EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director General

Brussels,

SANTE/E5/CS/mcd 1205107

Sent by e-mail only

Dear Prof Rasi,

Subject: Implementing measures under Article 55(3) of Regulation (EU) 2019/6 on veterinary medicinal products as regards the database provided for in Article 55(1)[1] and the technical and functional analysis necessary for its establishment

On 7 January 2019, the new Regulation on veterinary medicinal products ("VMP Regulation") was published.

In accordance with its Article 160, it will start applying 3 years from its entry into force, i.e. from 28 January 2022.

The Union product database is the cornerstone of the effective and successful implementation and achieving the objectives of the VMP Regulation, in particular in light of its interconnections with other relevant Union databases. It would collect, collate and allow sharing of pertinent data and as a result, improve transparency, streamline and facilitate the flow of information between authorities, as well as reduce the administrative burden. In this way, it will meet the needs of health professionals, authorities, companies and the public.

[1] Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC, OJ L 4, 7.1.2019, p. 43.

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Article 55(1) of the newly adopted Regulation (EU) 2019/6 requires the Agency to establish and, in collaboration with the Member States, maintain such a Union database of veterinary medicinal products, also referred to as "product database".

The minimum content of that product database is laid down in Article 55(2). Article 56 specifies the various levels of access to the database. Articles 58(6) and (12), 61(1) and (3), 67(4), and 102(4) outline some of the functionalities of the database in light of those access rights. According to Article 74(2), the product database should also be interconnected with the pharmacovigilance database provided for in Article 74(1).

According to Article 55(3), the Commission is to adopt, by means of implementing acts, the necessary measures and practical arrangements relating to the electronic exchange mechanism and format, the functioning of the database, the detailed specifications of the information therein, contingency arrangements and, possibly, additional data.

Article 155 requires the Member States to submit, electronically, information on all veterinary medicinal products authorised within their territories in the format referred to in point (a) of Article 55(3) by the date of application of the VMP Regulation.

Article 153(3) requires the Commission to adopt the necessary implementing acts at the latest 12 months before the date of application of the VMP Regulation.

As stated previously, in terms of governance of the IT project the Commission intends to have the oversight and be in charge of quality assurance and quality control with the possibility to escalate. It is of utmost importance to ensure a governance that helps to respect deadlines, deliverables and the financial planning.

In light of this strict timeline set for the adoption of the required implementing act, I would like to request the Agency to provide advice in accordance with the terms of reference as included in Annex I hereto. The Commission suggests that Phases 1 and 2 focus on the technical specifications, practical and contingency arrangements, as well as potential additional data, for the Union product database that are required for the drafting of the implementing act. Phase 3 tasks the Agency to deliver the technical and functional analysis allowing for the actual development of the Union product database to be launched.

Given the amount of IT development work required, you may find it useful to start with taking stock of existing IT systems or tools, which could be used as stepping stones towards the building of the product database. It might also be prudent to break down the development process into increments and iterations, which would allow early issue detection and help to avoid unacceptable delays in delivery.

We suggest that the Agency deals with the different aspects following the order in Annex I to this letter, and where possible treat them in parallel. We require the Agency to update our services on the progress of its work on a monthly basis. We expect the Agency to complete Phases 1 and 2 as soon as practically possible and by end of August 2019 at the very latest. The deliverables from Phase 3 would be due by end of 2019 at the latest.

Relevant excerpts from the VMP Regulation are included in Annex II for your convenience.

I would like to thank you for your collaboration.

Yours sincerely,

Anne BUCHER

Encl.: Annex I, Annex II

ANNEX I

The European Commission would like to request the Agency to address, in cooperation with the member states, the following aspects in three different phases as follows:

Phase 1:

Project Governance

- Establish with the Commission the governance model that will ensure delivery of results and usage of existing expert knowledge during Phases 1 and 2, while remaining practical and capable of fast decision making.

Scope Definition

- Define the scope of the veterinary medicinal products database (referred to as "system" below) as laid down in the VMP Regulation by the prescribed time limit taking into account the view of the policy/business reasoning and purpose of the system (e.g. short- and long-term goals of the Union product database in terms of the legal requirements, improved process efficiency and meeting animal patient needs) in the format of a detailed business case.

Phase 2 Preparation

- Definition of project plan and deliverables for phase 2.

Phase 2:

Use the outcome of Phase 1 to establish detailed requirements:

High-Level Functional Requirements

- Detail the functional requirements in the form of use cases initially (user stories to be provided later), which would allow for the relevant levels of data access and sharing as provided for in the VMP Regulation while ensuring the required security, privacy and degree of protection of commercially confidential information.
- Provide the non-functional requirements and specifications including personal data protection and protection of commercially confidential information.

- Define the "to be" business processes for all operators at different levels including national and Union levels.

High-Level Architecture Model

- Provide a high-level application architecture view and conceptual data model.

Interoperability and Interface

- Describe the interactions with all other relevant databases provided for in the VMP Regulation and with the MRL database required under Regulation (EC) 470/2009.
- Provide a high-level view of the electronic data exchange mechanism and the format for electronic submission.

Contingency Arrangements under point (d) of Article 55(3)

- Review the best available backup and contingency options, both within EMA and the wider context, to ensure the continuity of data entry, updating and sharing in case of functionality failures.

Additional Information under point (e) of Article 55(3)

- Explore what information in addition to the minimum required data might safely be considered for inclusion in the product database coverage in view of its utility for ongoing operations or for potential future policy and IT developments without compromising the delivery timeline.

Use the outcome of the above two phases to define the key elements of the implementing act, including operational model, data, procedures, transition and implementation by stakeholders.

Phase 3:

Use the outcome of Phase 2 to define the actual project for delivering the implementing act as well as the Union Database. Phase 3 may overlap with Phase 2, elaborating on results of phase 2 as soon as they become available.

Development Project Governance and Management

- Establish with the Commission the governance model and the project management methodology to be used for the development project, from inception to full implementation.

"As-is" Situation

- Establish a list of systems (registers or databases), which already exist, are in use or under development at Union level, or at network and/or national level as appropriate, for either veterinary medicinal products, or medicinal products for human use.
- Assess which of those systems may serve as building blocks for the establishment of the Union database of veterinary medicinal products.
- Detail the "as is" business processes related to veterinary medicinal products, or medicinal products for human use, defining the current state of those business processes within and outside the organisation. This should include all procedure types, i.e. centralised, decentralised, mutual recognition, national procedures and parallel import processes.
- Provide the architectural blueprint for the medicinal products for human use operation, data exchanges and key functions (in form of use cases for EU-wide and national cases).

Future Architecture and Development

- Elaborate a suitable blueprint for the system architecture and database design.
- Consider the file formats, indexing and search capabilities and the specifications of the information to be stored, updated and shared in the system.
- Elaborate on the system security, performance, scalability, availability, reliability and maintainability.
- Define the possible increments in the establishment of the system, which would allow for the gradual, timely and seamless delivery of the required outcome.
- Elaborate on the adequate state-of-the-art data exchange mechanisms and electronic formats, which should allow the product database sufficient compatibility, integration and inter-operability with existing national systems or data exports therefrom, as well as with other Union IT tools and databases, while ensuring compliance with international standards in force and recommended by international organisations, e.g. VICH, WHO, and OECD.

- Propose a test and risk management strategy and acceptance criteria that should allow for validation of the produced system and gradual deployment and usage by all users and integration with national systems exchanging information.
- Propose a solution for introducing existing product information in the Union database.
- Revise with the Commission, as needed, the governance model and the project management methodology to be used for the project, from inception to full implementation.

ANNEX II

EXCERPTS FROM THE VMP REGULATION
CONTAINING REFERENCES TO THE PRODUCT DATABASE

(29) It is recognised that improved access to information contributes to public awareness, gives the public the opportunity to express its observations and enables authorities to take due account of those observations. The general public should therefore have access to information in the product database, the pharmacovigilance database and the manufacturing and wholesale distribution database, after the deletion of any commercially confidential information by the competent authority. Regulation (EC) No 1049/2001 of the European Parliament and of the Council gives the fullest possible effect to the right of public access to documents and lays down the general principles and limits on such access. The Agency should therefore give the widest possible access to the documents while carefully balancing the right for information with existing data protection requirements. Certain public and private interests, such as personal data and commercially confidential information, should be protected by way of exceptions in accordance with Regulation (EC) No 1049/2001.

(84) Information on veterinary medicinal products is essential in order to enable health professionals, authorities and companies make informed decisions. A key aspect is the creation of a Union database that should collate information on marketing authorisations granted in the Union. That database should enhance overall transparency, streamline and facilitate the flow of information between authorities, and prevent multiple reporting requirements.

CHAPTER IV
POST-MARKETING AUTHORISATION MEASURES

Section 1
Union product database

Article 55
Union database on veterinary medicinal products

1. The Agency shall establish and, in collaboration with the Member States, maintain, a Union database on veterinary medicinal products (‘product database’).

2. The product database shall contain at least the following information:

(a) for veterinary medicinal products authorised within the Union by the Commission and by the competent authorities:

(i) name of the veterinary medicinal product;

(ii) active substance or substances, and the strength of the veterinary medicinal product;

(iii) summary of product characteristics;

(iv) package leaflet;

(v) the assessment report;

(vi) list of sites where the veterinary medicinal product is manufactured; and

(vii) the dates of the placing of the veterinary medicinal product on the market in a Member State;

(b) for homeopathic veterinary medicinal products registered in accordance with Chapter V within the Union by the competent authorities:

(i) name of the registered homeopathic veterinary medicinal product;

(ii) package leaflet; and

(iii) lists of sites where the registered homeopathic veterinary medicinal product is manufactured;

(c) veterinary medicinal products allowed to be used in a Member State in accordance with Article 5(6);

(d) the annual volume of sales and information on the availability for each veterinary medicinal product.

3. The Commission shall, by means of implementing acts, adopt the necessary measures and practical arrangements laying down:

(a) the technical specifications of the product database including the electronic data exchange mechanism for exchanging with the existing national systems and the format for electronic submission;

(b) the practical arrangements for the functioning of the product database, in particular to ensure protection of commercially confidential information and security of exchange of information;

(c) detailed specifications of the information to be included, updated and shared in the product database and by whom;

(d) contingency arrangements to be applied in case of unavailability of any of the functionalities of the product database;

(e) where appropriate, data to be included in the product database in addition to the information referred to in paragraph 2 of this Article.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 145(2).

Article 56

Access to the product database

1. The competent authorities, the Agency and the Commission shall have full access to the information in the product database.

2. Marketing authorisation holders shall have full access to the information in the product database as regards their marketing authorisations.

3. The general public shall have access to information in the product database, without the possibility to change the information therein, as regards the list of the veterinary medicinal products, the summary of product characteristics, package leaflets and, after the deletion of any commercially confidential information by the competent authority, assessment reports.

Article 58

Responsibilities of the marketing authorisation holders

6. The marketing authorisation holder shall record in the product database the dates when its authorised veterinary medicinal products are placed on the market, information on the availability for each veterinary medicinal product in each relevant Member State and, as applicable, the dates of any suspension or revocation of the marketing authorisations concerned.

12. The marketing authorisation holder shall record in the product database the annual volume of sales for each of its veterinary medicinal products.

Article 61

Variations that do not require assessment

1. Where a variation is included in the list established in accordance with Article 60(1), the marketing authorisation holder shall record the change including, as applicable, the summary of product characteristics, labelling or package leaflet in languages referred to in Article 7, in the product database within 30 days following the implementation of that variation.

3. The competent authority of the reference Member State or, in the case of variation to the terms of a national marketing authorisation, the competent authority of the relevant Member State, or the Commission, as applicable, shall inform the marketing authorisation holder and the competent authorities in the relevant Member States as to whether the variation is approved or rejected by recording that information in the product database.

Article 67

Measures to close the procedure for variations requiring assessment

4. The competent authority, the Commission, the Agency, or the competent authorities in the Member States listed in accordance with point (e) of Article 62(2), as applicable, shall update the product database accordingly.

Article 74

Union pharmacovigilance database

2. The pharmacovigilance database shall be interconnected with the product database referred to in Article 55.

Article 102

Parallel trade in veterinary medicinal products

4. Competent authorities of the destination Member State shall, in the product database as referred to in Article 55, make available to public the list of veterinary medicinal products that are parallel traded in that Member State.

Article 153

Transitional measures regarding delegated and implementing acts

3. Without prejudice to the date of application of this Regulation, the Commission shall adopt the delegated acts referred to in Articles 57(3) and 146(2) and the implementing acts referred to in Articles 55(3) and 60(1) at the latest by 27 January 2021. Such delegated and implementing acts shall apply from 28 January 2022.

Article 155

Initial input to the product database by competent authorities

At the latest by 28 January 2022, the competent authorities shall submit, electronically, information on all veterinary medicinal products authorised in their Member State at that time to the Agency, using the format referred to in point (a) of Article 55(3).

ANNEX III

LIST OF THE OBLIGATIONS REFERRED TO IN ARTICLE 136(1)

(7) the obligation to record in the product database the dates when its authorised veterinary medicinal products are placed on the market and information on the availability for each veterinary medicinal product in each relevant Member State and, as applicable, the dates of any suspension or revocation of the marketing authorisations concerned, as well as data relating to the volume of sales of the medicinal product, as provided in Article 58(6) and (11) respectively;