

Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use (Text with EEA relevance)

Article 1

Amendments to Regulation (EC) No 726/2004

Regulation (EC) No 726/2004 is amended as follows:

- (1) the title is replaced by the following:

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency;
- (2) the word ‘Community’ is replaced by the word ‘Union’ and any necessary grammatical changes are made;
- (3) the words ‘Community Register’ in Article 13(1) and (2) are replaced by the words ‘Union Register’;
- (4) the words ‘Court of Justice of the European Communities’ are replaced by the words ‘Court of Justice of the European Union’;
- (5) the words ‘Protocol on the Privileges and Immunities of the European Communities’ are replaced by the words ‘Protocol on the Privileges and Immunities of the European Union’;
- (6) in Article 1, the first paragraph is replaced by the following:

The purpose of this Regulation is to lay down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use and to establish a European Medicines Agency (“the Agency”) which shall carry out the tasks relating to medicinal products for human use and veterinary medicinal products that are laid down in this Regulation and other relevant Union legislation.;
- (7) in Article 2, the first paragraph is replaced by the following:

The definitions laid down in Article 1 of Directive 2001/83/EC shall apply for the purposes of this Regulation.

As a consequence, in this Regulation, the terms, “medicinal product” and “medicinal product for human use” mean a medicinal product as defined in point (2) of Article 1 of Directive 2001/83/EC.

In addition, the following definitions shall apply for the purposes of this Regulation:

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- (1) “veterinary medicinal product” means a medicinal product as defined in point (1) of Article 4 of Regulation (EU) 2019/6 of the European Parliament and of the Council⁽¹⁾ ;
 - (2) “antimicrobial” means an antimicrobial as defined in point (12) of Article 4 of Regulation (EU) 2019/6.;
- (8) Article 3 is amended as follows:
- (a) paragraph 2 is replaced by the following:
 2. Any medicinal product not appearing in Annex I may be granted a marketing authorisation by the Union in accordance with this Regulation, if:
 - a the medicinal product contains an active substance which, on 20 May 2004, was not authorised in the Union; or
 - b the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorisation in accordance with this Regulation is in the interest of patients' health at Union level.;
 - (b) in paragraph 3, the introductory wording and point (a) are replaced by the following:

A generic medicinal product of a reference medicinal product authorised by the Union may be authorised by the competent authorities of the Member States in accordance with Directive 2001/83/EC under the following conditions:

 - (a) the application for authorisation is submitted in accordance with Article 10 of Directive 2001/83/EC.;
 - (c) paragraph 4 is deleted;
- (9) in Article 4, paragraph 3 is deleted;
- (10) in Article 9(1), point (d) is replaced by the following:
- (d) the authorisation needs to be granted subject to the conditions provided for in Article 14(8) and Article 14-a.;
- (11) Article 10 is amended as follows:
- (a) paragraph 2 is replaced by the following:
 2. The Commission shall, by means of implementing acts, take a final decision within 15 days after obtaining the opinion of the Standing Committee on Medicinal Products for Human Use. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).;
 - (b) paragraph 5 is replaced by the following:
 5. The Commission shall, by means of implementing acts, adopt detailed rules for the implementation of paragraph 4 which specify the applicable time limits and procedures. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 87(2).;

