Official Journal of the European Union

L 7

Volume 64

English edition

Legislation

11 January 2021

Contents

II *Non-legislative acts*

REGULATIONS

★ **Commission Implementing Regulation (EU) 2021/16 of 8 January 2021 laying down the necessary measures and practical arrangements for the Union database on veterinary medicinal products (Union product database)** 1

★ **Commission Implementing Regulation (EU) 2021/17 of 8 January 2021 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council** [1] 22

Corrigenda

★ **Corrigendum to Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007** (OJ L 150, 14.6.2018) 53

[1] Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2021/16

of 8 January 2021

laying down the necessary measures and practical arrangements for the Union database on veterinary medicinal products (Union product database)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 [1], and in particular Article 55(3) thereof,

Whereas:

(1) Article 55(1) of Regulation (EU) 2019/6 requires the European Medicines Agency ('the Agency') to establish and, in cooperation with the Member States, maintain a Union database on veterinary medicinal products ('Union product database').

(2) The Commission is required under Article 55(3) of Regulation (EU) 2019/6 to adopt, by means of implementing acts, necessary measures and practical arrangements for the establishment and maintenance of the Union product database.

(3) The Union product database is aimed at enhancing the single market by providing information on veterinary medicinal products available in Member States and allowing health professionals to obtain information on veterinary medicinal products which might be considered for elaboration of potential treatment alternatives where no suitable veterinary medicinal product is authorised in their Member State.

(4) The Union product database should increase overall transparency by providing the general public with the widest possible access to the information it contains after the deletion of commercially confidential information and personal data by the competent authorities.

(5) The Union product database should contain harmonised and consistent data of quality, provide capabilities that offer interoperability with other national and Union IT systems which utilise veterinary medicinal product data and allow integration in the activities of the regulatory network.

(6) Regulation (EU) 2019/6 provides also for the establishment of other databases. To ensure interoperability and to enable the Union product database to interface with those databases, the structure of data should be harmonised between the different systems using the same reference data.

(7) The Union product database should be functional and operational from the date of application of Regulation (EU) 2019/6 (28 January 2022) to enable the regulatory processes provided for therein. It should also be able to adapt to any changes which occur within the regulatory network, to meet the needs of the regulatory operating models as they develop and to keep up to speed with technical and scientific progress. This necessitates an incremental

[1] OJ L 4, 7.1.2019, p. 43.

approach to its establishment and maintenance. By the date of application of Regulation (EU) 2019/6, the Agency should ensure that the Union product database meets at least all functional requirements stemming from that Regulation. Thereafter, the Agency should continue developing additional functionalities, including such that could further reduce administrative burden and contribute to the harmonisation of processes across the regulatory network.

(8) In order to alleviate the administrative burden of the competent authorities, the initial input of information by the competent authorities to the Agency on all veterinary medicinal products should be permitted on a phased basis.

(9) The Union product database should be composed of interrelated components which will allow a comprehensive and uniform management of the information which will be stored. It should also be able to receive up-to-date information from existing catalogues of terms maintained by the Agency. Therefore, it is to be understood as a database system, rather than a standalone IT solution.

(10) The Union product database should be developed with the aim of avoiding the duplicate input of data in different Union systems. This should ensure that there is a single source for each type of information provided and that data is entered only once to reduce excessive administrative burden and to mitigate the risk of inconsistency. The datasets contained in the Union product database should be the most recent and correct ones. To this end, the Union product database should make available the latest datasets to enable the competent authorities to keep their respective national systems aligned and synchronised with the Union product database. It should also be possible for the competent authorities, the Commission and marketing authorisation holders to use their own systems to update the Union product database as needed.

(11) To the highest extent possible, the data and documents contained in the Union product database should be in a format which allows machine readability. However, not all documents required under Regulation (EU) 2019/6, especially those to be submitted by the competent authorities for initial input into the Union product database, may be available in such a format. Therefore, specific arrangements should be in place as regards documents to be provided by the competent authorities at the time of initial input of data from the Member States on veterinary medicinal products.

(12) In accordance with Commission Implementing Regulation (EU) 2021/17 ([2]), certain variations that do not require assessment would result in changes to the datasets in the Union product database while others would not. Both types could also necessitate supporting documentation. All such variations should be recorded by marketing authorisation holders and logged by the Union product database for approval or rejection by the competent authorities as provided for in Article 61 of Regulation (EU) 2019/6. The Union product database should also allow marketing authorisation holders to record subsequent changes before the ones recorded previously have been processed by the competent authorities. Furthermore, the regulatory process allows for concurrent applications for and processing of variations requiring assessment, as well as their grouping and work-sharing. Therefore, the Union product database should support the competent authorities in receiving variations in parallel.

(13) Different actors should have different access levels to the Union product database as provided for in Article 56 of Regulation (EU) 2019/6. A detailed access policy should therefore be drawn up and applied by the Agency, in collaboration with the competent authorities and the Commission and in consultation with marketing authorisation holders, before the Union product database becomes operational. It should enable actors to perform their obligations as set down in Regulation (EU) 2019/6, while protecting commercially confidential information and personal data, and should therefore provide different levels of access to the Union product database processes.

([2]) Commission Implementing Regulation (EU) 2021/17 of 8 January 2021 establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (see page 22 of this Official Journal).

(14) Continuity must be safeguarded should the Union product database, or any of its components, become unavailable. Adequate contingency arrangements should therefore be drawn up and applied by the Agency before the Union product database becomes operational.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products referred to in Article 145 of Regulation (EU) 2019/6,

HAS ADOPTED THIS REGULATION:

SECTION 1

GENERAL PROVISIONS

Article 1

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(a) 'user' means any person which interacts with the Union product database via its functions;

(b) 'super user' means one user who is designated by each marketing authorisation holder, competent authority, the Agency or the Commission and is authorised by the Agency to perform actions in the Union product database in accordance with the access rights assigned to their user profiles;

(c) 'controlled user' means any user authorised by a super user to perform actions in the Union product database on that super user's behalf in accordance with the access rights assigned to that super user's profile;

(d) 'open format' means open format as defined in Article 2(14) of Directive (EU) 2019/1024 of the European Parliament and of the Council ([3]);

(e) 'machine-readable format' means machine-readable format as defined in Article 2(13) of Directive (EU) 2019/1024;

(f) 'structured data' means data in predefined and standardised format which can be parsed, organised and processed by computers;

(g) 'Union systems' means European Union IT systems under the control of the Agency, the Commission or the Member States;

(h) 'restricted data' means any data not classified as public, as set out in the access policy referred to in Article 13 of this Regulation.

Article 2

Development, maintaining and upgrading of the Union product database

1. At the latest by 28 January 2022, the Agency shall develop and put into use a database which meets at least the requirements laid down in this Regulation.

2. After 28 January 2022, the Agency shall upgrade existing functionalities of the database and develop whatever other functionalities are considered appropriate and are agreed upon by the competent authorities and the Commission.

At the latest, by 28 January 2022, the Agency shall, in consultation with the Member States, the Commission and marketing authorisation holders, develop a plan for the further development and upgrading of the Union product database. The Agency shall update this plan every two years in light of the progress made and the needs identified by the

([3]) Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information (OJ L 172, 26.6.2019, p. 56).

regulatory network referred to in Chapter X of Regulation (EU) 2019/6 and the feedback provided by the users of the Union product database.

3. When establishing the Union product database, the Agency shall, as much as possible, use solutions which already exist, are under development across the regulatory network or are commercially available provided that they meet the objectives of the Union product database.

Article 3

Submission of information on veterinary medicinal products by the competent authorities for the initial input to the Union product database

1. The competent authorities shall submit, in electronic form, the information required under Article 155 of Regulation (EU) 2019/6 in the format for the initial input to the Union product database prescribed by the Agency.

Not later than 21 January 2021, the Agency shall prescribe the format of the data and documents ('dataset') which together form the information to be provided.

2. Before submitting their data on veterinary medicinal products to the Agency, the competent authorities shall map them against the detailed specifications laid down in Annexes II and III of this Regulation.

The Agency shall ensure that the required controlled terms, including substance terms and organisation data, with unique term and data identifiers and whose values can only be selected from a predefined set of values specified or maintained by the Agency are available for the mapping of the data.

3. Where a dataset for a specific veterinary medicinal product is incomplete for historical reasons (as a result of data or documents not being required from competent authorities or from marketing authorisation holders prior to the application of Regulation (EU) 2019/6), the competent authorities shall clearly indicate in the datasets they provide any fields for which no value is available at time of initial input.

4. The competent authorities shall submit the available documents in an open and, for as many documents as possible, machine-readable format which supports long term archiving.

5. The competent authorities shall submit the information in at least one official language of the Union.

6. Not later than 28 July 2021, the Agency shall make available the necessary environment and IT support to be used by the competent authorities for the testing of the bulk upload of the information for the initial input to the Union product database.

Article 4

Timelines for the submission for the initial input of data on various types of veterinary medicinal products

1. In addition to the requirement laid down in Article 155 of Regulation (EU) 2019/6:

(a) at the latest by 28 January 2022, the competent authorities shall submit to the Agency, in electronic form, information on:

  (i) all homeopathic veterinary medicinal products registered in their Member State at that time;

  (ii) all veterinary medicinal products parallel-traded in their Member State at that time;

(b) at the latest by 28 January 2024, the competent authorities shall submit to the Agency, in electronic form, information on all veterinary medicinal products that had been exempted in their Member State from the provisions for marketing authorisation at that time.

2. The competent authorities shall use the format referred to in Article 3(1) and the detailed specifications of the information to be provided laid down in Annexes II and III to this Regulation.

Article 5

Order of precedence

In case of discrepancies between the datasets already existing in the Member States' systems and the Union product database, the latter shall prevail in respect of the information contained therein.

This shall not preclude the Member States from synchronising the Union product database with the most up-to-date information on veterinary medicinal products which results from the ongoing regulatory process and is contained in their national systems.

SECTION 2

TECHNICAL SPECIFICATIONS OF THE UNION PRODUCT DATABASE

Article 6

User interface

1. The Union product database shall include graphical user interfaces providing access to users in accordance with their access rights established in Articles 12 and 13.

2. The Agency shall ensure that the development, operation and maintenance of the Union product database is done in a manner that conforms to Directive (EU) 2016/2102 of the European Parliament and of the Council ([4]).

3. The graphical user interface of the Union product database shall support responsive web design.

4. The graphical user interface of the Union product database for the general public shall be available in all official languages of the Union.

5. The graphical user interface of the Union product database for super users and controlled users shall be available at least in the English language.

Article 7

Components

The Union product database shall consist of at least the following components:

(a) an access management component which, with the use of authentication and authorisation processes, manages the control of access to data or functionalities and ensures that super users and controlled users have the appropriate access to the resources provided by the Union product database and the proper permissions to perform actions in the Union product database;

(b) a data and document submission component which allows submission to the Union product database of data and documents relating to new veterinary medicinal products, variations and other post-authorisation changes to the datasets already existing in the Union product database for veterinary medicinal products;

(c) a data and document repository component which manages all data and documents that enter into the Union product database and uses at least the following functionalities:

([4]) Directive (EU) 2016/2102 of the European Parliament and of the Council of 26 October 2016 on the accessibility of the websites and mobile applications of public sector bodies (OJ L 327, 2.12.2016, p. 1).

(i) a data recording functionality which manages the capability of recording data, including versioning;

(ii) a data quality validation functionality which automatically manages the technical validation and quality check on data prior to their recording in the Union product database;

(iii) a data history functionality which manages the audit trail and traceability of data changes;

(iv) a document management functionality which manages the storage, versioning of the stored documents to distinguish between the latest approved versions, versions which have been approved previously but replaced by newer versions, as well as any versions rejected as a result of rejections of variations that do not require assessment, and access to documents.

