The members and alternate members of the Pharmacovigilance Risk Assessment Committee shall be appointed on the basis of their relevant expertise in pharmacovigilance matters and risk assessment of medicinal products for human use, in order to guarantee the highest levels of specialist qualifications and a broad spectrum of relevant expertise. For this purpose, Member States shall liaise with the Management Board and the Commission in order to ensure that the final composition of the Committee covers the scientific areas relevant to its tasks.
5. The members and alternate members of the Pharmacovigilance Risk Assessment Committee shall be appointed for a term of 3 years, which may be renewed following the procedures referred to in paragraph 1. The Committee shall elect its chairperson and vice-chairperson from among its members for a term of three years, which may be prolonged once.

Article 150

Scientific working parties and scientific advisory groups

1. The scientific committees referred to in Article 146 may establish scientific working parties and scientific advisory groups in connection with the performance of their tasks.

The scientific committees may rely on scientific working parties for the performance of certain tasks. The scientific committees shall retain the final responsibility for the assessment or any scientific opinion related to these tasks.

Working parties established by the Committee for Veterinary Medicinal Products are governed by Regulation (EU) 2019/6.

2. The Committee for Human Medicinal Products shall establish for the evaluation of specific types of medicinal products or treatments, working parties with scientific expertise in the fields of pharmaceutical quality, methodologies, non-clinical and clinical evaluations.

For the provision of scientific advice the Committee for Human Medicinal Products shall establish a scientific advice working party.

The Committee may establish an Environmental Risk Assessment working party and other scientific working parties, as necessary.

3. The composition of the working party and the selection of members shall be based on the following criteria:
 - (a) a high level of scientific expertise;
 - (b) meeting the needs for the specific multi-disciplinary expertise of the working party to which they will be appointed.

The majority of the members of the working parties shall consist of experts from the competent authorities of the Member States. Where appropriate, the Committee for Human Medicinal Products may, following consultation with the Management Board, set a minimum number of experts from the competent authorities in a working party.

4. Competent authorities of the Member States that are not represented in a working party may request to attend meetings of working parties as an observer.
5. The Agency shall make documents discussed in working parties accessible to all competent authorities of the Member States.
6. When establishing working parties and scientific advisory groups, the scientific committees shall in their rules of procedures provide for:
 - (a) the appointment of members of these working parties and scientific advisory groups on the basis of the lists of experts referred to in Article 151(2); and
 - (b) consultation of these working parties and scientific advisory groups.

Article 151
Scientific experts

1. The Agency or any of the committees referred to in Article 142 may use the services of experts and service providers for the discharge of specific tasks for which they are responsible.
2. Member States shall transmit to the Agency the names of national experts with proven experience in the evaluation of medicinal products for human use and veterinary medicinal products who, taking into account conflicts of interest pursuant to Article 147, would be available to serve on working parties or scientific advisory groups of any of the committees referred to in Article 142, together with an indication of their qualifications and specific areas of expertise.
3. Where necessary, for the nomination of other experts the Agency may publish a call for expression of interest after endorsement by the Management Board of the necessary criteria and fields of expertise, in particular to ensure a high level of public health and animal protection.

The Management Board shall adopt the appropriate procedures on a proposal from the Executive Director.

4. The Agency shall establish and maintain a pool of accredited experts. That expert pool shall include the national experts referred to in paragraph 2 and any other experts appointed by the Agency or the Commission, and shall be updated.
5. Accredited experts shall have access to training provided by the Agency, as appropriate.
6. Rapporteurs of any of the committees referred to in Article 142 may use the services of accredited experts for the fulfilment of their tasks in accordance with Article 152. Any remuneration of such accredited expert shall be deducted from the remuneration due to the rapporteurs.
7. The remuneration of experts and service providers for services used by the Agency under paragraph 1 shall be financed through the Agency's budget, in accordance with the financial rules applicable to the Agency.

Article 152

Rapporteurship

1. Where, in accordance with this Regulation, any of the Committees referred to in Article 142 is required to evaluate a medicinal product for human use, it shall appoint one of its members to act as rapporteur, taking into account existing expertise in the Member State. The Committee concerned may appoint a second member to act as co-rapporteur.