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- (12) in Article 10b, paragraph 1 is replaced by the following:
1. The Commission is empowered to adopt delegated acts in accordance with Article 87b, in order to supplement this Regulation by determining the situations in which post-authorisation efficacy studies may be required under point (cc) of Article 9(4) and point (b) of Article 10a(1).;
- (13) Article 14 is amended as follows:
- (a) paragraph 1 is replaced by the following:
 1. Without prejudice to paragraphs 4 and 5 of this Article and to Article 14-a, a marketing authorisation shall be valid for five years.;
 - (b) paragraph 7 is deleted.
- (14) the following Article is inserted before Article 14a:
- Article 14-a*
- 1 In duly justified cases, to meet unmet medical needs of patients, a marketing authorisation may, for medicinal products intended for the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases, be granted prior to the submission of comprehensive clinical data provided that the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. In emergency situations, a marketing authorisation for such medicinal products may be granted also where comprehensive pre-clinical or pharmaceutical data have not been supplied.
 - 2 For the purposes of this Article, “unmet medical needs” means a condition for which there exists no satisfactory method of diagnosis, prevention or treatment authorised in the Union or, even if such a method exists, in relation to which the medicinal product concerned will be of major therapeutic advantage to those affected.
 - 3 Marketing authorisations may be granted pursuant to this Article only if the risk-benefit balance of the medicinal product is favourable and the applicant is likely to be able to provide comprehensive data.
 - 4 Marketing authorisations granted pursuant to this Article shall be subject to specific obligations. Those specific obligations and, where appropriate, the time limit for compliance shall be specified in the conditions to the marketing authorisation. Those specific obligations shall be reviewed annually by the Agency.
 - 5 As part of the specific obligations referred to in paragraph 4, the holder of a marketing authorisation granted pursuant to this Article shall be required to complete ongoing studies, or to conduct new studies, with a view to confirming that the risk-benefit balance is favourable.
 - 6 The summary of product characteristics and the package leaflet shall clearly mention that the marketing authorisation for the medicinal product has been granted subject to specific obligations as referred to in paragraph 4.
 - 7 By way of derogation from Article 14(1), a marketing authorisation granted pursuant to this Article shall be valid for one year, on a renewable basis.
 - 8 When the specific obligations referred to in paragraph 4 of this Article have been fulfilled, the Commission may, following an application by the marketing authorisation holder, and after receiving a favourable opinion from the Agency, grant

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a marketing authorisation valid for five years and renewable pursuant to Article 14(2) and (3).

- 9 The Commission is empowered to adopt delegated acts in accordance with Article 87b in order to supplement this Regulation by specifying:
- a the categories of medicinal products to which paragraph 1 of this Article applies; and
 - b the procedures and requirements for granting a marketing authorisation pursuant to this Article and for its renewal.;

(15) in Article 16, paragraph 4 is deleted;

(16) the following Articles are inserted:

Article 16a

1 Variations shall be classified in different categories depending on the level of risk to public health and the potential impact on the quality, safety and efficacy of the medicinal product concerned. Those categories shall range from changes to the terms of the marketing authorisation that have the highest potential impact on the quality, safety or efficacy of the medicinal product, to changes that have no or minimal impact thereon.

2 The procedures for examination of applications for variations shall be proportionate to the risk and impact involved. Those procedures shall range from procedures that allow implementation only after approval based on a complete scientific assessment to procedures that allow immediate implementation and subsequent notification by the marketing authorisation holder to the Agency.

3 The Commission is empowered to adopt delegated acts in accordance with Article 87b in order to supplement this Regulation by:

- a specifying the categories in which variations shall be classified; and
- b establishing procedures for the examination of applications for variations to the terms of marketing authorisations.

Article 16b

A marketing authorisation may be transferred to a new marketing authorisation holder. Such a transfer shall not be considered to be a variation. The transfer shall be subject to prior approval by the Commission, following the submission of an application for the transfer to the Agency.

The Commission is empowered to adopt delegated acts in accordance with Article 87b in order to supplement this Regulation by establishing procedures for the examination of applications to the Agency for the transfer of marketing authorisations.;

(17) Article 20 is amended as follows:

(a) paragraph 3 is replaced by the following:

3. At any stage of the procedure laid down in this Article, following appropriate consultation of the Agency, the Commission may take temporary measures. Those temporary measures shall be applied immediately.

Without undue delay, the Commission shall, by means of implementing acts, adopt a final decision concerning the measures to be taken in respect of the medicinal product concerned. Those implementing acts shall be adopted in

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accordance with the examination procedure referred to in Article 87(2) of this Regulation.

The Commission may also, pursuant to Article 127a of Directive 2001/83/EC, adopt a decision addressed to the Member States.;

(b) paragraph 6 is replaced by the following:

6. The suspensive measures referred to in paragraph 4 may be maintained in force until such time as a final decision has been adopted in accordance with paragraph 3.;

(18) the following Article is inserted before Chapter 3:

Article 20a

Where the Agency concludes that a holder of a marketing authorisation granted pursuant to Article 14-a failed to comply with the obligations laid down in the marketing authorisation, the Agency shall inform the Commission accordingly. The Commission shall adopt a decision to vary, suspend or revoke that marketing authorisation in accordance with the procedure set out in Article 10.;

(19) Articles 30 to 54 are deleted;

(20) Article 55 is replaced by the following:

Article 55

A European Medicines Agency is hereby established.

