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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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

[…]

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This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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, be interoperable 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.

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

This necessitates an incremental 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 should provide 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 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/[…], 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.

(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) 'users' means any persons which interact with the Union product database via its functions;

(b) 'super users' 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 users' means any users authorised by super users to perform actions in the Union product database on their behalf in accordance with the access rights assigned to their user profiles;

(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[2];

(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.

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.

[2] 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).

At the latest, by 28 January 2022, the Agency shall, in consultation with the Member States and the Commission, 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 regulatory network referred to in Chapter X of Regulation (EU) 2019/6.

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:

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(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 State 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[3].

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.

[3] 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).

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:

  (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.

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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 data in a structured format and documents 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.

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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 and functions that only super users and controlled users 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

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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 by a permanent identifier allowing the identification of veterinary medicinal products authorised in several Member States under the same marketing authorisation procedure. That identifier shall be detailed to pack size level.

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

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

4. 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.

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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 and, as applicable, 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 the above obligation as regards any suspension or revocation of a marketing authorisation 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.

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

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7. 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.

8. 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), 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.

9. 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 whose access is 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

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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 Functionality 4.1 provided for in Annex I.

2. The Agency, in collaboration with the competent authorities and the Commission, 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.

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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,

For the Commission
The President
Ursula VON DER LEYEN

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