A member of a Committee shall not be appointed rapporteur for a particular case if they declare, in accordance with Article 147 any interest that might be, or might be perceived as, prejudicial to the impartial assessment of that case. The Committee concerned may replace the rapporteur or co-rapporteur by another member at any time, if they are unable to fulfil their duties within the prescribed time limits, or if an actual or potential prejudicial interest is detected.

A rapporteur appointed for that purpose by the Pharmacovigilance Risk Assessment Committee shall closely collaborate with the rapporteur appointed by the Committee for Medicinal Products for Human Use or the Reference Member State for the medicinal product for human use concerned.

When consulting the scientific advisory groups referred to in Article 150, the Committee shall forward to them the draft assessment report or reports drawn up by the rapporteur or the co-rapporteur. The opinion issued by the scientific advisory group shall be forwarded to the chairperson of the relevant committee in such a way as to ensure that the deadlines laid down in Article 6 are met.

The substance of the opinion shall be included in the assessment report published pursuant to Article 16(3).

2. Without prejudice to Article 151(7), the provision of services by rapporteurs or experts shall be governed by a written contract between the Agency and the person concerned, or where appropriate between the Agency and its employer.

The person concerned, or their employer, shall be remunerated in accordance with [a scale of fees to be included in the financial arrangements established by the Management Board/mechanism under the new fee legislation].

The first and second subparagraphs shall also apply:

- (a) to the services provided by the chairpersons of the scientific committees of the Agency; and
- (b) to the work of rapporteurs in the coordination group as regards the fulfilment of its tasks in accordance with Articles 108, 110, 112, 116 and 121 of [revised Directive 2001/83/EC].

Article 153

Methods to determine added therapeutic value

At the request of the Commission, the Agency shall, in respect of authorised medicinal products for human use, collect any available information on methods that Member States' competent authorities use to determine the added therapeutic value that any new medicinal product for human use provides.

Section 3

Financial provisions

Article 154

Adoption of the budget of the Agency

1. Estimates of all the revenue and expenditure of the Agency shall be prepared for each financial year, corresponding to the calendar year, and shall be shown in the budget of the Agency.
2. The revenue and expenditure shown in the budget shall be in balance.
3. The Agency's revenue shall consist of:
 - (a) a contribution from the Union;
 - (b) a contribution from third countries participating in the work of the Agency with which the Union has concluded international agreements for that purpose;
 - (c) fees paid by undertakings and entities not engaged in an economic activity:
 - (i) for obtaining and maintaining Union marketing authorisations for medicinal products for human use and for veterinary medicinal products and for other services provided by the Agency, as provided for in this Regulation and in Regulation (EU) 2019/6; and
 - (ii) for services provided by the coordination group as regards the fulfilment of its tasks in accordance with Articles 108, 110, 112, 116 and 121 of [revised Directive 2001/83/EC];

- (d) charges for other services provided by the Agency;
- (e) Union funding in the form of grants for participation in research and assistance projects, in accordance with the Agency's financial rules referred to in Article 155(11) and with the provisions of the relevant instruments supporting the policies of the Union.

The European Parliament and the Council ('the budgetary authority') shall re-examine, when necessary, the level of the Union contribution, referred to in the first subparagraph, point (a), on the basis of an evaluation of needs and by taking account of the level of revenue provided by the sources referred to in the first subparagraph, points (c), (d) and (e).

- 4. Activities relating to the assessment of marketing authorisation applications, subsequent variations, pharmacovigilance, to the operation of communications networks and to market surveillance shall be under the permanent control of the Management Board in order to guarantee the independence of the Agency. This shall not preclude the Agency from charging fees to marketing authorisation holders for performing these activities by the Agency on the condition that its independence is strictly guaranteed.
- 5. The expenditure of the Agency shall include staff remuneration, administrative and infrastructure costs, and operational expenditure. In respect of operational expenditure, budgetary commitments for actions which extend over more than one financial year may be broken down over several years into annual instalments, as necessary.

The Agency may award grants related to the fulfilment of the tasks incumbent upon it under this Regulation or other relevant Union legal acts or related to the fulfilment of other entrusted tasks.

- 6. Each year the Management Board, on the basis of a draft drawn up by the Executive Director, shall produce an estimate of revenue and expenditure for the Agency for the following financial year. That estimate, which shall include a draft establishment plan, shall be forwarded by the Management Board to the Commission by 31 March at the latest.