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.;

(21) Article 56 is amended as follows:

(a) in paragraph 1, point (b) is replaced by the following:

(b) the Committee for Veterinary Medicinal Products set up pursuant to Article 139(1) of Regulation (EU) 2019/6.;

(b) in paragraph 2, the first subparagraph is replaced by the following:

2. The committees referred to in points (a), (aa), (c), (d), (da) and (e) of paragraph 1 of this Article may each establish standing and temporary working parties. The committee referred to in point (a) of paragraph 1 of this Article may establish scientific advisory groups in connection with the evaluation of specific types of medicinal products or treatments, to which it may delegate certain tasks associated with drawing up the scientific opinions referred to in Article 5.;

(c) paragraph 3 is replaced by the following:

3. The Executive Director, in consultation with the Committee for Medicinal Products for Human Use and the Committee for Veterinary Medicinal Products, shall set up the administrative structures and procedures allowing the development of advice for undertakings, as referred to in point (n) of Article 57(1), including advice on the use of novel methodologies and

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tools in research and development, particularly regarding the development of new therapies.

Those committees shall each establish a standing working party with the sole remit of providing scientific advice to undertakings.;

- (d) in paragraph 4, the words ‘the Committee for Medicinal Products for Veterinary use’ are replaced by the words ‘the Committee for Veterinary Medicinal Products’;

(22) Article 57 is amended as follows:

- (a) paragraph 1 is amended as follows:

- (i) the introductory wording and points (a) to (f) are replaced by the following:

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

To that end, 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 and of veterinary medicinal products which are subject to Union marketing authorisation procedures;
- b transmitting on request and making publicly available assessment reports, summaries of product characteristics, labels and package leaflets for the medicinal products for human use;
- c coordinating the monitoring of medicinal products for human use and of veterinary medicinal products 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;
- d ensuring the collation and dissemination of information on suspected adverse reactions to medicinal products for human use and to veterinary medicinal products authorised in the Union by means of databases that are permanently accessible to all Member States;
- e 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 national competent authorities;

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- f 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;;
- (ii) points (g) and (h) are deleted;
- (iii) points (i) to (t) are replaced by the following:
 - (i) 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 and, as regards medicinal products for human use, the verification of compliance with pharmacovigilance obligations;
 - (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 of medicinal products for human use and of veterinary medicinal products, in particular in the context of discussions organised in the framework of international conferences on harmonisation;
 - (k) recording the status of marketing authorisations for medicinal products for human use and for veterinary medicinal products granted in accordance with Union marketing authorisation procedures;
 - (l) 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;
 - (m) 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;
 - (n) advising undertakings on the conduct of the various tests and trials necessary to demonstrate the quality, safety and efficacy of medicinal products for human use and of veterinary medicinal products;
 - (o) checking that the conditions laid down in Union legislation on medicinal products for human use and on veterinary medicinal products and in the marketing

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- 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;
- (p) 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 and of veterinary medicinal products;
 - (q) 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;
 - (r) 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 by an Official Medicines Control Laboratory or by a laboratory that a Member State has designated for that purpose;
 - (s) forwarding annually to the budgetary authority any information relevant to the outcome of the evaluation procedures for medicinal products for human use and veterinary medicinal products;
 - (t) taking decisions as referred to in Article 7(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council⁽²⁾;
- (iv) the following point is added:
- (u) 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.;
- (b) in paragraph 2, the first subparagraph is replaced by the following:
2. The database provided for in point (l) of paragraph 1 of this Article shall include the summaries of product characteristics, the package leaflet and the information shown on the labelling. That database shall be developed in stages, priority being given to medicinal products authorised under this Regulation and those authorised under Chapter 4 of Title III of Directive

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2001/83/EC. The database shall subsequently be extended to include any medicinal product for human use authorised in the Union.;