(d) a Union product database portal which, with the use of data publishing, data searching, viewing and exporting, as well as data analytics, presents information to users and makes certain features available to them in accordance with their access rights;

(e) a component for managing variations that do not require assessment which allows the relevant competent authority or the Commission, as applicable, to be notified and to approve or reject variations that do not require assessment prior to the update in the Union product database, to update the datasets accordingly and to store and update related documentation;

(f) a general public module which is accessed via the Union product database portal and allows the general public to view and perform searches on all publicly available data and documents on veterinary medicinal products referred to in Article 56 of Regulation (EU) 2019/6.

Article 8

Functionalities of the Union product database

The Union product database shall have at least the functionalities listed in Annex I.

Article 9

Electronic data and document exchange mechanism for exchanging with other systems

The Agency shall ensure that:

(a) the electronic data and document exchange mechanism follows, to the extent that optimal operability of the Union product database does not adversely impact other Union systems, current recognised international standards for the identification of medicinal products and exchange of medicinal product information or relevant subsets thereof;

(b) the structure of data is consistent between the Union product database and other Union systems using the same reference data;

(c) the Union product database functions as the Union master data repository where information about veterinary medicinal products is registered;

(d) the Union product database provides a functionality to enable other systems to interoperate with it;

(e) the Union product database consumes reference data from other existing databases or IT tools to avoid duplication of data input at Union level and ensure data quality;

(f) the Union product database is able to consume structured data provided in the course of the regulatory process, as relevant;

(g) the Union product database provides the necessary data to the Union pharmacovigilance database;

(h) the Union product database is linked to the Union database of manufacturing, import and wholesale distribution;

(i) the Union product database has a service-oriented Application Programming Interface ('API') for the exchange of data and documents with the systems used by marketing authorisation holders, competent authorities, the Agency and the Commission.

Article 10

Format for electronic submission to the Union product database

The Agency shall ensure that:

(a) the format for electronic submission consists of documents and structured data on veterinary medicinal products, as applicable;

(b) the data format:

(i) follows, to the extent that optimal operability of the Union product database does not adversely impact other Union systems, current recognised international standards for the identification of medicinal products and exchange of medicinal product information or relevant subsets thereof;

(ii) uses, as much as possible, structured data and controlled terms, including substance terms and organisation data, to ensure data quality;

(c) documents are provided in an open and machine-readable document format which supports long term archiving.

SECTION 3

PRACTICAL ARRANGEMENTS FOR THE FUNCTIONING OF THE UNION PRODUCT DATABASE

Article 11

Protection of commercially confidential information

Data on the annual volume of sales of veterinary medicinal products shall be visible in the Union product database only to the relevant competent authorities, the Commission and the Agency, as well as to the marketing authorisation holders to whose veterinary medicinal products those data refer.

Article 12

Security of exchange of information

1. The Agency, in collaboration with the competent authorities and the Commission and in consultation with marketing authorisation holders, shall submit the Union product database to security testing procedures prior to putting it into operation.

2. The Agency shall ensure that the Union product database components accessible over the internet are sufficiently protected against risks of cybercrime throughout the database's lifetime.

3. The Agency shall make it mandatory for super users and controlled users to undergo authentication and authorisation procedures each time they use the Union product database.

4. The Agency shall ensure the secure storage and exchange of all data stored in the Union product database using security protocols and connectivity rules from non-proprietary open standards established by international standards bodies or organisations.

5. The Agency shall limit access to the types of information that only super users and controlled users are permitted to access and to the functions only they are permitted to exercise. The access policy provided for in Article 13 shall conform to the security classification of the data exposed and follow the Agency's security requirements, ensuring the segregation of responsibilities and restricting access to data.

6. The Agency shall ensure that the Union product database provides audit trail and traceability of:

(a) regulatory actions performed therein by super users or controlled users; and

(b) changes to the datasets contained therein made by super users or controlled users.

Article 13

Access policy for super users and controlled users

1. The Agency shall, in collaboration with the competent authorities and the Commission and in consultation with marketing authorisation holders, develop and maintain an access policy.

2. The access policy shall establish the access levels permitted for super users in a manner that ensures the proper functioning of the Union product database while also safeguarding commercially confidential information and personal data and ensuring that the specifications of the Union product database laid down in this Regulation are respected.

3. The Agency shall be responsible for the management of access rights of super users for the Union product database as laid down in the access policy.

4. Super users shall be responsible for managing the access rights of controlled users in respect of the datasets for veterinary medicinal products under their responsibility. That shall not relieve super users of their legal responsibility.

Article 14

Access for the general public

1. The general public shall be able to view and perform advanced searches by one or more criteria based on the data fields contained in the Union product database on the publicly available information contained therein with the possibility to export the search results.

2. No registration, authorisation or authentication shall be required for access to publicly available information by the general public. That access shall also be free of charge.

SECTION 4

DETAILED SPECIFICATIONS OF THE INFORMATION AND DATA TO BE INCLUDED, UPDATED AND SHARED IN THE UNION PRODUCT DATABASE

Article 15

Detailed specifications of the information to be included, updated and shared

1. The Union product database shall contain the relevant information based on the data and documents submitted in accordance with Articles 8, 58, 61, 62, 87 and 102 and Annex III of Regulation (EU) 2019/6.

2. The Union product database shall identify each veterinary medicinal product permanently and uniquely. That identification shall be detailed to pack size level.

Marketing authorisation holders shall refer to this unique identification in any subsequent submission relating to that veterinary medicinal product.

3. The Union product database shall identify veterinary medicinal products authorised in several Member States under the same marketing authorisation procedure.

4. Appropriate references shall be maintained to link together related data and documents held in the Union product database.

5. The Agency shall ensure that references to veterinary medicinal products and documents remain stable over the lifetime of products.

Article 16

Information referred to in Article 55(2) of Regulation (EU) 2019/6

The Agency shall ensure that the Union product database contains the data fields specified in Annex II with their descriptions and the format of data therein to record the information referred to in Article 55(2) of Regulation (EU) 2019/6.

Article 17

Data to be included in the Union product database in addition to the information referred to in Article 55(2) of Regulation (EU) 2019/6

The Agency shall ensure that, in addition to the information referred to in Article 55(2) of Regulation (EU) 2019/6 recorded by means of the data fields provided for in Article 16, the Union product database also contains at least the data fields specified in Annex III with their descriptions and the format of data therein.

Article 18

Responsibilities for including, updating and sharing information

1. As of 28 January 2022, competent authorities or the Commission, as applicable, shall, within 30 days of a positive outcome of the procedure for marketing authorisation in accordance with Chapter III of Regulation (EU) 2019/6, registration in accordance with Chapter V of Regulation (EU) 2019/6, permission to use in accordance with Article 5(6) of Regulation (EU) 2019/6 or approval for parallel trade in accordance with Article 102 of Regulation (EU) 2019/6, create new or provisional entries, as relevant, in the Union product database for products under their responsibility by providing to it data and documents submitted in electronic form to them by applicants.

The relevant competent authority or the Commission, as applicable, shall update those entries with the assessment report, after deleting any commercially confidential information contained therein, as soon as it becomes available.

2. The Agency, in collaboration with the Member States and the Commission, shall ensure that business rules are defined and guidance is provided to facilitate data consistency between national systems and the Union product database.

3. Competent authorities, the Commission and the Agency shall ensure that the data entered into the Union product database conform to the format and specifications laid down in this Regulation.

4. The updates to the Union product database referred to in Article 67(4) of Regulation (EU) 2019/6 shall be made within 30 days of the completion of the procedure provided for in Article 67(1) of the same Regulation.

5. Marketing authorisation holders shall record any changes in the availability of each veterinary medicinal product in each relevant Member State as soon as they become aware of them.

6. Marketing authorisation holders shall record the dates of any suspension or revocation of the marketing authorisations concerned as soon as those changes occur.

Where the marketing authorisation holder fails to fulfil this obligation within 30 days, the competent authorities or the Commission, as applicable, shall record and update this information.

In case of disagreement, the competent authorities' entries in the Union product database shall take precedence.

7. Competent authorities of the destination Member State shall be responsible for recording the necessary information on parallel-traded veterinary medicinal products under their responsibility.

8. Marketing authorisation holders shall be responsible for ensuring that the data and documents they record in datasets existing in the Union product database for their veterinary medicinal products are correct and up to date.

9. Where holders of a marketing authorisation granted in accordance with Chapter III of Regulation (EU) 2019/6, of a registration for homeopathic veterinary medicinal products granted in accordance with Chapter V of Regulation (EU) 2019/6, of veterinary medicinal products referred to in Article 5(6) of Regulation (EU) 2019/6 or of an approval to parallel trade veterinary medicinal products in accordance with Article 102 of Regulation (EU) 2019/6 identify data or document quality issues in the entries created for their veterinary medicinal products in accordance with paragraph (1), or updated in accordance paragraph (4), they shall immediately notify the relevant competent authorities or the Commission, as applicable, which shall correct the data without delay upon verification that the requests are justified.

10. The Agency shall ensure that the responsibilities laid down in this Article may be performed either by super users or controlled users or by systems external to the Union product database. The access of those systems to the Union product database shall be handled as if they were super users or controlled users.

Article 19

Union Product Database Functionalities Enabling Post-Authorisation Changes to Product Data

1. The Agency shall ensure that the Union product database:

(a) allows competent authorities, the Commission and marketing authorisation holders to make changes to datasets in at least the following cases, which shall also be possible to be introduced in parallel:

   i) variations that do not require assessment;

   ii) variations requiring assessment;

   iii) all other changes provided for in Regulation (EU) 2019/6, in particular annual volume of sales, information on availability, placing on the market, marketing authorisation status;

(b) allows competent authorities and the Commission to make any other changes to update or maintain the quality of the datasets contained in the Union product database;

(c) allows marketing authorisation holders to group changes to veterinary medicinal product datasets, such as to introduce the same change for several veterinary medicinal products or to introduce several changes to one product dataset;

(d) keeps a log of the recorded variations that do not require assessment and their respective outcomes linked to the relevant veterinary medicinal products, as well as a log of the super users or controlled users who recorded those variations, who approved or rejected them and when those actions were performed;

(e) allows marketing authorisation holders to record, in the data and document submission component, the necessary procedural information for variations that do not require assessment as described by the relevant fields included in Annex III to this Regulation, as well as to enter draft changes to the data contained in the Union product database or upload updated versions of the documents stored in the Union product database at the time variations are recorded in the Union product database;

(f) allows draft changes to the data to be confirmed or the most recent document versions to be displayed and the previously approved document versions to be marked and stored as outdated upon the approval of variations that do not require assessment which result in changes to the datasets already existing in the Union product database;

(g) allows recording rejections for variations that do not require assessment, which otherwise would have resulted in changes to the datasets already existing in the Union product database, by recording the draft data changes or the updated document versions uploaded as rejected;

(h) allows updating the relevant data or documents stored in the Union product database in the case of approval of variations requiring assessment which result in changes to the datasets already existing in the Union product database and keeps a log of the super users or controlled users who recorded those variations and when those actions were performed;

(i) sends the necessary automatic notifications in accordance with Functionalities 4.1 and 4.2 provided for in Annex I.

2. The Agency, in collaboration with the competent authorities and the Commission and in consultation with marketing authorisation holders, shall establish the principles and approach for managing the regulatory process in case of parallel variations.

SECTION 5

CONTINGENCY ARRANGEMENTS TO BE APPLIED IN CASE OF UNAVAILABILITY OF ANY OF THE FUNCTIONALITIES OF THE UNION PRODUCT DATABASE

Article 20

Contingency arrangements in case of failure or unavailability of the Union product database

1. The Agency shall ensure that in cases within its control the Union product database is not unavailable for periods longer than 3 working days.

2. In case of unavailability of the Union product database, the Agency shall ensure that a clear message to that effect is displayed to all users.