7. The estimate shall be forwarded by the Commission to the budgetary authority together with the preliminary draft general budget of the European Union.
8. On the basis of the estimate, the Commission shall enter in the preliminary draft general budget of the European Union the estimates it deems necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 272 of the Treaty.
9. The budgetary authority shall authorise the appropriations for the subsidy to the Agency.

The budgetary authority shall adopt the establishment plan for the Agency.

10. The budget shall be adopted by the Management Board. It shall become final following final adoption of the general budget of the European Union. Where appropriate, it shall be adjusted accordingly.
11. Any modification of the establishment plan and of the budget shall be the subject of an amending budget, which is forwarded for the purposes of information to the budgetary authority.
12. The Management Board shall, as soon as possible, notify the budgetary authority of its intention to implement any project which may have significant financial implications for the funding of its budget, in particular any projects relating to property such as the rental or purchase of buildings. It shall inform the Commission thereof.

Where a branch of the budgetary authority has notified its intention to deliver an opinion, it shall forward its opinion to the Management Board within a period of six weeks from the date of notification of the project.

Article 155

Implementation of the Agency's budget

1. The Executive Director shall implement the budget of the Agency in accordance with Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council².
2. By 1 March of financial year n+1, the Agency's accounting officer shall send the provisional accounts for year n to the Commission's accounting officer and to the Court of Auditors.
3. By 31 March of financial year n+1, the Executive Director shall send the report on the budgetary and financial management for year n to the European Parliament, to the Council, to the Commission and to the Court of Auditors.
4. By 31 March of financial year n+1, the Commission's accounting officer shall send the Agency's provisional accounts for year n, consolidated with the Commission's provisional accounts, to the Court of Auditors.

On receipt of the Court of Auditors' observations on the Agency's provisional accounts pursuant to Article 246 of Regulation (EU, Euratom) 2018/1046, the Agency's accounting officer shall draw up the Agency's final accounts and the Executive Director shall submit them to the Management Board for an opinion.

5. The Management Board shall deliver an opinion on the Agency's final accounts for year n.
6. The Agency's accounting officer shall, by 1 July of financial year n+1, send the final accounts, together with the Management Board's opinion, to the European Parliament, to the Council, to the Court of Auditors and to the Commission's accounting officer.

² Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

7. The final accounts for year n shall be published in the *Official Journal of the European Union* by 15 November of financial year n+1.
8. The Executive Director shall send to the Court of Auditors a reply to its observations by 30 September of financial year n+1. The Executive Director shall also send that reply to the Management Board.
9. The Executive Director shall submit to the European Parliament, at the latter's request, any information required for the smooth application of the discharge procedure for the financial year concerned, as laid down in Article 261(3) of Regulation (EU, Euratom) 2018/1046.
10. The European Parliament, upon a recommendation from the Council, shall, before 15 May of financial year n+2, give a discharge to the Executive Director in respect of the implementation of the budget for year n.
11. The financial rules applicable to the Agency shall be adopted by the Management Board after the Commission has been consulted. They shall not depart from Commission Delegated Regulation (EU) 2019/715³ unless specifically required for the Agency's operation and with the Commission's prior consent.

³ Commission Delegated Regulation (EU) 2019/715 of 18 December 2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council (OJ L 122, 10.5.2019, p. 1).

Article 156
Fraud prevention

1. In order to combat fraud, corruption and other unlawful activities, the Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council⁴ shall apply without restriction.
2. The Agency shall accede to the Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council of the European Union and the Commission of the European Communities⁵ and shall adopt, without delay, the appropriate provisions applicable to all the employees of the Agency using the template set out in the Annex to that Agreement.
3. The European Court of Auditors shall have the power of audit, on the basis of documents and on the spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds from the Agency.
4. OLAF may carry out investigations, including on-the-spot checks and inspections with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant or a contract funded by the Agency, in accordance with the provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 and Council Regulation (Euratom, EC) No 2185/96⁶.

⁴ Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

⁵ Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council of the European Union and the Commission of the European Communities concerning internal investigations by the European Anti-fraud Office (OLAF) (OJ L 136, 31.5.1999, p. 15).