(23) in Article 59, paragraph 4 is replaced by the following:

4. Unless otherwise provided for in this Regulation, Regulation (EU) 2019/6 or Directive 2001/83/EC, where there is a fundamental conflict over scientific points and the body concerned is a body in a Member State, the Agency and the national body concerned shall work together either to resolve the conflict or to prepare a joint document clarifying the scientific points of conflict. Such joint document shall be published immediately after its adoption.;

(24) Article 61 is amended as follows:

(a) paragraphs 1 and 2 are replaced by the following:

1. Each Member State shall, after consultation of the Management Board, appoint, for a three-year term which may be renewed, one member and one alternate to the Committee for Medicinal Products for Human Use.

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 62.

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 national competent authorities.

2. 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.;

(b) in paragraphs 3, 5 and 8, the words ‘each committee’ are replaced by the words ‘the Committee for Medicinal Products for Human Use’;

(c) paragraph 4 is replaced by the following:

4. The Executive Director of the Agency or his or her representative and representatives of the Commission shall be entitled to attend all meetings of the committees referred to in Article 56(1), working parties and scientific advisory groups and all other meetings convened by the Agency or its committees.;

(d) paragraphs 6 and 7 are replaced by the following:

6. Members of the Committee for Medicinal Products for Human Use and experts responsible for evaluating medicinal products shall rely on the scientific evaluation and resources available to national marketing authorisation bodies. Each competent national authority shall monitor the scientific level and independence of the evaluation carried out and facilitate the activities of nominated members of that Committee and experts. Member States shall refrain from giving those members and experts any instruction

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which is incompatible with their own individual tasks or with the tasks and responsibilities of the Agency.

7 When preparing the opinion, the committees referred to in Article 56(1) 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.;

(25) Article 62 is amended as follows:

(a) in paragraph 1, the third and fourth subparagraphs are replaced by the following:

When consulting the scientific advisory groups referred to in Article 56(2), 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 chairman of the relevant committee in such a way as to ensure that the deadlines laid down in Article 6(3) are met.

The substance of the opinion shall be included in the assessment report published pursuant to Article 13(3).;

(b) paragraph 2 is replaced by the following:

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 Article 63(2), would be available to serve on working parties or scientific advisory groups of any of the committees referred to in Article 56(1), together with an indication of their qualifications and specific areas of expertise.

The Agency shall establish and maintain a list of accredited experts. That list shall include the national experts referred to in the first subparagraph and any other experts appointed by the Agency or the Commission, and shall be updated.;

(26) Article 64 is amended as follows:

(a) paragraph 1 is replaced by the following:

1. The Executive Director shall be appointed by the Management Board, on a proposal from the Commission, for a period of five years on the basis of a list of candidates proposed by the Commission following a call for expressions of interest published in the *Official Journal of the European Union* and, as appropriate, by other means. 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. The mandate of the Executive Director may be renewed once by the Management Board, upon a proposal from the Commission. The Management Board may, upon a proposal from the Commission, remove the Executive Director from his or her post.;

(b) in paragraph 3, the second subparagraph is replaced by the following:

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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.;

- (27) Article 66 is amended as follows:
- (a) point (a) is replaced by the following:
 - (a) adopt an opinion on the rules of procedures of the Committee for Medicinal Products for Human Use (Article 61 of this Regulation) and the Committee for Veterinary Medicinal Products (Article 139 of Regulation (EU) 2019/6);;
 - (b) point (j) is deleted;
 - (c) point (k) is replaced by following:
 - (k) adopt rules to ensure the availability to the public of information concerning the authorisation or supervision of medicinal products for human use and of veterinary medicinal products (Article 80).;
- (28) in Article 67, paragraph 3 is replaced by the following:
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 this purpose;
 - c fees paid by undertakings:
 - (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 107c, 107e, 107g, 107k and 107q of 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 68(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 point (a) of the first subparagraph, on the basis of an evaluation of needs and by taking account of the level of fees referred to in point (c) of the first subparagraph.;

- (29) Article 68 is replaced by the following:

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Article 68

1 The Executive Director shall implement the budget of the Agency in accordance with Regulation (EU) 2018/1046 of the European Parliament and of the Council⁽³⁾ (“the Financial Regulation”).