3. The Agency shall ensure that the data and documents stored in the Union product database are recoverable.

4. The Agency, in collaboration with the competent authorities and the Commission and in consultation with marketing authorisation holders, shall develop detailed contingency arrangements to be applied in cases of prolonged failure or unavailability of the Union product database or any of its components or functionalities for reasons outside the Agency's control.

5. The detailed contingency arrangements shall describe the procedures to be followed to ensure continuity of the regulatory processes supported by the Union product database using appropriate alternative electronic means.

Article 21

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

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

Done at Brussels, 8 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Functionalities of the Union product database

Functionality ID	Functionality	Functionality Description
1.	**New Product Data**	
1.1	Create new veterinary medicinal product entry	The relevant competent authority or the Commission, as applicable, shall be able to create new entries for veterinary medicinal products upon a positive outcome of the procedure for marketing authorisation in accordance with Chapter III of Regulation (EU) 2019/6, registration in accordance with Chapter V of Regulation (EU) 2019/6, permission to use in accordance with Article 5(6) of Regulation (EU) 2019/6 or approval for parallel trade in accordance with Article 102 of Regulation (EU) 2019/6. These entries shall contain the fields laid down in this Regulation. It shall be possible to upload the information from a dataset in the format referred to in Article 10 of this Regulation via the user interface provided for in Article 6 or via the API referred to in Article 9(i) of this Regulation.
1.2	Create provisional veterinary medicinal product entry	The reference Member State shall be able to create, for all Member States concerned, provisional entries with version control for veterinary medicinal products in the case of a positive outcome of the procedures for decentralised marketing authorisation, for mutual recognition of national marketing authorisations or for subsequent recognition in the mutual recognition and decentralised marketing authorisation procedures laid down in Sections 3, 4 and 5 of Chapter III of Regulation (EU) 2019/6, respectively, pending the issuing of a marketing authorisation in certain Member States. This shall support variation procedures prior to the issuing of a marketing authorisation in certain Member States and ensure data quality. These entries shall contain the fields laid down in this Regulation. It shall be possible to upload the information from a dataset in the format referred to in Article 10 of this Regulation via the user interface provided for in Article 6 or via the API referred to in Article 9(i) of this Regulation.
1.3	Submit veterinary medicinal product data and documents for the initial input of data	The competent authorities or the Commission, as applicable, shall be able to submit, in electronic form, data and documents for the initial input to the Union product database in accordance with the requirements laid down in this Regulation. This shall be possible in the form of a bulk upload through a user interface or file transfer.
1.4	Submit information on parallel-traded veterinary medicinal products	In the case of parallel trade as addressed in Article 102 of Regulation (EU) 2019/6, the competent authority of the destination Member State shall be able to submit, in electronic form, information on the parallel-traded veterinary medicinal products in the Union product database in accordance with the requirements laid down in this Regulation.
1.5	Use controlled terms, substance terms and organisation data	The Union product database shall use controlled terms, including substance terms and organisation data.

Functionality ID	Functionality	Functionality Description
1.6	Use consistent product data in the case of a positive outcome of the procedure for decentralised marketing authorisation, for mutual recognition of national marketing authorisations or for subsequent recognition in the mutual recognition and decentralised marketing authorisation procedures	The Union product database shall provide the means to ensure the consistency of data that are common to multiple product entries in the case of a positive outcome in the procedure for decentralised marketing authorisation, for mutual recognition of national marketing authorisations or for subsequent recognition in the mutual recognition and decentralised marketing authorisation procedures laid down in Sections 3, 4 and 5 of Chapter III of Regulation (EU) 2019/6, respectively. This shall support the submission of variations. This shall exclude data and documents provided for the initial input.
1.7	Data validation	The Union product database shall validate new veterinary medicinal product data against a set of values and rules agreed upon by the competent authorities, the Commission and the Agency.
1.8	Provide datasets for updates to competent authority databases	It shall be possible for competent authorities to obtain the updated datasets from the Union product database in a format that enables them to apply the update to their own databases.
1.9	Assign unique product identifier	The Union product database shall assign unique identifiers to veterinary medicinal products to enable automatised data exchange between the Union product database and other Union or competent authorities' databases.
1.10	Provide data to the Union pharmacovigilance database	The Union product database shall allow the Union pharmacovigilance database to obtain the relevant veterinary medicinal product data (including the volumes of sales).
2.	**Post-Authorisation Changes to Veterinary Medicinal Product Data**	
2.1	Record variation that does not require assessment	Where a variation is included in the list established in accordance with Implementing Regulation (EU) 2021/17 the marketing authorisation holder shall be able to record it in the Union product database.
2.2	Provide product data for creating variation procedures	Marketing authorisation holders shall be able to select from their authorised veterinary medicinal products and export the relevant master data that are to be changed, if applicable.
2.3	Approve or reject variations that do not require assessment	Approvals or rejections of variations that do not require assessment shall be possible at least via the user interface provided for in Article 6.
2.4	Report on changes to dataset	Competent authorities shall be able to obtain a report on the history of changes to the datasets already existing in the Union product database. Marketing authorisation holders shall be able to obtain a report on the history of changes to the datasets already existing in the Union product database for their veterinary medicinal products.
2.5	Update the Union product database following variations requiring assessment or transfers of marketing authorisations	The relevant competent authorities shall be able to update the Union product database following variations requiring assessment where this affects the datasets already existing in that database for veterinary medicinal products under their responsibility. This shall include the transfer of marketing authorisations.

Functionality ID	Functionality	Functionality Description
2.6	Collect volumes of sales	Holders of a marketing authorisation granted in accordance with Chapter III of Regulation (EU) 2019/6, of a registration for homeopathic veterinary medicinal products granted in accordance with Chapter V of Regulation (EU) 2019/6, of veterinary medicinal products referred to in Article 5(6) of Regulation (EU) 2019/6 shall be able to record in the Union product database the annual volume of sales at the appropriate level for each of their veterinary medicinal products.
2.7	Provide volumes of sales for analysis	The Union product database shall enable obtaining information on the data on the volume of sales of veterinary medicinal products for analysis.
2.8	Record availability information	Marketing authorisation holders shall be able to record and update information on the availability of each of their authorised veterinary medicinal products at the appropriate level in each relevant Member State. Competent authorities shall also be able to record and update this information for veterinary medicinal products under their responsibility in their respective Member States.
2.9	Record marketing authorisation status	Competent authorities shall be able to record and update the marketing authorisation status of veterinary medicinal products under their responsibility. Marketing authorisation holders shall be able to update the marketing authorisation status of their veterinary medicinal products in case of suspension or revocation of the marketing authorisations concerned.
2.10	Process post-authorisation changes in parallel	The Union product database shall support the processing of post-authorisation changes in parallel.
2.11	Link variations to multiple marketing authorisations	The Union product database shall allow for the linking of a single variation to an unlimited number of different marketing authorisations.
2.12	Enter draft data changes	Marketing authorisation holders shall be able to enter draft changes to the datasets already existing in the Union product database for their veterinary medicinal products when recording variations that do not require assessment.
3.	**Access Management**	
3.1	Public access	The general public shall be able to search and view publicly available data.
3.2	Marketing authorisation holder access	Marketing authorisation holders shall be able to access (read) all information about their veterinary medicinal products following secure authentication and authorisation. They shall also be able to access (write) selected information about their veterinary medicinal product in order to fulfil any post-marketing obligations provided for in Regulation (EU) 2019/6 following secure authentication and authorisation.
3.3	Competent authorities read access	Super users or controlled users from the competent authorities shall be able to access (read) all information contained in the Union product database following secure authentication and authorisation.

Functionality ID	Functionality	Functionality Description
3.4	Competent authorities write access	Super users or controlled users from the competent authorities shall be able to access (write) the data for the veterinary medicinal products under their responsibility following secure authentication and authorisation.
3.5	Controlled users access right management	Super users shall be able to manage the access of controlled users to manage veterinary medicinal product data on their behalf.
4.	**Provide Data to Super Users and Controlled Users**	
4.1	Notification of changes to competent authorities	Competent authorities shall be automatically notified of: — any changes made by marketing authorisation holders to the datasets existing in the Union product database for veterinary medicinal products under their responsibility; — variations that do not require assessment which have been recorded in the Union product database in respect of veterinary medicinal products under their responsibility; — the outcomes of variations that do not require assessment recorded by reference Member States in respect of veterinary medicinal products under their responsibility; — any updates made by other competent authorities or the Agency as part of the measures to close procedures for variations requiring assessment to the datasets existing in the Union product database for veterinary medicinal products under their responsibility; and — all changes concerning centrally authorised products.
4.2	Notification of changes to marketing authorisation holders	Marketing authorisation holders shall be automatically notified of any change made by the relevant competent authorities, the Agency or the Commission, as applicable, to the datasets existing in the Union product database for their veterinary medicinal products. Marketing authorisation holders shall also be automatically notified of the outcomes of variations that do not require assessment recorded by the relevant competent authority or the Commission, as applicable, in respect of their veterinary medicinal products.
4.3	Search restricted data	Super users and controlled users shall be able to search the restricted data in the Union product database according to their access rights and export the search results.

ANNEX II

Data fields to record the information referred to in Article 55(2) of Regulation (EU) 2019/6

Data Field ID	Data Field	Description	Format
1.	**For all veterinary medicinal products**		
1.1	Product Domain	A statement that the entry is a veterinary medicinal product to distinguish between veterinary medicinal products and medicinal products for human use.	Controlled terms
1.2	Product Type	Distinction between authorised veterinary medicinal products, registered homeopathic veterinary medicinal products, veterinary medicinal products allowed to be used in a Member State in accordance with Article 5(6) of Regulation (EU) 2019/6 or exempted from the provisions in Articles 5 to 8 of Directive 2001/82/EC in accordance with Article 4 (2) of the same Directive, as applicable, and parallel-traded veterinary medicinal products.	Controlled terms
1.3	Product Name	The name of the veterinary medicinal product as approved in the Union or in a Member State.	Free text
1.4	Active Substance(s)	Name of the active substance or substances.	Controlled substance terms
1.5	Strength/Composition	The content of active substances in a veterinary medicinal product, expressed quantitatively per dosage unit, per unit of volume or per unit of weight according to the pharmaceutical form.	Structured data
		Biological activity, potency or titre in case of immunological veterinary medicinal products.	Structured data or, where not possible for justifiable reasons, free text.
1.6	Manufacturing Sites	List of the sites where the veterinary medicinal product is manufactured.	Controlled organisation data
1.7	Documents	Documents to be attached to veterinary medicinal product record, including selection of type (summary of product characteristics, package leaflet, labelling and assessment report).	Controlled terms for document types plus documents uploaded in the format laid down in this Regulation
2.	**Only for authorised veterinary medicinal products**		
2.1	Dates of Placing on the Market	The dates of the placing of the veterinary medicinal product on the market in each Member State.	Date
2.2	Annual Volume of Sales	Annual volume of sales of veterinary medicinal products.	Structured data

Data Field ID	Data Field	Description	Format
2.3	Date of Availability Status	Date of the marketing status.	Date
2.4	Availability Status	Marketing status: product available on the market per Member State.	Controlled terms

ANNEX III

Data fields to be included in the Union product database in addition to the information referred to in Article 55(2) of Regulation (EU) 2019/6