⁶ Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

5. Working agreements with third countries and international organisations, contracts, grant agreements and grant decisions of the Agency shall contain provisions expressly empowering the European Court of Auditors and OLAF to conduct such audits and investigations, according to their respective competences.
6. In accordance with Council Regulation (EU) 2017/1939⁷, the EPPO may investigate and prosecute fraud and other illegal activities affecting the financial interests of the Union as provided for in Directive (EU) 2017/1371 of the European Parliament and of the Council⁸.

Section 4

General provisions governing the Agency

Article 157

Liability

1. The contractual liability of the Agency shall be governed by the law applicable to the contract in question. The Court of Justice of the European Union shall have jurisdiction pursuant to any arbitration clause contained in a contract concluded by the Agency.
2. In the case of non-contractual liability, the Agency shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or by its staff in the performance of their duties.

The Court of Justice shall have jurisdiction in any dispute relating to compensation for any such damage.

3. The personal liability of its staff towards the Agency shall be governed by the provisions laid down in the Staff Regulations or Conditions of Employment of Other Servants applicable to them.

⁷ Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office ('the EPPO') (OJ L 283, 31.10.2017, p. 1).
⁸ Directive (EU) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law (OJ L 198, 28.7.2017, p. 29).

Article 158

Access to documents

Regulation (EC) No 1049/2001 shall apply to documents held by the Agency.

The Agency shall set up a register pursuant to Article 2(4) of Regulation (EC) No 1049/2001 to make available all documents that are publicly available pursuant to this Regulation.

The Management Board shall adopt the arrangements for implementing Regulation (EC) No 1049/2001.

Decisions taken by the Agency pursuant to Article 8 of Regulation (EC) No 1049/2001 may give rise to the lodging of a complaint with the Ombudsman or form the subject of an action before the Court of Justice, under the conditions laid down in Article 228 and Article 263 of the Treaty respectively.

Article 159

Privileges

Protocol No 7 on the Privileges and Immunities of the European Union annexed to the Treaty on the Functioning of the European Union shall apply to the Agency and its staff.

Article 160

Staff

The Staff Regulations and the rules adopted by agreement between the institutions of the Union for giving effect to those Staff Regulations and Conditions of Employment of Other Servants shall apply to the staff of the Agency.

The Agency may make use of seconded national experts or other staff not employed by the Agency. The Management Board, in agreement with the Commission, shall adopt the necessary implementing provisions.

Article 161

Security rules on the protection of classified and sensitive non-classified information

The Agency shall adopt own security rules equivalent to the Commission's security rules for protecting European Union Classified Information (EUCI) and sensitive non-classified information, as set out in Commission Decisions (EU, Euratom) 2015/443⁹ and 2015/444¹⁰. The security rules of the Agency shall cover, inter alia, provisions for the exchange, processing and storage of such information.

Members of the Management Board, the Executive Director, members of the committees, external experts participating in ad hoc working groups, and members of the staff of the Agency shall comply with the confidentiality requirements under Article 339 TFEU, even after their duties have ceased.

The Agency may take the necessary measures to facilitate the exchange of information relevant to its tasks with the Commission and the Member States and, where appropriate, the relevant Union institutions, bodies, offices and agencies. Any administrative arrangements concluded to that end with regard to the sharing of EU classified information (EUCI) or, in the absence of such arrangements, any exceptional ad hoc release of EUCI, shall have received the Commission's prior approval.

⁹ Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

¹⁰ Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

Article 162

Consultation process

1. The Agency shall establish a consultation process with relevant national authorities or bodies for the exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency, in particular guidelines on unmet medical needs and the design of clinical trials, other studies and the generation of evidence along the life cycle of medicinal products.

The consultation process shall include bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 and national bodies responsible for pricing and reimbursement.

The conditions of participation shall be set by the Management Board in agreement with the Commission.

2. The Agency may extend the consultation process to patients, medicine developers, healthcare professionals, industries or other stakeholders, as relevant.

Article 163

Contacts with civil society representatives

The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and the representatives of the industry, consumers and patients and the healthcare professions. These contacts may include the participation of observers in certain aspects of the Agency's work, under conditions determined beforehand by the Management Board, in agreement with the Commission.