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 the Financial Regulation, 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.

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 the Financial Regulation.

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) No 1271/2013⁽⁴⁾ unless specifically required for the Agency’s operation and with the Commission’s prior consent.;

(30) Article 70 is deleted;

(31) in Article 75, the first paragraph is replaced by the following:

The staff of the Agency shall be subject to the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the

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European Union. In respect of its staff, the Agency shall exercise the powers which have been devolved to the appointing authority.;

- (32) Article 77 is replaced by the following:

Article 77

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.;

- (33) in Article 78, paragraph 2 is replaced by following:

2. The committees referred to in Article 56(1) of this Regulation and any working parties and scientific advisory groups established in accordance with that Article or Article 139(3) of Regulation (EU) 2019/6 shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products for human use and of veterinary medicinal products, in particular patient organisations and healthcare professionals' associations. Rapporteurs appointed by those committees may, on an advisory basis, establish contacts with representatives of patient organisations and healthcare professionals' associations relevant to the indication of the medicinal product for human use or veterinary medicinal product concerned.;

- (34) Article 79 is deleted;

- (35) in Article 80, the first paragraph is replaced by the following:

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 and of veterinary medicinal products which is not of a confidential nature.;

- (36) in Article 82, paragraph 3 is replaced by the following:

3. Without prejudice to the unique Union nature of the content of the documents referred to in points (a) to (d) of Article 9(4), this Regulation shall not prohibit the use of two or more commercial designs for a given medicinal product for human use covered by a single marketing authorisation.;

- (37) In Article 84, paragraph 3 is deleted;

- (38) the following Article is inserted:

Article 84a

- 1 The Commission may impose financial penalties in the form of fines or periodic penalty payments on the holders of marketing authorisations granted under this Regulation if they fail to comply with any of the obligations laid down in Annex II in connection with the marketing authorisations.

- 2 The Commission may, insofar as specifically provided for in the delegated acts referred to in point (b) of paragraph 10, impose the financial penalties referred to in paragraph 1 also on a legal entity or legal entities other than the marketing

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authorisation holder provided that such entities form part of the same economic entity as the marketing authorisation holder and that such other legal entities:

- a exerted a decisive influence over the marketing authorisation holder; or
- b were involved in, or could have addressed, such failure to comply with the obligation by the marketing authorisation holder.

3 Where the Agency or a competent authority of a Member State is of the opinion that a marketing authorisation holder has failed to comply with any of the obligations, as referred to in paragraph 1, it may request the Commission to investigate whether to impose financial penalties pursuant to that paragraph.

4 In determining whether to impose a financial penalty and in determining its appropriate amount, the Commission shall be guided by the principles of effectiveness, proportionality and dissuasiveness and take into consideration, where relevant, the seriousness and the effects of the failure to comply with the obligations.

5 For the purposes of paragraph 1, the Commission shall also take into account:

- a any infringement procedure initiated by a Member State against the same marketing authorisation holder on the basis of the same legal grounds and the same facts; and
- b any sanctions, including penalties, already imposed on the same marketing authorisation holder on the basis of the same legal grounds and the same facts.

6 Where the Commission finds that the marketing authorisation holder has failed, intentionally or negligently, to comply with its obligations, as referred to in paragraph 1, it may adopt a decision imposing a fine not exceeding 5 % of the marketing authorisation holder's Union turnover in the business year preceding the date of that decision.

Where the marketing authorisation holder continues to fail to comply with its obligations referred to in paragraph 1, the Commission may adopt a decision imposing periodic penalty payments per day not exceeding 2,5 % of the marketing authorisation holder's average daily Union turnover in the business year preceding the date of that decision.

Periodic penalty payments may be imposed for a period running from the date of notification of the relevant Commission's decision until the failure to comply with the obligation by the marketing authorisation holder, as referred to in paragraph 1, has been brought to an end.

7 When conducting the investigation on a failure to comply with any of the obligations referred to in paragraph 1, the Commission may cooperate with national competent authorities and rely on resources provided by the Agency.

8 Where the Commission adopts a decision imposing a financial penalty, it shall publish a concise summary of the case, including the names of the marketing authorisation holders involved and the amounts of and reasons for the financial penalties imposed, having regard to the legitimate interest of the marketing authorisation holders for the protection of their business secrets.

9 The Court of Justice of the European Union shall have unlimited jurisdiction to review decisions whereby the Commission has imposed financial penalties. The Court of Justice of the European Union may cancel, reduce or increase the fine or periodic penalty payment imposed by the Commission.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2019/5 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

- 10 The Commission is empowered to adopt delegated acts in accordance with Article 87b in order to supplement this Regulation by laying down:
- a procedures to be applied by the Commission when imposing fines or periodic penalty payments, including rules on the initiation of the procedure, measures of inquiry, rights of the defence, access to file, legal representation and confidentiality;
 - b further detailed rules on the imposition by the Commission of financial penalties on legal entities other than the marketing authorisation holder;
 - c rules on duration of procedure and limitation periods;
 - d elements to be taken into account by the Commission when setting the level of and imposing fines and periodic penalty payments, as well as the conditions and methods for their collection.;
- (39) Article 86 is replaced by the following:
- Article 86*
- At least every 10 years, the Commission shall publish a general report on the experience acquired as a result of the operation of the procedures laid down in this Regulation and in Chapter 4 of Title III of Directive 2001/83/EC.;
- (40) the following Article is inserted:
- Article 86a*
- By 2019, the Commission shall review the regulatory framework for fees payable to the Agency in relation to medicinal products for human use and veterinary medicinal products. The Commission shall put forward, as appropriate, legislative proposals with a view to update that framework. When reviewing the regulatory framework for fees payable to the Agency, the Commission shall pay attention to potential risks related to the fluctuations in the fee revenue of the Agency.;
- (41) Article 87 is replaced by the following:
- Article 87*
- 1 The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use established by Article 121 of Directive 2001/83/EC. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council⁽⁶⁾.
- 2 Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.;
- (42) Article 87b is replaced by the following:
- Article 87b*
- 1 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
- 2 The power to adopt delegated acts referred to in Articles 10b(1), 14-a(9), 16a(3), the second paragraph of Article 16b, and Article 84a(10) shall be conferred on the Commission for a period of five years from 28 January 2019. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2019/5 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

3 The delegation of power referred to in Articles 10b(1), 14-a(9), 16a(3), the second paragraph of Article 16b, and Article 84a(10) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4 Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁽⁶⁾.

5 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6 A delegated act adopted pursuant to Articles 10b(1), 14-a(9), 16a(3), the second paragraph of Article 16b, and Article 84a(10) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.;

(43) Articles 87c and 87d are deleted;

(44) the Annex becomes Annex I;

(45) point 2 of Annex I is deleted;

(46) the text set out in the Annex to this Regulation is added as Annex II.

Article 2

Amendments to Directive 2001/83/EC

Directive 2001/83/EC is amended as follows:

(1) in Article 1, the following point is inserted:

26a. Variation or variation to the terms of a marketing authorisation:

An amendment to the contents of the particulars and documents referred to in:

(a) Article 8(3) and Articles 9 to 11 of this Directive and Annex I thereto, Article 6(2) of Regulation (EC) No 726/2004 and in Article 7 of Regulation (EC) No 1394/2007; and

(b) the terms of the decision granting the marketing authorisation for a medicinal product for human use, including the summary of the product characteristics and any conditions, obligations, or restrictions affecting the marketing authorisation, or changes to the labelling or the package leaflet related to changes to the summary of the product characteristics.;

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(2) Article 23b is amended as follows:

(a) paragraphs 1 to 4 are replaced by the following:

1. Variations shall be classified in different categories depending on the level of risk to public health and the potential impact on the quality, safety and efficacy of the medicinal product concerned. Those categories shall range from changes to terms of the marketing authorisation that have the highest potential impact on the quality, safety or efficacy of the medicinal product, to changes that have no or minimal impact thereon.

2 The procedures for examination of applications for variations shall be proportionate to the risk and impact involved. Those procedures shall range from procedures that allow implementation only after approval based on a complete scientific assessment to procedures that allow immediate implementation and subsequent notification by the marketing authorisation holder to the competent authority.

2a The Commission is empowered to adopt delegated acts in accordance with Article 121a in order to supplement this Directive by:

- a specifying the categories in which variations shall be classified; and
- b establishing procedures for the examination of applications for variations to the terms of marketing authorisations.

3 When adopting the delegated acts referred to in this Article, the Commission shall endeavour to make possible the submission of a single application for one or more identical changes made to the terms of different marketing authorisations.

4 A Member State may continue to apply national provisions on variations applicable at the time of entry into force of Commission Regulation (EC) No 1234/2008⁽⁷⁾ to marketing authorisations granted before 1 January 1998 to medicinal products authorised only in that Member State. Where a medicinal product subject to national provisions in accordance with this Article is subsequently granted a marketing authorisation in another Member State, Regulation (EC) No 1234/2008 shall apply to that medicinal product from that date.;

(b) in paragraph 5, the words ‘the implementing regulation’ are replaced by the words ‘Regulation (EC) No 1234/2008’;

(3) Articles 121a, 121b and 121c are replaced by the following:

Article 121a

1 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2 The power to adopt delegated acts referred to in Articles 22b, 23b(2a), 47, 52b and 54a shall be conferred on the Commission for a period of five years from 28 January 2019. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

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3 The delegation of power referred to in Articles 22b, 23b(2a), 47, 52b and 54a may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4 Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making⁽⁸⁾.

5 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6 A delegated act adopted pursuant to Articles 22b, 23b(2a), 47, 52b and 54a shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council..

Article 3

Amendment to Regulation (EC) No 1901/2006

In Article 49 of Regulation (EC) No 1901/2006, paragraph 3 is replaced by the following:

3. The Commission may, in relation to medicinal products authorised in accordance with Regulation (EC) No 726/2004, impose, in accordance with the procedure laid down in Article 84a of that Regulation, financial penalties in the form of fines or periodic penalty payments for the failure to comply with the obligations set out in this Regulation that are listed in Annex II to Regulation (EC) No 726/2004..

Article 4

Transitional provisions

1 Regulations (EC) No 2141/96, (EC) No 2049/2005, (EC) No 507/2006 and (EC) No 658/2007 shall remain in force and continue to apply unless and until repealed.

2 Regulation (EC) No 1234/2008 shall continue to apply unless and until repealed as regards medicinal products for human use that are covered by Regulation (EC) No 726/2004 and Directive 2001/83/EC and that are not excluded from the scope of Regulation (EC) No 1234/2008 pursuant to Article 23b(4) and (5) of Directive 2001/83/EC.

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Article 5

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Points (2) to (5), (10), (12) to (16), (18), (26), (28), (29), (31), (37), (38), (40), (42) to (44) and (46) of Article 1, and Articles 2, 3 and 4 shall apply from 28 January 2019.

Points (1), (6) to (9), (11), (17), (19) to (25), (27), (30), (32) to (36), (39), (41) and (45) of Article 1 shall apply from 28 January 2022.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 11 December 2018.

For the European Parliament

The President

A. TAJANI

For the Council

The President

J. BOGNER-STRAUSS

Changes to legislation: There are outstanding changes not yet made to Regulation (EU) 2019/5 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

- (1) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC ([OJ L 4, 7.1.2019, p. 43](#)).’;
- (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](#)).’;
- (3) 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](#)).
- (4) Commission Delegated Regulation (EU) No 1271/2013 of 30 September 2013 on the framework financial regulation for the bodies referred to in Article 208 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council ([OJ L 328, 7.12.2013, p. 42](#)).’;
- (5) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers ([OJ L 55, 28.2.2011, p. 13](#)).’;
- (6) [OJ L 123, 12.5.2016, p. 1](#).’;
- (7) Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products ([OJ L 334, 12.12.2008, p. 7](#)).’;
- (8) [OJ L 123, 12.5.2016, p. 1](#).’.

Changes to legislation:

There are outstanding changes not yet made to Regulation (EU) 2019/5 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

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Changes and effects yet to be applied to :

- Regulation revoked in part by S.I. 2019/775, Sch. 9 para. 1(jj) (as inserted) by [S.I. 2020/1488 Sch. 2 para. 195](#)