Data Field ID	Data Field	Description	Format
3.	**For all veterinary medicinal products**		
3.1	Permanent Identifier	Unique identifier of the veterinary medicinal product in the Union product database.	Structured data
3.2	Product Identifier	Unique identifier for the same veterinary medicinal products across Member States to enable grouping of veterinary medicinal products authorised under the decentralised, mutual recognition, or subsequent recognition procedures or which underwent harmonisation of their summaries of product characteristics.	Structured data
3.3	Product Owner	Holder of the marketing authorisation for a veterinary medicinal product, of the registration for a homeopathic veterinary medicinal product, of a veterinary medicinal product referred to in Article 5 (6) of Regulation (EU) 2019/6 or exempted from the provisions in Articles 5 to 8 of Directive 2001/82/EC in accordance with Article 4(2) of the same Directive, as applicable.	Controlled organisation data
3.4	Authorisation Status	Marketing authorisation status of the veterinary medicinal product.	Controlled terms
3.5	Date of Authorisation Status Change	Date when the status of the marketing authorisation changed.	Date
3.6	Route of Administration	Routes of administration.	Controlled terms
3.7	Pharmaceutical Form	Pharmaceutical dose form.	Controlled terms
3.8	Target Species	Target species.	Controlled terms
3.9	ATCvet Code	Anatomical Therapeutic Chemical Veterinary Code.	Controlled terms
3.10	Withdrawal Period	Withdrawal period per species, per route of administration and per food commodity. Only for veterinary medicinal products intended to be used in food-producing animals.	Structured data or, where not possible for justifiable reasons, free text.
3.11	PSMF [1] Number	The reference number of the pharmacovigilance system master file. It shall be stored in the Union product database and communicated to the Union pharmacovigilance database by means of the interconnection as foreseen in Article 74(2) of Regulation (EU) 2019/6.	Free text

Data Field ID	Data Field	Description	Format
3.12	PSMF Location	Where the pharmacovigilance system master file is located. It shall be stored in the Union product database and communicated to the Union pharmacovigilance database by means of the interconnection as foreseen in Article 74(2) of Regulation (EU) 2019/6.	Controlled organisation data
3.13	QPPV ([2]) Name	Name of the qualified person responsible for pharmacovigilance. It shall be stored in the Union product database and communicated to the Union pharmacovigilance database by means of the interconnection provided for in Article 74(2) of Regulation (EU) 2019/6.	Free text
3.14	QPPV Location	Where the qualified person responsible for pharmacovigilance is located. It shall be stored in the Union product database and communicated to the Union pharmacovigilance database by means of the interconnection as foreseen in Article 74(2) of Regulation (EU) 2019/6.	Controlled organisation data
3.15	Package Description	Pack sizes.	Free text for description and structured data for pack sizes
3.16	Legal Status for Supply	Classification of veterinary medicinal products: subject to prescription or not.	Controlled terms
4.	**Procedural information for initial authorisation**		
4.1	Authorisation Procedure Type	Type of the procedure for marketing authorisation.	Controlled terms
4.2	Authorisation Procedure Number	Number of the initial procedure for marketing authorisation.	Structured data or, where not possible for justifiable reasons, free text.
4.3	Marketing Authorisation Date	Date on which the first marketing authorisation was granted.	Date
4.4	Authorisation Country	Country in which the marketing authorisation was granted, including, as applicable, European Union.	Controlled terms
4.5	Reference Member State	Name of the reference Member State. Only in the case of decentralised marketing authorisation, mutual recognition of national marketing authorisations or subsequent recognition in the mutual recognition and decentralised marketing authorisation procedures.	Controlled terms

Data Field ID	Data Field	Description	Format
4.6	Member States Concerned	Names of the Member States concerned. Only in the case of decentralised marketing authorisation, mutual recognition of national marketing authorisations or subsequent recognition in the mutual recognition and decentralised marketing authorisation procedures.	Controlled terms
4.7	Legal Basis	Legal basis for the marketing authorisation, including for example generic, hybrid or combination veterinary medicinal products, applications based on informed consent or on bibliographic data, as well as marketing authorisations for limited market and in exceptional circumstances.	Controlled terms
4.8	Authorisation Number	— Marketing authorisation number for authorised veterinary medicinal products. — Registration number for registered homeopathic veterinary medicinal products. — Declaration number for veterinary medicinal products allowed to be used in a Member State in accordance with Article 5(6) of Regulation (EU) 2019/6 or exempted from the provisions in Articles 5 to 8 of Directive 2001/82/EC in accordance with Article 4(2) of the same Directive, as applicable. — Approval number for parallel-traded veterinary medicinal products.	Free text
4.9	Reference Product Identifier	Identifier of the authorised reference product, if the Legal Basis field refers to generic, hybrid or combination veterinary medicinal products, as well as to applications based on informed consent. In the case of parallel-traded veterinary medicinal products, identifier of the veterinary medicinal product sharing a common origin in the destination Member State.	Identifier
4.10	Source Product Identifier	In the case of parallel-traded veterinary medicinal products, identifier of the veterinary medicinal product sharing a common origin in the source Member State.	Identifier
5.	**Procedural information for post-authorisation changes *(multiples, for at least every variation that does not require assessment)***		
5.1	Submission Identifier	Identifier generated by the submission system.	Structured data
5.2	Authorisation Procedure Number	Number of the procedure for centralised, decentralised, national marketing authorisation, mutual recognition of national marketing authorisations or for subsequent recognition in the mutual recognition and decentralised marketing authorisation procedures.	Structured data, or free text where that is not possible

Data Field ID	Data Field	Description	Format
5.3	Responsible Authority	Member State and competent authority.	Controlled terms
5.4	Variation Classification Code	Variation classification code.	Controlled terms
5.5	Submission Comment	Comment from Product Owner as part of the submission.	Free text
5.6	Date of Implementation	Date when the variation that does not require assessment was implemented.	Date
5.7	Date of Submission	Date of submission generated by the submission system.	Date
5.8	Decision	Approval or rejection.	Controlled terms
5.9	Date of Decision	Date when the decision was made.	Date
5.10	Author of Decision	The competent authority or the Commission making the decision.	Controlled terms
6.	**Only for parallel-traded veterinary medicinal products**		
6.1	Source Wholesale Distributor	Wholesale distributor who is providing the parallel-traded veterinary medicinal product in the source Member State.	Controlled organisation data
6.2	Destination Wholesale Distributor	Wholesale distributor who is parallel trading the veterinary medicinal product in the destination Member State.	Controlled organisation data

([1]) PSMF = Pharmacovigilance System Master File
([2]) QPPV = Qualified Person Responsible for Pharmacovigilance

COMMISSION IMPLEMENTING REGULATION (EU) 2021/17

of 8 January 2021

establishing a list of variations not requiring assessment in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ([1]), and in particular Article 60(1) thereof,

Whereas:

(1) The Commission is required under Regulation (EU) 2019/6 to establish a list of changes to the terms of the marketing authorisation, so called variations, that do not require assessment in order to be implemented. When doing so, the Commission is to take account of the criteria listed in Article 60(2) thereof.

(2) The European Medicines Agency, established by Regulation (EC) No 726/2004, provided advice on a list of variations not requiring assessment to the Commission on 30 August 2019, based on the current framework and classifying most minor variations as having no impact on the quality, safety or efficacy of the veterinary medicinal product. The Commission took into account the advice, the criteria listed in Article 60(2), as well as all necessary conditions and most current documentation requirements to ensure that the variations not requiring assessment do not present a risk to public health, animal health or the environment.

(3) In order for certain variations to be classified as not requiring assessment, different requirements need to be fulfilled. It is therefore necessary to list these requirements, including conditions and documentation to be provided by the marketing authorisation holder, to keep the product dossier updated. Fulfilment of the requirements will form a basis for rejection or approval of the variation.

(4) As regards variations recorded in the Union product database by the marketing authorisation holder, the competent authority of the Member State or the Commission, as applicable, should record the information whether this is tacitly approved or rejected within the applicable administrative deadline.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Variations listed in the Annex, which satisfy the requirements applicable to them as set out therein, shall not require assessment.

([1]) OJ L 4, 7.1.2019, p. 43.

Article 2

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

It shall apply from 28 January 2022.

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

Done at Brussels, 8 January 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Variations not requiring assessment

	Variation	**Requirements** The requirements indicated in the line for the main section are valid for each sub-section of the given section. Any additional requirement specified in the sub-section should be read together with the requirements indicated in the main section.	
Number		Conditions	Documents to be provided
A	**Administrative changes**		
1	Change in the name or address or contact details of:		
a)	— the marketing authorisation holder	The marketing authorisation holder shall remain the same legal entity.	
b)	— a manufacturer or supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance or a quality control testing site (where specified in the dossier) where no European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) is part of the approved dossier.	The manufacturing or quality control site and all manufacturing operations shall remain the same. The manufacturer or supplier shall already be incorporated in the Union IT systems storing and providing organisational data.	
c)	— an active substance master file (ASMF) holder	The manufacturing site and all manufacturing operations shall remain the same. The ASMF holder shall already be incorporated in the Union IT systems storing and providing organisational data.	Updated 'letter of access' to the Active Substance Master File.
d)	— a manufacturer of an excipient (where specified in the dossier)	The manufacturing site and all manufacturing operations shall remain the same. The manufacturer shall already be incorporated in the Union IT systems storing and providing organisational data.	
e)	— a manufacturer or importer of the finished product (including batch release or quality control testing sites)	The manufacturing site and all manufacturing operations shall remain the same. The manufacturer or importer shall already be incorporated in the Union IT systems storing and providing organisational data.	

2	Change in the (invented) name of the veterinary medicinal product	The acceptability review of the new name by the Agency or the national competent authority, as applicable, shall be finalised and is positive.	
3	Change in name of the active substance or of an excipient	The substance shall remain the same. For veterinary medicinal products for food-producing species, the entry in Regulation (EC) No°470/2009 for this substance shall be amended before implementation of this change.	
4	Change in ATCvet Code	The change shall only be introduced following alteration to the index of the ATCvet Code.	
B	**Changes to the quality part of the dossier**		
1	Change in the name or address or contact details of a supplier of a packaging component or of a device of the finished product (where mentioned in the dossier)	The supplier shall already be incorporated in the Union IT systems storing and providing organisational data. The manufacturing site shall remain the same.	
2	Change in the nomenclature ([1]) of the material for immediate packaging of the finished product	The change shall only be introduced following amendment to the name of the container in the standard terms database on the European Directorate for the Quality of Medicines and HealthCare (EDQM) website.	
3	Deletion of:		Amendment of the relevant section(s) of the dossier.
a)	— a manufacturing site for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material for an active substance, reagent or excipient (when mentioned in the dossier)	The deletion shall not be due to critical deficiencies concerning manufacturing. There shall at least remain one site or manufacturer, as previously authorised, performing the same function as the one(s) concerned by the deletion. There shall at least remain one site or manufacturer responsible for batch release within the European Union or the European Economic Area.	
b)	— a manufacturing process for the active substance or the finished product, including an intermediate used in the manufacture of the finished product when an alternative is already approved	The finished product, active substance, intermediates or in-process materials used in the manufacture of the finished product shall still conform to the approved specifications. The deletion shall not be due to critical deficiencies concerning manufacturing.	

c)	— a non-significant in-process test during the manufacture of the active substance (e.g. deletion of an obsolete in-process test)	The change shall not relate to a commitment or to an unexpected event during manufacture. The change shall not concern a critical in-process test and shall not have the potential to affect the identity, quality, purity, potency or physical characteristics of the active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance.	Comparative table of former and new in-process test.
d)	— a non-significant specification parameter (e.g. deletion of an obsolete parameter) of — an active substance; — a starting material; — an intermediate or reagent used in the manufacturing process of the active substance	The change shall not relate to a commitment or to an unexpected event during manufacture. The change shall not concern a critical specification parameter or have the potential to affect the identity, quality, purity, potency or physical characteristics of the active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance.	Comparative table of former and new specifications.
e)	— a test procedure — for the active substance or a starting material, reagent or intermediate of the active substance; — for the immediate packaging of the active substance; — for an excipient or the finished product; — for the immediate packaging of the finished product	An alternative test procedure shall already be authorised by the national competent authority or the Agency and this test procedure has not been added through a variation procedure according to Article 61 of Regulation (EU) 2019/6.	
f)	— one of the authorised bulk or final containers (including packaging of an active substance) or immediate packaging of the finished product that does not lead to the complete deletion of a strength or pharmaceutical form	Where applicable, the remaining product presentations shall be adequate for the dosing instructions and treatment duration as defined in the summary of product characteristics.	
g)	— a non-significant specification parameter (e.g. deletion of an obsolete parameter) in the specification parameters or limits of the immediate packaging of the active substance or the finished product	The change shall not relate to a commitment or to an unexpected event during manufacture of the immediate packaging material and storage of the active substance or the finished product. The change shall not concern a critical parameter or have the potential to affect the identity or quality of the immediate packaging.	Comparative table of former and new specifications.