Article 164

Support to SMEs and to not-for profit entities

1. The Agency shall ensure that micro, small and medium-sized enterprises ('SMEs') and not-for-profit entities are offered a support scheme.
2. The support scheme shall be comprised of regulatory, procedural and administrative support and reduction, deferral or waivers of fees.
3. The scheme shall cover the various steps involved in pre-authorisation procedures, and in particular scientific advice, the submission of the marketing authorisation application, and the post-authorisation procedures.
4. SMEs shall benefit from the incentives laid down in Commission Regulation (EC) No 2049/2005 and [revised Council Regulation (EC) No 297/95]¹¹.
5. For not-for-profit entities, the Commission shall adopt specific provisions clarifying the definitions, establishing waivers, reductions or deferrals of fees, as appropriate, in accordance with the procedure referred to in Article 10 and Article 12 of [revised Regulation (EC) No 297/95].

¹¹ Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products (OJ L 35, 15.2.1995, p. 1).

Article 165
Transparency

To ensure an appropriate level of transparency, the Management Board shall, on the basis of a proposal by the Executive Director and in agreement with the Commission, adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the authorisation or supervision of medicinal products for human use which is not of a confidential nature.

The internal rules and procedures of the Agency, its committees and its working groups shall be made available to the public at the Agency and on the Internet.

The Agency may engage in communication activities on its own initiative within its field of competence. The allocation of resources to communication activities shall not be detrimental to the effective exercise of the tasks of the Agency. Communication activities shall be carried out in accordance with relevant communication and dissemination plans adopted by the Management Board.

Article 166
Personal health data

1. To support its public health tasks and in particular the evaluation and monitoring medicinal products or the preparation of regulatory decisions and scientific opinions, the Agency may process personal health data, from sources other than clinical trials, for the purpose of improving the robustness of its scientific assessment or verifying claims of the applicant or marketing authorisation holder in the context of the evaluation or supervision of medicinal product.
2. The Agency may consider and decide upon additional evidence available, independently from the data submitted by the marketing authorisation applicant or marketing authorisation holder. On that basis, the summary of product characteristics shall be updated if the additional evidence has an impact on the benefit-risk balance of a medicinal product.

3. The Agency shall adopt adequate data governance practices and the required standards to ensure the appropriate use and protection of personal health data, in accordance with this Regulation and Regulation (EU) 2018/1725.

Article 167

Protection against cyber attacks

The Agency shall equip itself with a high level of security controls and processes against cyber attacks, cyber espionage and other data breaches to ensure the protection of health data and the normal functioning of the Agency at all times, especially during public health emergencies or major events at Union level.

For the purposes of the first subparagraph, the Agency shall actively identify and implement cybersecurity best practices adopted within Union institutions, bodies, offices and agencies for preventing, detecting, mitigating, and responding to cyber attacks.

Article 168

Confidentiality

1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001 and Directive (EU) 2019/1937 of the European Parliament and of the Council¹², and existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the commercially confidential information and trade secrets of natural or legal persons in accordance with Directive (EU) 2016/943 of the European Parliament and of the Council¹³, including intellectual property rights.

¹² Directive (EU) 2019/1937 of the European Parliament and of the Council of 23 October 2019 on the protection of persons who report breaches of Union law (OJ L 305, 26.11.2019, p. 17).

¹³ Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (OJ L 157, 15.6.2016, p. 1).

2. Without prejudice to paragraph 1, all parties involved in the application of this Regulation shall ensure that no commercially confidential information is shared in a way which has the potential to enable undertakings to restrict or distort competition within the meaning of Article 101 TFEU.
3. Without prejudice to paragraph 1, information exchanged on a confidential basis between competent authorities of the Member States and between competent authorities of the Member States and the Commission and the Agency shall not be disclosed without the prior agreement of the authority from which that information originates.
4. Paragraphs 1, 2 and 3 do not affect the rights and obligations of the Commission, the Agency, Member States or other actors identified in this Regulation with regard to the exchange of information and the dissemination of warnings, nor do they affect the obligations of the persons concerned to provide information under criminal law.
5. The Commission, the Agency, and Member States may exchange commercially confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.

Article 169

Processing of personal data

1. The Agency may process personal data, including personal health data, for the performance of its tasks as referred to in Article 135, in particular for the purpose of improving the robustness of its scientific assessment or verifying claims of the applicant or marketing authorisation holder in the context of the evaluation or supervision of medicinal products.

Additionally, the Agency may process such data for the performance of regulatory science activities, as defined in paragraph 2, provided that the processing of those personal data:

- (a) is strictly required and duly justified to achieve the objectives of the project or of the horizon scanning activities concerned;
- (b) as regards special categories of personal data, is strictly necessary and subject to appropriate safeguards, which may include pseudonymisation.

2. For the purpose of this Article, ‘regulatory science activities’ shall mean scientific projects to complement available scientific evidence with regard to diseases or horizontal questions related to medicinal products, to fill evidence gaps that cannot be fully addressed through data in the possession of the Agency, or to support horizon scanning activities.
3. The processing of personal data by the Agency in the context of this Article shall be guided by the principles of transparency, explainability, fairness, and accountability.
4. The Management Board shall establish the general scope for the regulatory science activities in consultation with the Commission and the European Data Protection Supervisor.
5. The Agency shall keep documentation containing a detailed description of the process and of the rationale behind the training, testing and validation of algorithms to ensure transparency of the process and the algorithms, including their compliance with the safeguards provided for in this Article, and to allow for verification of the accuracy of the results based on the use of such algorithms. Upon request, the Agency shall make relevant documentation available to interested parties, including Member States.
6. If the personal data to be processed for the regulatory science activities have been directly provided by a Member State, a Union body, a third country or an international organisation, the Agency shall request authorisation from that provider of data, unless the provider of data has granted its prior authorisation to such processing for the purpose of regulatory science activities, either in general terms or subject to specific conditions.
7. Processing of personal data under this Regulation shall be subject to Regulations (EU) 2016/679 and (EU) 2018/1725, as applicable.

Article 170

Evaluation

1. Not later than [*note to OP = five years after the date of entry into application*], and every 10 years thereafter, the Commission shall commission an evaluation of the Agency's performance in relation to its objectives, mandate, tasks, governance and location(s) in accordance with Commission's guidelines.
2. The evaluation shall, in particular, address the possible need to modify the mandate of the Agency, and the financial implications of any such modification.
3. On the occasion of every second evaluation, there shall be an assessment of the results achieved by the Agency having regard to its objectives, mandate, governance and tasks, including an assessment of whether the continuation of the Agency is still justified with regard to these objectives, mandate, governance and tasks. This assessment shall also include the experience acquired as a result of the operation of the procedures laid down in this Regulation and in Chapter III, Sections 4 and 5 of [revised Directive 2001/83/EC] on the basis of input from Member States and the Coordination group referred to in Article 37 of [revised Directive 2001/83/EC].
4. The Commission shall report to the European Parliament, the Council and the Management Board on the evaluation findings. The findings of the evaluation shall be made public.
5. By 10 years following the entering into application, the Commission shall assess the application of this Regulation and produce an evaluation report on the progress towards achievement of the objectives contained herein including an assessment of the resources required to implement this Regulation.

CHAPTER XIV

AMENDMENTS TO OTHER LEGAL ACTS

Article 176

Amendments to Regulation (EC) No 1394/2007

Regulation (EC) No 1394/2007 is amended as follows:

- (1) Articles 8, 17 and 20 to 23 are deleted;
- (2) in Article 9(3), the fourth subparagraph is replaced by the following:

‘If the application does not include the results of the assessment, the Agency shall seek an opinion on the conformity of the device part with Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council* from a notified body identified in conjunction with the applicant, unless the Committee for Medicinal Products for Human Use advised by its experts for medical devices decides that involvement of a notified body is not required.

*Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).’

Article 178
Amendments to Regulation (EU) 2022/123

Regulation (EU) No 2022/123 is amended as follows:

1. In Article 18, the following paragraph (7) is added:

‘(7) Where a request has been made in accordance with Article 18(3) of Regulation (EU) 2022/123 and there is an application for a temporary emergency marketing authorisation for the medicinal product concerned in accordance with Article 30 of Regulation [Note to OP: Please fill in with the number of this Regulation]*, the procedure initiated under that Regulation shall prevail.’

* [OP: Insert the full title of that Regulation and the OJ reference, please]

2. Articles 33 and 34 are deleted.