h)	— an approved change management protocol related to the active substance or the finished product	The change shall not be the result of an unexpected event or an out of specification result during the implementation of the change(s) described in the protocol.	
i)	— a component or components of the flavouring or colouring system	The change shall not be applicable to a biological or immunological medicinal product. The change shall not have the potential to affect the identity, strength, quality, purity, potency, safety or effectiveness of the finished product.	
j)	— a solvent or diluent container from the pack	The pharmaceutical form shall remain unchanged. There shall be appropriate alternative means to obtain the solvent or diluent as required for the safe and effective use.	
k)	— a non-significant in-process test (e.g. deletion of an obsolete test) during the manufacture of the finished product	The change shall not relate to a commitment or to an unexpected event during manufacture. The change shall not concern a critical parameter or have the potential to affect the identity, quality, purity, potency or physical characteristics of the finished product or starting material, intermediate or reagent used in the manufacturing process of the finished product.	Comparative table of former and new in-process tests and limits.
l)	— details on testing frequency by the finished product manufacturer of an excipient or an active substance or of packaging material for the immediate packaging of an active substance or the finished product, when mentioned in the dossier		
m)	— a non-significant specification parameter (e.g. deletion of an obsolete parameter) in the specification parameters or limits of an excipient	The change shall not relate to a commitment or to an unexpected event during manufacture. The change shall not concern a critical parameter or have the potential to affect the identity, quality, purity, potency or physical characteristics of the excipient.	Comparative table of former and new specification parameters or limits.
n)	— a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) in the specification parameters or limits of the finished product	The change shall not relate to a commitment or to an unexpected event during manufacture. The change shall not concern a critical parameter or have the potential to affect the identity, strength, quality, purity, potency or physical characteristics of the finished product.	Comparative table of former and new specification parameters or limits.

o)	— a measuring or administration device	The change shall not affect the delivery, use or safety of the finished product.	
p)	— a non-significant specification parameter (e.g. deletion of an obsolete parameter) of a measuring or administration device	The change shall not relate to a commitment or to an unexpected event during manufacture. The change shall not concern a critical parameter or have the potential to affect the identity or quality of the measuring or administration device.	Comparative table of former and new specifications.
q)	— a test procedure of a measuring or administration device	An alternative test procedure shall already be authorised by the national competent authority or the Agency.	
r)	— pack size(s) of the finished product	The remaining pack-sizes shall be consistent with the posology and treatment duration as approved in the summary of product characteristics.	
s)	— a supplier of packaging components or devices (when mentioned in the dossier)	The change shall not include the deletion of a packaging component(s) or a device(s).	
t)	— a Ph. Eur. CEP — for an active substance; — for a starting material, reagent or intermediate used in the manufacturing process of the active substance; — for an excipient	At least one manufacturer for the same substance shall remain in the dossier.	
u)	— a Ph. Eur. Transmissible Spongiform Encephalopathy (TSE) CEP — for an active substance; — for a starting material, reagent or intermediate of an active substance; — for an excipient	At least one manufacturer for the same substance shall remain in the dossier.	
v)	— a pharmaceutical form or strength ([2])	Remaining form(s) or strength(s) shall be suitable to allow accurate dosing of the product and treatment duration without the use of multiple presentations (e.g. several pipettes or tablets) or the use of unapproved divided doses (e.g. half tablets that are not already authorised).	
4	Changes to the production process or the storage of active substance where no Ph. Eur. CEP is part of the approved dossier of an active substance (including starting material, reagent or intermediate)	For starting materials and reagents the specifications (including in-process controls, methods of analysis of all materials), shall be identical to those already approved. For intermediates and active substance(s) the specifications (including in process controls, methods of analysis of all materials), method of preparation (including batch size) and detailed route of synthesis shall be identical to those already approved.	

a)	— change in the manufacturer of the active substance (including relevant quality control testing sites)	The change shall not be applicable to a sterile active substance or a biological or immunological substance. The change shall not be applicable to a herbal substance or a herbal preparation in a herbal medicinal product. The new manufacturer shall be part of the same pharmaceutical group as the currently approved manufacturer and already be incorporated in the Union IT-systems storing and providing organisational data. The change shall not have the potential to affect the identity, quality, purity, potency or physical characteristics of the active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance.	The Amendment of the relevant section (s) of the dossier shall be provided, as appropriate, for: — TSE data, — batch data, — qualified person (QP) declaration and — confirmation of GMP compliance.
b)	— changes to quality control testing arrangements for the active substance: replacement or addition of a site where batch control or testing of the active substance takes place	The change shall not be applicable to a sterile active substance or a biological or immunological substance. The new manufacturer or site shall already be incorporated in the Union IT-system storing and providing organisational data. Method transfer from the former to the new site shall have been successfully completed.	
c)	— introduction of a new site of micronisation for the manufacturer of the active substance (including relevant quality control testing sites)	The change shall not be applicable to a sterile active substance or a biological or immunological substance. The new manufacturer or site shall already be incorporated in the Union IT-systems storing and providing organisational data. The change shall not provoke an adverse change in physico-chemical properties. The particle size specification for the active substance and the corresponding analytical method shall remain the same.	Amendment of the relevant section(s) of the dossier for QP declaration and comparative batch data from the former and new site, as appropriate.
d)	— new storage site of Master Cell Bank or Working Cell Banks for the manufacturer of a starting material, reagent or intermediate used in the manufacturing process of the active substance or the active substance itself	No change shall be made to the storage conditions, the shelf-life and the specifications. The new manufacturer or site shall already be incorporated in the Union IT-systems storing and providing organisational data.	

5	Reduction of re-test period or storage period where no Ph. Eur. CEP covering the retest period is part of the approved dossier	The change shall not be the result of unexpected events arising during manufacture or because of stability concerns.	Amendment of the relevant section(s) of the dossier including specifications and stability confirmation, as appropriate.
6	Change to more restrictive storage conditions:	The change shall not be the result of unexpected events arising during manufacture or because of stability concerns.	Amendment of the relevant section(s) of the dossier including specifications and stability confirmation, as appropriate.
a)	— of the reference standard (when mentioned in the dossier)		
b)	— of the active substance		
7	Change to an approved stability protocol of an active substance (including starting material, reagent or intermediate)	The change shall not be the result of unexpected events arising during manufacture or because of stability concerns. The change shall not have the potential to affect the identity, strength, quality, purity, potency or physical characteristics of the active substance.	Amendment of the relevant section(s) of the dossier including results of appropriate real time stability studies.
8	Implementation of changes foreseen in an approved change management protocol (CMP) for the active substance	The change shall be in accordance with the approved CMP and the results of studies performed indicate that the predefined acceptance criteria specified in the protocol are met. The implementation of the change shall require no further supportive data to the CMP.	Amendment of the relevant section(s) of the dossier.
9	Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance	The change shall not be applicable to a sterile active substance or a biological or immunological substance. The change shall not adversely affect the reproducibility of the process. The change shall not be the result of unexpected events arising during manufacture or because of stability concerns. Changes to the manufacturing methods shall only be those necessitated by scale-up or downscaling, e.g. use of different-sized equipment. The batches tested shall have the proposed batch size.	Amendment of the relevant section(s) of the dossier including batch data, as appropriate.
a)	— up to 10-fold increase compared to the originally approved batch size	The active substance and all intermediates, reagents, catalysts or solvents shall still conform to the approved specifications.	

b)	— downscaling down to 10-fold		
c)	— more than 10-fold increase compared to the originally approved batch size	The intermediates, reagents, catalysts or solvents used in the process shall remain the same. The active substance and all intermediates, reagents, catalysts or solvents shall still conform to the approved specifications. The change shall not provoke an adverse change in qualitative and quantitative impurity profile, potency or in physico-chemical properties of the active substance. The change shall not refer to the restricted part of an ASMF.	
10	Change to in-process tests or limits applied during the manufacture of the active substance	The change shall not be a consequence of any commitment from previous assessments to review specification limits. The change shall not result from unexpected events arising during manufacture e.g. new unqualified impurity; change in total impurity limits.	Amendment of the relevant section(s) of the dossier for the new test method, validation and batch data, as appropriate. Comparative table of former and new in-process tests and limits.
a)	— tightening of in-process limits	The change shall be within the range of currently approved limits. The test procedure shall remain the same, or changes in the test procedure shall be minor.	
b)	— addition of a new in-process test and limits	Any new test method shall not concern a novel non-standard technique or a standard technique used in a novel way. The new test method shall not be a biological, immunological or immunochemical method, or a method using a biological reagent for a biological active substance, except if this method is a standard pharmacopoeial microbiological method.	
11	Change in the specification parameters or limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance or of the immediate packaging of the active substance	The change shall not result from unexpected events arising during manufacture (e.g. new unqualified impurity or change in total impurity limits). The change shall not be a consequence of any commitment from previous assessments to review specification limits (e.g. made during the procedure for the marketing authorisation application or a variation procedure according to Article 62 of Regulation (EU) 2019/6) unless it has been previously assessed and agreed as part of a follow-up measure in a previous procedure under Regulation (EU) 2019/6.	Amendment of the relevant section(s) of the dossier. Comparative table of former and new specification parameters and limits.

a)	— tightening of specification limits for veterinary medicinal products subject to Official Control Authority Batch Release (OCABR)	The test procedure shall remain the same, or changes in the test procedure shall be minor. The change shall be within the range of currently approved limits.	
b)	— tightening of specification limits of an active substance, starting material, intermediate or reagent used in the manufacturing process of the active substance	The test procedure shall remain the same, or changes in the test procedure shall be minor. The change shall be within the range of currently approved limits.	
c)	— tightening of specification limits of the immediate packaging of the active substance	The test procedure shall remain the same, or changes in the test procedure shall be minor.	
d)	— addition of a new specification parameter to the specification with its corresponding test method	The new test method shall not concern a novel non-standard technique or a standard technique used in a novel way. The new test method shall not be a biological, immunological or immunochemical method, or a method using a biological reagent for a biological active substance, except if this method is a standard pharmacopoeial microbiological method. The change shall not concern a genotoxic impurity.	Amendment of the relevant section(s) of the dossier for the new method and validation, and batch data, as appropriate.
12	Minor changes:		
a)	— to an approved test procedure — for active substance; — for the finished product; — for the immediate packaging of the active substance or the finished product; — of a measuring or administration device	The test method shall not be a biological, immunological or immunochemical method, or a method using a biological reagent for a biological active substance. Appropriate validation studies shall have been performed in accordance with the relevant guidelines and show that the updated test procedure is at least equivalent to the former test procedure. There shall be no changes of the total impurity limits; no new unqualified impurities shall be detected. The method of analysis shall remain the same (e.g. a change in column length or temperature, but not a different type of column or method).	Amendment of the relevant section(s) of the dossier and comparative validation data, as appropriate.

b)	— to an approved test procedure — for a starting material, reagent or intermediate used in the manufacturing process of the active substance; — for an excipient	The test method shall not be a biological, immunological or immunochemical method, or a method using a biological reagent for a biological active substance. Appropriate validation studies shall have been performed in accordance with the relevant guidelines and show that the updated test procedure is at least equivalent to the former test procedure. There shall be no changes of the total impurity limits; no new unqualified impurities shall be detected. The method of analysis shall remain the same (e.g. a change in column length or temperature, but not a different type of column or method).	Amendment of the relevant section(s) of the dossier and comparative data, as appropriate.
c)	— to an approved test procedure for an in-process test — for active substance; — for the finished product	The test method shall not be a biological, immunological or immunochemical method, or a method using a biological reagent for a biological active substance. Appropriate validation studies shall have been performed in accordance with the relevant guidelines and show that the updated test procedure is at least equivalent to the former test procedure. There shall be no changes of the total impurity limits; no new unqualified impurities shall be detected. The method of analysis shall remain the same (e.g. a change in column length or temperature, but not a different type of column or method).	Amendment of the relevant section(s) of the dossier.
d)	— in the manufacturing process of an active substance	The change shall not be applicable to a biological or immunological active substance. The change shall not be a change in the geographical source, manufacturing route or production for a herbal medicinal substance. The change shall relate only to an immediate release solid oral dosage form or oral solution and shall not provoke an adverse change in qualitative and quantitative impurity profile or in physico-chemical properties.	Amendment of the relevant section(s) of the dossier.

		The active substance and all intermediates, reagents, catalysts or solvents shall still conform to the approved specifications. The change shall not refer to the restricted part of an ASMF. The manufacturing steps shall remain the same.	
e)	— in synthesis or recovery of a non-pharmacopoeial excipient (when described in the dossier) or a novel excipient	The excipients and all intermediates, reagents, catalysts, solvents or in-process controls shall still conform to the approved specifications (e.g. qualitative and quantitative impurity profile). Adjuvants and preservatives shall be excluded from the scope of this entry. Synthetic routes and specifications shall be identical, and there shall be no change in physico-chemical properties.	Amendment of the relevant section(s) of the dossier for batch data, comparative data, and specification, as appropriate.
f)	— to an in-process limit range for the finished product	The change shall not be the result of unexpected events arising during manufacture or because of stability concerns. The change shall concern an in-process test, which is also part of the finished product specification at release, and the new in-process limit range shall be within the approved release limit.	Amendment of the relevant section(s) of the dossier. Comparative table of former and new in-process limits.
g)	— to an approved change management protocol of the active substance that does not change the strategy defined in the protocol	The intermediates, reagents, catalysts or solvents used in the process shall remain the same. The active substance and all intermediates, reagents, catalysts or solvents shall still conform to the approved specifications. There shall be no adverse change in qualitative and quantitative impurity profile or in physico-chemical properties. The change shall not refer to the restricted part of an ASMF. The changes shall be within the range of currently approved limits. In case of biological products, this change shall be only possible if comparability is not required. Changes in the geographical source, manufacturing route or production of a herbal substance or herbal preparation of a herbal medicinal product shall be excluded.	Amendment of the relevant section(s) of the dossier.

13	Changes to a test procedure (including replacement or addition) for a reagent used in the manufacturing process of the active substance or immediate packaging of the active substance:	The new test method shall not concern a novel non-standard technique or a standard technique used in a novel way.	Amendment of the relevant section(s) of the dossier for comparative validation data, as appropriate.
a)	— for a reagent, which does not have a significant effect on the overall quality of the active substance	The active substance shall not be a biological or immunological substance. There shall be no changes to the total impurity limits; no new unqualified impurities shall be detected. The method of analysis shall remain the same (e.g. a change in column length or temperature, but not a different type of column or method). Appropriate validation studies, performed in accordance with the relevant guidelines, shall show that the updated test procedure is at least equivalent to the former test procedure.	
b)	— for the immediate packaging of the active substance	The active substance shall not be a biological or immunological substance. When the change concerns replacement of a method, the change shall not be a consequence of any commitment from previous assessments to review specification limits (e.g. made during the procedure for the marketing authorisation application or a variation procedure according to Article 62 of Regulation (EU) 2019/6) unless it has been previously assessed and agreed as part of a follow-up measure in a previous procedure under Regulation (EU) 2019/6.	A document listing the comparative validation results or, if justified, the comparative analysis results, showing that the former test and the new one are equivalent.
14	Change in qualitative or quantitative composition of the immediate packaging for the active substance	Sterile or liquid formulations or biological or immunological active substances shall be excluded. The new packaging material shall be at least equivalent to the approved material in respect of its relevant properties and no interaction shall occur between the content and the packaging material. Stability studies shall have been started according to the current approved stability protocol and under International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) conditions; relevant stability parameters shall have been assessed in at least two pilot scale or industrial scale batches, and at least three months satisfactory stability data shall be at the disposal of the applicant. The stability profile shall be similar to the currently	Amendment of the relevant section(s) of the dossier including stability confirmation. If the new packaging is more resistant than the former packaging, studies which have only started shall be finalised and the data shall be provided immediately afterwards to the competent authorities.

		registered situation. However, if the new packaging is more resistant than the existing packaging, the three months' stability data do not yet have to be available.	
15	Addition of or change to a calendar package for a pack size already registered in the dossier	The primary packaging material shall remain the same.	
16	Change or addition of imprints, bossing or other markings including replacement, or addition of inks used for product marking of the finished product	The change shall not affect the delivery, use or safety of the finished product. The finished product release and shelf life specifications shall not have been changed except for appearance. The ink shall comply with the relevant pharmaceutical legislation. The change shall not relate to a scored tablet that is intended to be divided into equal doses.	Amendment of the relevant section(s) of the dossier.
17	Change in the shape or dimensions of the pharmaceutical form for immediate release tablets, capsules, suppositories and pessaries	The dissolution profile of the product shall remain unchanged. For herbal medicinal products, where dissolution testing may not be feasible the new disintegration time of the product shall be comparable to the former one. The release and end of shelf-life specifications of the product shall not have been changed. The qualitative or quantitative composition and mean mass shall remain unchanged. The change shall not relate to a scored tablet that is intended to be divided into equal doses.	Amendment of the relevant section(s) of the dossier.
18	Change(s) in the composition (excipients) of a non-sterile finished product	The change shall not be applicable to a biological or immunological medicinal product. The change shall not have the potential to affect the identity, strength, quality, purity, potency, physical characteristics, safety or effectiveness of the finished product. Stability studies shall have been started according to the current approved stability protocol and under International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) conditions; relevant stability parameters	Amendment of the relevant section(s) of the dossier including stability confirmation.

		shall have been assessed in at least two pilot scale or industrial scale batches, and at least three months satisfactory stability data shall be at the disposal of the applicant. The stability profile shall be similar to the currently registered situation.	
a)	— increase or reduction of a component or components of the flavouring or colouring system	Quantitative change(s) shall not exceed +/- 10 % of the existing concentration of the component. There shall be no change in functional characteristics of the pharmaceutical form (e.g. disintegration time, dissolution profile). The finished product specification shall only have been updated in respect of appearance, odour or taste and, if relevant, deletion of an identification test. For veterinary medicinal products for oral use, the change shall not negatively affect the uptake by target animal species.	
b)	— any minor adjustment of the quantitative composition of the finished product with respect to excipients	Quantitative change(s) shall not exceed +/- 10 % of the existing concentration of the component. The change shall not affect the functional characteristics of the pharmaceutical form (e.g. disintegration time, dissolution profile). For solid oral dosage forms, the dissolution profile of the changed product shall be determined on a minimum of two pilot scale batches and shall be comparable to the former one. No significant differences regarding comparability shall occur. For herbal medicinal products, where dissolution testing may not be feasible, the disintegration time of the changed product shall be comparable to the former one. The change shall not be the result of stability issues and shall not result in potential safety concerns, e.g. differentiation between strengths.	Amendment of the relevant section(s) of the dossier. Either a Ph. Eur. Certificate of Suitability for any new component of animal susceptible to TSE risk or where applicable, documentary evidence that the specific source of the TSE risk material has been previously assessed by the competent authority and shown to comply with the scope of the current Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathies via Human and Veterinary Medicinal Products. The following information shall be included for each such material: name of manufacturer, species and tissues from which the material is a derivative, country of origin of the source animals and its use.

c)	— addition or replacement of a component or components of the flavouring or colouring system	The change shall not affect the functional characteristics of the pharmaceutical form (e.g. disintegration time, dissolution profile). For veterinary medicinal products for food-producing species, the entry in Regulation (EC) No° 470/2009 for this substance shall be amended before implementation of this change. For solid oral dosage forms, the dissolution profile of the changed product shall be determined on a minimum of two pilot scale batches and shall be comparable to the former one. No significant differences regarding comparability shall occur. For herbal medicinal products, where dissolution testing may not be feasible, the disintegration time of the changed product shall be comparable to the former one. The change shall not be the result of stability issues and shall not result in potential safety concerns (e.g. differentiation between strengths).	Amendment of the relevant section(s) of the dossier. Either a Ph. Eur. Certificate of Suitability for any new component of animal susceptible to TSE risk or where applicable, documentary evidence that the specific source of the TSE risk material has been previously assessed by the competent authority and shown to comply with the scope of the current Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathies via Human and Veterinary Medicinal Products. The following information shall be included for each such material: name of manufacturer, species and tissues from which the material is a derivative, country of origin of the source animals and its use.
19	Change in coating weight of oral dosage forms or change in weight of capsule shells for a solid oral pharmaceutical form	The change shall not be the result of stability issues and shall not result in potential safety concerns (e.g. differentiation between strengths). For veterinary medicinal products for oral use, the coating shall not be a critical factor for the release mechanism and the change shall not affect the uptake by target animal species. The finished product specification shall only be updated in respect of weight and dimensions, if applicable. The dissolution profile of the changed product shall be determined on a minimum of two pilot scale batches and shall be comparable to the former one. For herbal medicinal products, where dissolution testing may not be feasible, the disintegration time of the changed product shall be comparable to the former one.	Amendment of the relevant section(s) of the dossier including stability confirmation.

		Relevant stability studies shall have been started under VICH conditions and relevant stability parameters shall have been assessed in at least two pilot scale or industrial scale batches and at least three months satisfactory stability data shall be at the disposal of the applicant at time of implementation.	
20	Replacement or addition of a primary packaging site of a non-sterile finished product	The change shall not be applicable to a biological or immunological medicinal product. The primary packaging site shall already be introduced in the Union IT systems storing and providing organisational data. The site shall be appropriately authorised to manufacture the pharmaceutical form or product concerned and satisfactorily inspected. The validation scheme shall be available or validation of the manufacture at the new site has been successfully carried out according to the current protocol with at least three production scale batches, as appropriate. If the manufacturing site and the primary packaging site are different, conditions of transport and bulk storage shall be specified and validated.	Amendment of the relevant section(s) of the dossier.
21	Replacement or addition of a secondary packaging site of a finished product	The secondary packaging site shall already be introduced in the Union IT systems storing and providing organisational data. The site shall be appropriately authorised to manufacture the pharmaceutical form or product concerned and satisfactorily inspected.	Amendment of the relevant section(s) of the dossier.
22	Change to importer, batch control arrangements and quality testing (replacement or addition of a site) for a finished product	The site shall be already introduced in the Union IT systems storing and providing organisational data. The site shall be appropriately authorised and satisfactorily inspected. The change shall not be applicable to a biological or immunological medicinal product. Method transfer from the former to the new site shall have been successfully completed.	

23	Replacement or addition of a manufacturer of a finished product responsible for importation	The site shall already be introduced in the Union IT systems storing and providing organisational data. The site shall be appropriately authorised and satisfactorily inspected	
24	Replacement or addition of a manufacturer responsible for batch release including batch control or testing of a non-sterile finished product	The manufacturer or the site shall already be introduced in the Union IT systems storing and providing organisational data. The site shall be appropriately authorised and satisfactorily inspected. The change shall not be applicable to a biological or immunological medicinal product. Method transfer from the former to the new site shall have been successfully completed.	
25	Change in the packaging material of bulk product (intermediate product) not in contact with the bulk product formulation (including replacement or addition)	The manufacturing steps shall remain the same. The finished product, intermediates or in-process controls used in the manufacture of the finished product shall still conform to the approved specifications. The secondary packaging shall not play a functional role on the stability of the bulk product, or if it does, it shall not be less protective than the approved one.	Amendment of the relevant section(s) of the dossier.
26	Change in the batch size (including batch size ranges) of the finished product:	The change shall not be applicable to a biological or immunological medicinal product. The change shall not be the result of unexpected events arising during manufacture or because of stability concerns. The change shall not affect reproducibility or consistency of the product. The changes to the manufacturing method or to the in-process controls shall be only those necessitated by the change in batch-size, e.g. use of different sized equipment. A validation scheme shall be available or a validation of the manufacture shall have been successfully carried out according to the current protocol with at least three batches of the new batch size in accordance with the relevant guidelines.	Amendment of the relevant section(s) of the dossier. Where relevant, the batch numbers, corresponding batch size, the manufacturing date of batches ([3]) used in the validation study and the validation data or the validation protocol (scheme) shall be provided.
a)	— up to 10-fold increase compared to the originally approved batch size of an immediate release oral pharmaceutical forms or of a non-sterile liquid based pharmaceutical form	The batch size shall be within the 10-fold range of the batch size foreseen when the marketing authorisation was granted.	

b)	— up to 10-fold increase compared to the originally approved batch size for the pharmaceutical form medicinal gas	The batch size shall be within the 10-fold range of the batch size foreseen when the marketing authorisation was granted.	
c)	— downscaling down to 10-fold compared to the originally approved batch size of an immediate release oral pharmaceutical forms or to non-sterile liquid based pharmaceutical form	The batch size shall be within the 10-fold range of the batch size foreseen when the marketing authorisation was granted.	
d)	— downscaling down to 10-fold (for the pharmaceutical form medicinal gas	The batch size shall be within the 10-fold range of the batch size foreseen when the marketing authorisation was granted.	
e)	— more than 10-fold increase compared to the originally approved batch size for an immediate release, solid oral pharmaceutical form		3 months stability data for at least one pilot batch under VICH condition.
27	Change to in-process tests or limits applied during the manufacture of the finished product:	The change shall not relate to a commitment or to an unexpected event during manufacture. The change shall not have the potential to affect the identity, strength, quality, purity, potency or physical characteristics of the finished product, intermediates or in-process materials.	Comparative table of former and new in-process tests or limits.
a)	— tightening of in-process limits	The change shall be within the range of currently approved limits. The test procedure shall remain the same, or changes in the test procedure shall be minor.	Amendment of the relevant section(s) of the dossier.
b)	— addition of a new in-process test and limits	Any new test method shall not concern a novel non-standard technique or a standard technique used in a novel way. The new test method shall not be a biological, immunological or immunochemical method, or a method using a biological reagent for a biological active substance, except if this method is a standard pharmacopoeial microbiological method.	Amendment of the relevant section(s) of the dossier for method and validation, batch data and relevant comparative data.
28	Change in the specification parameters or limits of an excipient	The change shall not be a consequence of any commitment from previous assessments to review specification limits (e.g. made during the procedure for the marketing authorisation application or a variation procedure according to Article 62 of Regulation (EU) 2019/6).	

		The change shall not be a result of unexpected events arising during manufacture, e.g. new unqualified impurity or change in total impurity limits.	
a)	— tightening of specification limits	The change shall be within the range of currently approved limits. The test procedure shall remain the same, or changes in the test procedure shall be minor.	
b)	— addition of a new specification parameter to the specification with its corresponding test method	Any new test method shall not concern a novel non-standard technique or a standard technique used in a novel way. The new test method shall not be a biological, immunological or immunochemical method, or a method using a biological reagent for a biological active substance, except if this method is a standard pharmacopoeial microbiological method. The change shall not concern a genotoxic impurity.	Amendment of the relevant section(s) of the dossier for method and validation, batch data and relevant comparative data.
29	Change in source of an excipient or reagent with TSE risk from material with TSE risk to vegetable or synthetic origin	The excipient, finished product release and end of shelf life specifications shall remain the same. The change shall not concern an excipient or reagent used in the manufacture of a biological or immunological active substance or in a biological or immunological medicinal product.	Amendment of the relevant section(s) of the dossier. Declaration from the manufacturer or the marketing authorisation holder of the material that it is purely of vegetable or synthetic origin.
30	Change in the specification parameters or limits of the finished product:	The change shall not be a consequence of any commitment from previous assessments to review specification limits (e.g. made during the procedure for the marketing authorisation application or a variation procedure according to Article 62 of Regulation (EU) 2019/6), unless the supporting documentation has already been assessed and approved within the context of another procedure under Regulation (EU) 2019/6. The change shall not result from unexpected events arising during manufacture, e.g. new unqualified impurity or change in total impurity limits.	Amendment of the relevant section(s) of the dossier. Comparative table of former and new specification parameters and limits.
a)	— tightening of specification limits	The change shall be within the range of currently approved limits. The test procedure shall remain the same, or changes in the test procedure shall be minor.	

b)	— tightening of specification limits for finished products subject to Official Control Authority Batch Release	The change shall be within the range of currently approved limits. The test procedure shall remain the same, or changes in the test procedure shall be minor.	
c)	— addition of a new specification parameter to the specification with its corresponding test method	Any new test method shall not concern a novel non-standard technique or a standard technique used in a novel way. The test method shall not be a biological, immunological or immunochemical method, or a method using a biological reagent for a biological active substance except if this method is a standard pharmacopoeial microbiological method. The change shall not concern any impurities (including genotoxic) or dissolution.	Amendment of the relevant section(s) of the dossier for method and validation, batch data and relevant comparative data.
d)	— update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur. for the finished product	The change shall be within the range of currently approved limits. The test procedure shall remain the same, or changes in the test procedure shall be minor. The change shall not concern any impurities (including genotoxic) or dissolution.	
31	Uniformity of dosage units is introduced to replace the currently registered method	The change shall follow changes to the Ph. Eur. Standard 2.9.5. Uniformity of mass or Ph. Eur. Standard 2.9.6 Uniformity of content.	Amendment of the relevant section(s) of the dossier. Comparative table of former and new specification parameters and limits.
32	Change in the specification parameters or limits of the finished product to describe more accurately the appearance of the product	The change shall not be a result of any unexpected events arising during manufacture or testing of the finished product.	Amendment of the relevant section(s) of the dossier. Comparative table of former and new specification parameters and limits.
33	Change in test procedure for the finished product to comply with Ph. Eur.:	The change shall not concern changes of the total impurity limits; no new unqualified impurities shall be detected.	Amendment of the relevant section(s) of the dossier.

		The method of analysis shall remain the same (e.g. a change in column length or temperature, but not a different type of column or method). The test method shall not be a biological, immunological or immunochemical method, or a method using a biological reagent for a biological active substance, except if this method is a standard pharmacopoeial microbiological method.	
a)	— update of the test procedure to comply with the updated general monograph in the Ph. Eur.		
b)	— update of the test procedure to reflect compliance with the Ph. Eur. and remove reference to the outdated internal test method and test method number		
34	Change in qualitative and quantitative composition of the immediate packaging for a solid pharmaceutical form for a finished product	For solid pharmaceutical forms, the change shall only concern the same packaging or container type (e.g. blister to blister). The finished product shall not be sterile. The change shall not affect the delivery, use, safety or stability of the finished product. Relevant stability studies shall have been started under VICH conditions and relevant stability parameters shall have been assessed in at least two pilot scale or industrial scale batches and at least three months satisfactory stability data shall be at the disposal of the applicant at time of implementation. However, if the new packaging is more resistant than the existing packaging, the three months' stability data do not yet have to be available. The new packaging material shall be at least equivalent to the approved material in respect of its relevant properties.	Amendment of the relevant section(s) of the dossier. Comparative table of former and new immediate packaging specifications, permeability data and interaction data, as appropriate.
35	Change in the specification parameters or limits of the immediate packaging of the finished product:	The changes shall not be a consequence of any commitment from previous assessments to review specification limits (e.g. made during the procedure for the marketing authorisation application or a variation procedure according to Article 62 of Regulation (EU) 2019/6) unless the supporting documentation has already been assessed and approved within the context of another procedure under Regulation (EU) 2019/6.	Comparative table of former and new specifications or limits.

		The change shall not result from unexpected events arising during manufacture.	
a)	— tightening of specification limits	The change shall be within the range of currently approved limits. The test procedure shall remain the same, or changes in the test procedure shall be minor.	
b)	— addition of a new specification parameter to the specification with its corresponding test method	Any new test method shall not concern a novel non-standard technique or a standard technique used in a novel way.	Amendment of the relevant section(s) of the dossier for method and validation and batch data, as appropriate.
36	Change in test procedure for the immediate packaging of the finished product (including replacement or addition)	The change shall not be applicable to a biological or immunological medicinal product. Appropriate validation studies shall have been performed in accordance with the relevant guidelines and show that the updated test procedure is at least equivalent to the former test procedure. Any new test method shall not concern a novel non-standard technique or a standard technique used in a novel way.	Amendment of the relevant section(s) of the dossier for method and validation and batch data, as appropriate.
37	Change in shape or dimensions of the container or closure (immediate packaging) of a non-sterile finished product	The change shall not concern a part of the packaging material, which affects the delivery, use, safety or stability of the finished product. The change shall not concern the qualitative or quantitative composition of the container. In case of a change in the headspace or a change in the surface/volume ratio, stability studies in accordance with the relevant guidelines shall have been started, relevant stability parameters shall have been assessed in at least two pilot scale or industrial scale batches, and at least three months stability data shall be at the disposal of the applicant.	Amendment of the relevant section(s) of the dossier.
38	Change in pack size (number of units e.g. tablets, ampoules, etc. in a pack) within the range of the currently approved pack size [3]	The new pack size shall be consistent with the posology and treatment duration as approved in the Summary of Product Characteristics. The primary packaging material shall remain the same.	

39	Change in any part of the primary packaging material not in contact with the finished product formulation (such as change of colour due to different plastic used for flip-off caps, colour code rings on ampoules or change of needle shield)	The change shall not concern a part of the packaging material that affects the delivery, use, safety or stability of the finished product.	Amendment of the relevant section(s) of the dossier.
40	Replacement or addition of a supplier of packaging components or devices (when mentioned in the dossier)	The qualitative and quantitative composition of the packaging components or device and design specifications shall remain the same. The change shall not have the potential to affect the identity, quality or purity of the packaging component or devices.	Amendment of the relevant section(s) of the dossier.
41	Change in the shelf-life or to an approved stability protocol of the finished product:	The change shall not be the result of unexpected events arising during manufacture or because of stability concerns.	Amendment of the relevant section(s) of the dossier.
a)	— reduction of the shelf life of the finished product as packaged for sale, after first opening or after dilution or reconstitution		
b)	— change to an approved stability protocol	The change shall not have the potential to affect the identity, strength, quality, purity, potency or physical characteristics of the finished product. The change shall not concern a widening of the acceptance criteria in the parameters tested, a removal of stability indicating parameters or a reduction in the frequency of testing.	
42	Implementation in practice of changes already foreseen in an approved change management protocol (CMP) for the finished product	The change shall be in accordance with the approved CMP and the results of studies performed indicate that the predefined acceptance criteria specified in the protocol are meet. The implementation of the change shall require no further supportive data to the CMP.	
43	Editorial changes to part 2 of the dossier if inclusion in an upcoming procedure concerning part 2 is not possible		Comparative table of the changes to the dossier.
44	Submission of a new or updated Ph. Eur. CEP from an already approved manufacturer for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient	The finished product release and end of shelf life specifications shall remain the same. The change shall not have the potential to affect the identity, quality, purity, potency or physical characteristics of the active substance, starting material, reagent or intermediate used in the manufacturing process of the active substance, or of the excipient.	Amendment of the relevant section(s) of the dossier, including a copy of the updated Ph. Eur. CEP and QP declaration, as appropriate.

		No additional data shall be required. The manufacturing process of the active substance, starting material, reagent, intermediate or excipient shall not include the use of material from human or animal origin. For a herbal substance or a herbal preparation the manufacturing route, physical form, extraction solvent and drug extract ratio (DER) shall remain the same. The manufacturer shall already be approved and incorporated in the Union IT systems storing and providing organisational data.	
45	Submission of a new Ph. Eur. CEP from a new manufacturer (replacement or addition) for a non-sterile: — active substance; — starting material, reagent or intermediate used in the manufacturing process of the active substance; — excipient	The finished product release and end of shelf life specifications shall remain the same. The change shall not have the potential to affect the identity, quality, purity, potency or physical characteristics of the active substance, starting material, reagent or intermediate used in the manufacturing process of the active substance, or of the excipient. No additional data shall be required. The manufacturing process of the active substance, starting material, reagent, intermediate or excipient shall not include the use of material from human or animal origin. For a herbal substance or a herbal preparation the manufacturing route, physical form, extraction solvent and drug extract ratio (DER) shall remain the same. The manufacturer shall already be incorporated in the Union IT systems storing and providing organisational data.	Amendment of the relevant section(s) of the dossier, including a copy of the updated Ph. Eur. CEP and QP declaration, as appropriate.
46	Submission of a new or updated Ph. Eur. TSE CEP for a non-sterile: — active substance; — starting material, reagent, intermediate used in the manufacturing process of the active substance; — excipient	The change shall not have the potential to affect the identity, quality, purity, potency or physical characteristics of the active substance, starting material, reagent or intermediate used in the manufacturing process of the active substance, or of the excipient. The change shall not impact the risk of extraneous agents contamination (e. g. no change of country of origin). The manufacturer shall already be approved and incorporated in the Union IT systems storing and providing organisational data.	Amendment of the relevant section(s) of the dossier including a copy of the updated Ph. Eur. CEP, QP declaration and TSE information, as appropriate.

47	Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State:	The change shall be made exclusively to fully comply with the pharmacopoeia. All the tests in the specification shall correspond to the pharmacopoeial standard after the change, except any additional tests. Additional validation of a new or changed pharmacopoeial method shall not be required. For a herbal substance or a herbal preparation the manufacturing route, physical form, extraction solvent and drug extract ratio (DER) shall remain the same.	Amendment of the relevant section(s) of the dossier ([4]). Comparative table of the former and new specifications, if applicable.
a)	— change of specification(s) of a former non EU Pharmacopoeial active substance, excipient or active substance starting material to fully comply with the Ph. Eur. or with a national pharmacopoeia of a Member State	Additional specifications to the pharmacopoeia for product specific properties shall be unchanged (e.g. particle size profiles, polymorphic form, bioassays or aggregates). The change shall not concern significant changes in qualitative and quantitative impurities profile unless the specifications are tightened.	Batch data and data demonstrating the suitability of the monograph to control the substance.
b)	— change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member State	Additional specifications to the pharmacopoeia for product specific properties shall be unchanged (e.g. particle size profiles, polymorphic form, bioassays or aggregates).	
c)	— change in specifications from a national pharmacopoeia of a Member State to the Ph. Eur.		Amendment of the relevant section(s) of the dossier, including batch data and data demonstrating the suitability of the monograph to control the substance.
d)	— to reflect compliance with the Ph. Eur. by removing reference to the internal test method and test method number		
48	Addition or replacement of a measuring or administration device which is not an integrated part of the primary packaging	The change shall not affect the delivery, use, safety or stability of the finished product. The change shall be only applicable to a device with CE marking. The new measuring or administration device shall accurately deliver the required dose for the product concerned in line with the approved posology, and results of such studies shall be available.	Amendment of the relevant section(s) of the dossier.

		The new device shall be compatible with the veterinary medicinal product. The change shall not lead to substantial amendments of the product information.	
49	Change in specification parameters or limits of a measuring or administration device:	The change shall not be a consequence of any commitment from previous assessments to review specification limits (e.g. made during the procedure for the marketing authorisation application or a variation procedure according to Article 62 of Regulation (EU) 2019/6) unless it has been previously assessed and agreed as part of a follow-up measure in a previous procedure under Regulation (EU) 2019/6. The change shall not be the result of unexpected events arising during manufacture.	Amendment of the relevant section(s) of the dossier. Comparative table of former and new specification parameters and limits.
a)	— tightening of specification limits	The change shall be within the range of currently approved limits. The test procedure shall remain the same, or changes in the test procedure shall be minor.	
b)	— addition of a new specification parameter to the specification with its corresponding test method	Any new test method shall not concern a novel non-standard technique or a standard technique used in a novel way.	Amendment of the relevant section(s) of the dossier for method and validation and batch data.
50	Change in test procedure (including replacement or addition) of a measuring or administration device	Appropriate validation studies shall have been performed in accordance with the relevant guidelines and show that the updated test procedure is at least equivalent to the former test procedure. Any new test method shall not concern a novel non-standard technique or a standard technique used in a novel way.	Amendment of the relevant section(s) of the dossier for method and validation and batch data.
51	Update of the quality dossier intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 2019/6:	This change shall only be applicable when no new or additional data is required for an assessment.	Amendment of the relevant section(s) of the dossier.
a)	— the finished product is covered by the defined scope of the procedure		
b)	— the finished product is not covered by the defined scope of the procedure but the change(s) implements the outcome of the procedure		

C	**Changes to the safety, efficacy and pharmacovigilance part of the dossier**		
1	Change(s) in the name or address or contact details of a qualified person for pharmacovigilance (QPPV)		
2	Change(s) in the Summary of Product Characteristics (SPC), labelling or package leaflet intended to implement the outcome of a Union interest referral procedure according to Article 83 of Regulation (EU) 2019/6	The veterinary medicinal product shall be covered by the defined scope of the referral. This change shall only be applicable when no new or additional data is required for an assessment. The proposed Summary of Product Characteristics, Labelling and Package Leaflet shall be identical for the concerned sections to that annexed to the Commission Decision on the referral procedure for the reference medicinal product.	
3	Change(s) in the SPC, labelling or package leaflet of a generic or hybrid medicinal product following assessment of the same change(s) for the reference product	This change shall only be applicable when no new or additional data is required for an assessment. The proposed changes to Summary of Product Characteristics, Labelling and Package Leaflet shall be identical to those changes approved for the reference medicinal product. The reference product shall be approved in the Member State concerned.	
4	Change(s) in the SPC, labelling or package leaflet intended to implement the outcome of a procedure or recommendation from the competent authority or the Agency concerning risk management measures in pharmacovigilance related to veterinary medicinal products	This change shall only be applicable when no new or additional data is required for an assessment. The proposed changes to Summary of Product Characteristics, Labelling and Package Leaflet shall be identical to wording agreed by the competent authority or the Agency.	
5	Change in the pharmacovigilance system master file (PSMF) location		
6	Introduction of a summary of the PSMF or changes to the summary of the PSMF not already covered elsewhere in this Annex		Summary of pharmacovigilance system master file according to Article 8(1)(c) of Regulation (EU) 2019/6.

7	Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan	The wording shall be limited to that agreed by the competent authority or the Agency.	
8	Implementation of changes in the SPC not already covered elsewhere in this Annex	This change shall only be applicable when no new or additional data is required for an assessment. The changes shall not affect the quality, safety or efficacy of the product. Changes shall be minor in nature and shall be consistent with the information currently included in the SPC.	
9	Editorial changes to SPC, package leaflet or labelling if inclusion in an upcoming procedure is not possible	The changes shall not affect the quality, safety or efficacy of the medicinal product.	
10	Changes to the labelling or the package leaflet which shall not be connected with the SPC:		
a)	— administrative information concerning the holder's representative		
b)	— other changes	Changes shall be minor in nature and shall be consistent with the information included in the SPC. The change shall not include the introduction of new batch release sites. Changes shall not be promotional in nature and shall not have a negative impact on the legibility of the product information.	
c)	— inclusion of traceability stickers in or on product carton	Addition shall not have a negative impact on the legibility of the product information.	
D	**Changes to the vaccine antigen master file (VAMF) part of the dossier**		
1	Change in the name or address or contact details of the VAMF certificate holder for biological products	The marketing authorisation holder shall remain the same legal entity.	Amendment of the relevant section(s) of the dossier, as appropriate.

2	Inclusion of an already certified VAMF in the marketing authorisation dossier of a veterinary medicinal product. (VAMF 2nd step procedure)	Changes shall not affect the properties of the finished product.	Amendment of the relevant section(s) of the dossier.

(1) As per EDQM standard terms the system of names and terms published by the EDQM for marketing authorisation applications.

(2) In cases where a given pharmaceutical form or strength has received an individual marketing authorisation which is separate to the marketing authorisation for other pharmaceutical forms or strengths of the same product, the deletion of the former will not be a variation but the withdrawal of the marketing authorisation.

(3) In cases where a given pack size has received an individual marketing authorisation which is separate to the marketing authorisation for other pack sizes of the same product, the change of the former will not be a variation according to Article 61, but a variation according to Article 62 of Regulation (EU) 2019/6.

(4) There is no need to notify the competent authorities of an updated monograph of the European pharmacopoeia or a national pharmacopoeia of a Member State in the case that reference is made to the 'current edition' in the dossier of an authorised medicinal product. Applicants are reminded that compliance with the updated monograph should be implemented within six months. If implementation does not occur within 6 months from the publication date, this variation applies.

CORRIGENDA

Corrigendum to Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007

(Official Journal of the European Union L 150 of 14 June 2018)

1. On page 37, point (b) and (c) of Article 30(5):

for:

'(b) only in the list of ingredients, provided that:

(i) less than 95 % of the agricultural ingredients of the product by weight are organic, and provided that those ingredients comply with the production rules set out in this Regulation; and

(ii) the processed food complies with the production rules set out in points 1.5, 2.1(a), 2.1(b) and 2.2.1 of Part IV of Annex II and with the rules laid down in accordance with Article 16(3);

(c) in the sales description and in the list of ingredients, provided that:

(i) the main ingredient is a product of hunting or fishing;

(ii) the term referred to in paragraph 1 is clearly related in the sales description to another ingredient which is organic and different from the main ingredient;

(iii) all other agricultural ingredients are organic; and

(iv) the food complies with points 1.5, 2.1(a), 2.1(b) and 2.2.1 of Part IV of Annex II and with the rules laid down in accordance with Article 16(3).',

read:

'(b) only in the list of ingredients, provided that:

(i) less than 95 % of the agricultural ingredients of the product by weight are organic, and provided that those ingredients comply with the production rules set out in this Regulation; and

(ii) the processed food complies with the production rules set out in points 1.5, 2.1(a), 2.1(b) and 2.2.1 of Part IV of Annex II, with the exception of the rules on restricted use of non-organic agricultural ingredients set out in point 2.2.1 of Part IV of Annex II, and with the rules laid down in accordance with Article 16(3);

(c) in the sales description and in the list of ingredients, provided that:

(i) the main ingredient is a product of hunting or fishing;

(ii) the term referred to in paragraph 1 is clearly related in the sales description to another ingredient which is organic and different from the main ingredient;

(iii) all other agricultural ingredients are organic; and

(iv) the processed food complies with the production rules set out in points 1.5, 2.1(a), 2.1(b) and 2.2.1 of Part IV of Annex II, with the exception of the rules on restricted use of non-organic agricultural ingredients set out in point 2.2.1 of Part IV of Annex II, and with the rules laid down in accordance with Article 16(3).'.

2. On page 38, point (a) of Article 30(6):

for:

'(a) the processed feed complies with the production rules set out in Parts II, III and V of Annex II and with the specific rules laid down in accordance with Article 16(3);',

read:

'(a) the processed feed complies with the production rules set out in Parts II, III and V of Annex II and with the specific rules laid down in accordance with Article 17(3);'.

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)

Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN