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Patient Health Protection

Introductory cover note to the List of European Union reference dates and frequency of submission of Periodic Safety Update Reports

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1. Introduction

This cover note should be read in conjunction with the Guideline on Good Pharmacovigilance Practices (GVP), Module VII – Periodic safety update report.

The list of Union reference dates and frequency of submission of periodic safety update reports (referred to as the "EU reference dates (EURD) list" in the GVP Module VII) consists of a list of active substances and combinations of active substances sorted in alphabetical order, for which Periodic Safety Update Reports (PSURs) shall be submitted in accordance with the EU reference dates and frequencies determined by the Committee for Medicinal Products for Human Use (CHMP) and the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) following consultation with the Pharmacovigilance and Risk Assessment Committee (PRAC) [DIR Art. 107c(4)[1]].

The EURD list has been compiled in order to facilitate the harmonisation of Data Lock Points (DLPs) and frequency of submission of PSURs for medicinal products containing the same active substance or the same combination of active substances, subject to different marketing authorisations, authorised in more than one Member State. This allows, where appropriate, the EU single assessment of the related PSURs as set out in the new EU pharmacovigilance legislation [DIR Art. 107e].

The EURD list is intended to optimise the management of PSURs assessment within the EU while supporting transparency, and to provide predictability to the various stakeholders in terms of workload related to PSURs, taking into account the currently known safety profile of the active substances and combinations of active substances, based on risk proportionality. The list is the relevant tool to anticipate as much as possible the PSUR-related activities, while respecting that competent authorities in Member States can request the submission of PSURs for nationally authorised products at any time [DIR Art. 107c (2)]. The list is a living document, i.e. it can be amended whenever considered necessary by the PRAC, CHMP or CMDh in response to the emergence of relevant new safety information, newly authorised substances and requests received from the marketing authorisation holders as defined in [DIR Art 107c(6)]. Substances can be added, but also removed as appropriate.

2. Scope of the EU reference dates list

The principles of the EURD list are included in the GVP Module VII – Periodic safety update report (VII.C.3).

The PSUR frequency as published on the EURD list for a given active substance or combination of active substances overrules the submission schedule described in [DIR Art 107c (2)] and any conditions related to the frequency of submission of PSURs included in the Marketing Authorisation. This approach is without prejudice to the right of a National Competent Authority (NCA) to request the submission of PSURs at any time.

As a result of the publication of the EURD list, any changes to the PSUR submission frequency and DLP will trigger the obligation of the marketing authorisation holders (MAHs) to submit, where applicable, a variation for the products where contradictory requirements are specified in the Marketing Authorisation [DIR 107c(4) and (6)].

[1] Any reference to Regulation (EC) No 726/2004 and Directive 2001/83/EC refers to the Regulation and Directive respectively, always including their latest amendments. Where reference is made to specific Articles in square brackets "REG" means Regulation (EC) No 726/2004 as amended and "DIR" means Directive 2001/83/EC as amended.

Although the Legislation establishes a derogation for the submission of PSURs for products authorised under Articles 10(1), 10a, 14 and 16a of Directive 2001/83/EC as amended [DIR Article 107b (3)], the EURD list is used as a way of simplifying NCA requests for submission of PSURs on the basis of concerns relating to pharmacovigilance data, or due to the lack of PSURs, relating to an active substance. This should allow optimisation of the management of PSUR assessments within the EU in terms of workload related to PSURs. This approach is without prejudice to the right of a NCA to request the submission of PSURs at any time.

In addition to the active substances, EU reference dates and DLPs, the following special considerations are highlighted in the list when relevant:

- Whether different PSURs should be submitted for medicinal products containing the same active substance and authorised for one MAH depending on different indications, routes of administration, dosage forms and dosing regiments [IM Article 34 (6)[2]]. In the case where different PSURs are required, the active substance or combination of active substances appears several times in the list including in brackets the scope that should be covered by the PSUR (e.g. PSUR for "topical formulations" versus PSUR for "oral formulation");
- Whether a stand-alone PSUR should be submitted for fixed dose combination products [IM Article 34 (7)];
- Whether PSURs for products authorised under Articles 10(1), 10a, 14 and 16a of Directive 2001/83/EC have been requested by competent authority(ies) on the basis of concerns relating to pharmacovigilance data or due to the lack of PSURs relating to an active substance [DIR 107b (3) (b)]. In case the list indicates that PSURs for such products are not required, this does not withdraw the obligation for MAHs of the products containing the same active substance or combination of active substances authorised under different legal basis than those specified above, to submit PSURs. It is important to highlight that given its objectives list (see section **1. Introduction**) and the risk-based approach underpinning the PSURs submission frequencies and DLPs, the EURD list can deviate from the PSUR submission schedule defined in [DIR Art 107c (2) (b)].

The first publication of the EURD list took place on 1st October 2012. The information it contains takes effect 6 months after the publication date following adoption by the CHMP and CMDh as appropriate after consultation of the PRAC. However for the sake of transparency and predictability regarding PSUR submissions and assessments, the need to include information related to PSUR submission schedules occurring before the aforementioned 6 months period was identified by the EU Regulatory Network.

3. Development of the EU Reference dates list

The EURD list was developed using the following data sources: the Eudravigilance Medicinal Product Dictionary (EVMPD) and the PSUR Work Sharing (WS) and Synchronisation lists.

The NCAs and the EMA have worked closely in order to compile the EURD list. On several occasions, NCAs were requested to review the content, propose Union reference dates, PSUR frequencies and DLPs based on the risk profile as currently known for each active substance and combination of active substances (reference to GVP VII.C.3.4). In addition, NCAs were requested to state whether PSURs for products authorised under Articles 10(1), 10a, 14 and 16a of Directive 2001/83/EC as amended should be submitted for each of the active substances and combinations of active substances contained in the list based on the criteria laid down in the legislation [DIR 107b (3) (b)].

[2] Any reference to specific Articles of the draft Commission Implementing Regulation on the Performance of Pharmacovigilance Activities Provided for in Regulation (EC) No 726/2004 and Directive 2001/83/EC is provided in square brackets with the indication "IM".

A draft version of the EURD list was published for consultation with stakeholders on 4th of April 2012 for a period of 2 months. Stakeholders, were invited to identify any compelling need for changes, on the grounds specified in the legislation [DIR Art 107c (6)]. In addition to submitting comments with relevance to the aforementioned legal provisions, MAHs were requested to indicate the date of the first marketing authorisation in the Union or alternatively whenever this was unavailable, the International Birth Date of their originator medicinal products containing the active substances and combinations of active substances.

4. Content of the EU Reference dates list

The names of the active substances and the combination of active substances are in English. A comma is used to separate the different active substances contained in a combination. A slash is used to indicate that a single EU PSUR assessment covering the different substances and/or combinations of active substances will be produced.

The European Union reference date corresponds to the date of the first or the earliest known date of the marketing authorisation in the Union of a medicinal product containing the active substance or combination of active substances [DIR Art 107c (5) (a,b)]. The term "Not available*" is indicated when the EURD is pending, since it has not been provided during the various rounds of consultation on the EURD list with the NCAs and the MAHs.

The column "*Submission date (According to the timelines defined in GVP Module VII, Section A)*" has been included next to the column "*DLP*" to support MAHs' planning in terms of the PSUR submission and ensure that all relevant PSURs are received prior to the start of the assessment procedure, for which the related Timetables are published on EMA website. In addition, the column "*Next DLP*" has been completed for active substances or combination of active substances with a PSUR frequency of up to 6 months. This is again to support predictability for stakeholders in terms of PSUR-related activities.

While some products are subject to a derogation from routine submission of PSURs, such reports can still be requested by competent authorities on the basis of pharmacovigilance concerns or for lack of PSURs [DIR Article 107b (3b)]. The column of the EURD list "*Are PSURs required for products referred to in Articles 10(1), 10a, 14, 16a of Directive 2001/83/EC as amended? Yes/No*" indicates whether PSURs for such products have to be submitted to the NCAs of the countries where these products are authorised.

Updates made to the EURD list as adopted by the CHMP and CMDh following consultation with the PRAC are highlighted in order to facilitate the review by stakeholders. The column "*Publication date*" refers to the publication date of changes related to the PSUR submission frequency and/or DLP for a given active substance or combination of active substances.

Following the outcome of the December 2012 EMA Management Board meeting, the single assessment of substances contained in nationally authorised products only (including products authorised through Mutual Recognition, Decentralised and National procedures), will not start in 2013. Such substances, with DLPs falling in this period have therefore been temporally removed from the EURD list. For more details, reference should be made to the cover note "*Assessment of Period Safety Update Reports for Nationally Authorised Products in 2013- 2014*", as well as the "*List of substances under PSUR Work Sharing scheme and other substances contained in Nationally Authorised Products with DLP synchronised*"[3]. However the EU single assessment of substances contained in both centrally and nationally authorised products (CAPs and NAPs) with involvement of the PRAC started in April 2013. The column "*Procedure number of the PSUR single assessment procedure for substances contained in both CAPs and NAPs*" has been included in the EURD list to ensure that all PSURs subject to a given

[3] PSUR Work Sharing webpage, HMA website: http://www.hma.eu/348.html

procedure are submitted with a common identification number. For more details, please refer to the section 5 of this cover note.

5. EU Reference dates list and EU single assessment of substances contained in both CAPs and NAPs (PSUSA): PSUR submission requirements

In February 2012, the European Medicines Agency (EMA) published a plan[4] for the implementation of the new Pharmacovigilance Legislation requirements. Following the outcome of the December 2012 EMA Management Board meeting, the EU single assessment of substances contained in both centrally and nationally authorised products (CAPs and NAPs) with involvement of the PRAC started in April 2013, corresponding to the entry into force of the EURD list.

Article 2 of Directive 2010/84/EU lays down transitional provisions regarding PSURs submission requirements. Until the EMA can ensure the functionalities agreed for the PSUR repository, MAHs shall submit PSURs to all Member States in which the medicinal product has been authorised.

The centralised submission of PSURs is a key element for the optimisation of the functioning of the EU PSUR single assessment procedure for substances contained in both CAPs and NAPs. As a consequence, MAHs concerned should submit their PSURs to **all the PRAC and CHMP members representing the National Competent Authorities (NCAs) of the countries where the medicinal products have been authorised, to the PRAC rapporteur of the procedure and to the EMA.**

In order to facilitate the identification of these substances, the extra column "*Procedure number of the PSUR single assessment procedure for substances contained in both CAPs and NAPs"* has been added in the EURD list. Once appointed, the PRAC rapporteur will also be indicated. **The assigned procedure number should be included in the cover letter sent to NCAs and EMA**. The format is as follows: "**PSUSA/00000000/YYYYMM**", where "PSUSA" indicates that the procedure is a single assessment of PSURs, the eight digit number corresponds to a unique identification number, and the combination "YYYYMM" corresponds to the month and year of the DLP as published in the EURD list for the given active substance or combination of active substances.

PSUR submission requirements according to the EURD list

For medicinal products with documentation previously submitted in eCTD format, PSURs should be presented in a new eCTD sequence in the respective eCTD lifecycle of the concerned product.

a) PSURs submission for substances in CAPs only.
There is no change in the submission rules. For EMA submissions, the use of **eCTD format** is mandatory, and it is **strongly recommended** to use the eSubmission Gateway and Web Client. The Formatted Table Template should be part of the submission.

b) PSURs submission for substances contained in both CAPs and NAPs:

b.1) Submission for CAPs to EMA and NCAs: in eCTD format only via eSubmission Gateway or eSubmission Web Client. Alternatively 1 DVD or CD-ROM with original signed cover letter is accepted. For more details, please see the document "*Dossier requirements for Centrally Authorised Products (CAPs)*".

[4] "Plan for implementation of the pharmacovigilance legislation by the European Medicines Agency" EMA/64750/2012: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/02/WC500121837.pdf

CAPs submitted to EMA where the substance is contained in both CAPs and NAPs: the following filename should be used for the submission via the Gateway or the Web Client:
ESUBPXYZ_ESUBPROD_HCxxxxxx_Wonderpill_00000000_Substance_MAH_YYYYMM_psusa_00xx.zip

ESUBPXYZ	ESUBPROD	HCxxxxxx	Wonderpill	00000000
Sender's Routing ID for Gateway (communicated to Applicant by EMA's Gateway registration team)	Receiver's routing ID for Gateway (communicated to Applicant by EMA's Gateway registration team)	Centralised procedure Number (HCxxxxxx) – 6 digit ID (from the eligibility confirmation letter which is sent by EMA)	Product name	8 digit Unique identification number as included in the published EURD list (without the Data Lock point)
Substance	**MAH**	**YYYYMM**	**psusa**	**00xx.zip**
Substance as mentioned in the EURD list*	MAH submitting the PSUR*	Month and year of the DLP (as per the suffix of the Procedure number	Submission type for single assessment of PSUR	Sequence Number of the submission (4 digits

The submission description field in the eCTD envelope for CAPs should contain the following:

Submission Description:	**substance, psusa/00000000/YYYYMM** *Procedure number of the PSUR single assessment procedure for substances contained in both CAPs and NAPs (as in EURD list)*

When submitting your PSUR to EMA, please use the formatted table cover note.

b.2) Submission for NAPs to the EMA: in eCTD or NeeS format **only** via eSubmission Gateway or eSubmission Web Client.

The following filename should be used:
ESUBPXYZ_ESUBPROD_00000000_substance_MAH_YYYYMM_psusa_00xx.zip

ESUBPXYZ	ESUBPROD	00000000	Substance	MAH	YYYYMM	psusa	00xx.zip
Sender's Routing ID for Gateway (communicated to Applicant by EMA's Gateway registration team)	Receiver's routing ID for Gateway (communicated to Applicant by EMA's Gateway registration team)	8 digit Unique identification number as included in the published EURD list (without the Data Lock point)	Substance as mentioned in the EURD list*	MAH submitting the PSUR*	Month and year of the DLP (as per the suffix of the Procedure number	Submission type for single assessment of PSUR	Sequence Number of the submission (4 digits

The submission description field in the eCTD envelope for NAPs should contain the following:

Submission Description:	**MAH name, NAP Invented name**

* Note: For substance and MAH name, please use a 'short' name, with a maximum of 30 characters. Use only letters as no special characters can be used in the file name. Underscore can be used to separate filenaming parts, e.g. substance_MAH. Do not leave spaces or use special characters. For example for INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED) / INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED, PREPARED IN CELL CULTURES) use 'InfluenzaVaccine' or Pharmaceuticals Company International Limited use 'PharmaceuticalsCompany'.

When submitting your PSUR, please use the formatted table cover note.

Useful links:

- To register to the eSubmission Gateway: http://esubmission.emea.europa.eu/esubmission.html
- To create an eCTD file for submission: http://esubmission.emea.europa.eu/ectd/index.html http://esubmission.emea.europa.eu/tiges/tigesdocuments.html
- To create a NeeS file for submission ('NeeS guidance for industry' covering NAPs/MRP/DCP): http://esubmission.emea.europa.eu/tiges/tigesdocuments.html

b.3) Submission for NAPs to the NCAs: please refer to the document "*NCAs and EMA requirements for submission of PSUR during the transitional period*"

The annex "*Summary of PSUR submission requirements for single assessment procedures*" has been included at the end of this document to provide stakeholders with an overview of the aforementioned guidance.
In case of any questions related to the submission of PSUR, please contact eCTD@ema.europa.eu.

Notice to all Marketing Authorisations Holders of medicinal products which are part of a single assessment of periodic safety update reports (PSUR) of active substances contained in both centrally and nationally authorised medicinal products: This is to inform all Marketing Authorisation Holders that have submitted periodic safety update reports (PSUR) subject to a single assessment, pursuant to Article 28(5) of Regulation (EC) No 726/2004 and Article 107e-g of Directive 2001/83/EC, that the said PSURs will be jointly assessed by the lead Pharmacovigilance Risk Assessment Committee (PRAC) Rapporteur and the PRAC with a view to forming a single assessment report.
In accordance with the procedural steps laid down in the aforementioned provisions, the preliminary single assessment report by the PRAC Rapporteur, the updated single assessment report by the PRAC Rapporteur, the PRAC recommendation and the single CHMP Opinion (if applicable) will be circulated amongst all the Marketing Authorisation Holders whose medicinal product(s) are part of the PSUR single assessment procedure. The data contained therein should be solely used for the purposes of the concerned procedure.

6. Submission of requests for amendments of the EU reference dates list

The EURD list is a living document which is amended as appropriate to reflect any changes required by the CHMP and CMDh after consultation with the PRAC:

- in response to any pharmacovigilance concerns, outcomes of referrals, on-going PSUR assessments, safety variations, line extension etc. that impact on PSUR submissions;
- in order to achieve international harmonisation;
- and to avoid duplication of assessments [DIR Art 107c (6)].

The requests have to be made by Thursday close of business ten days prior to PRAC meeting using the specific template published on the EMA website "*Requests for amendments of the EU reference dates list*"[5], and should be addressed to EMA through the EURD list mailbox <EURDList@ema.europa.eu> (please see also below the "*Note related to the requests for alignment of DLPs with the International Birth Date (IBD)*").

Stakeholders should complete the fields "*Administrative Information*" to ensure all requests are correctly tracked in order to be considered by the PRAC, CHMP and CMDh as appropriate.

The template consists of an excel table containing 2 tabulations; relevant instructions are below:

Tabulation 1 "Request for amendments"

Names of active substances/combinations of active substances	Ground of the Request	Request for change and Details on justification	MAH of the originator product
Copy the name as included in the EURD list	*Select the category from the drop down list of options based on DIR Article 107c (6)*	*Clearly define and justify here your request*	*State the MAH of the originator product*

To comment, the requester should complete the cells as presented above:

- Copy the name of the relevant of active substance(s) and/or combination of active substances as published in the EU Reference date list;
- Select the relevant category of request using the available drop down list that appears when clicking on the cells of the column "*Ground of the Request*";
- In case of more than two comments related to the same active substance or combinations of active substances, select in the Column "*Category of Request*" the option "*Other/ Multiple Comments*".

Note related to the requests for alignment of DLPs with the International Birth Date (IBD) of the originator product authorised through the centralised procedure instead of the European Union reference date (EURD):

- Until the product is authorised in the EU (i.e. until the marketing authorisation is granted by the European Commission), such requests should be addressed by email to the relevant EMA Product Team Leader (EMA PTL);

[5] http://www.ema.europa.eu/docs/en_GB/document_library/Template_or_form/2012/10/WC500133160.xls

- When the product has been authorised (i.e. the marketing authorisation has been granted by the European Commission), such requests should be addressed to the EMA via the EURD list mailbox <EURDList@ema.europa.eu>;
- Please note that for newly authorised products, the 1st PSUR submitted in the EU cannot cover a period longer than 6 months, example:
    - European Birth Date (EBD) is 15 August 2012,
    - MAH requests to align the submission of PSUR according to the International Birth Date (IBD) which is 30 October 2010,
    - 2 options, either:
        - The 1st PSUR covers the period 15 August 2012 to 30 October 2012, followed by a 6 months PSUR covering the period 1 November to 30 April 2013, **OR**
        - The 1st PSUR covers the period 15 August 2012 to 15 February 2013, followed by a 2nd PSUR covering the period 16 February 2013 to 30 April 2013.

Tabulation 2 "Request for additions"

Names of active substances or combinations of active substances	European Union reference date (EURD) as defined in DIR Article 107c(5)	Current marketing authorisation status and Countries where the originator product is authorised	MAH of the originator product	Justification for inclusion in the list

To propose a new active substance or combination of active substances for inclusion in the EURD list, please clearly indicate the information in the second tabulation of the excel document as presented above, and return the request to the EURD list mailbox <EURDList@ema.europa.eu>.

Annex - Summary of PSUR submission requirements for single assessment procedures

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PSUR procedure type	Marketing Authorisation type of the products concerned	Addressees	Submission requirements	Reference document(s)	File name to be used when submitting to EMA
PSUR Assessment of substances contained in 1 or several centrally authorised product(s)	CAP	EMA	No change in the submission rules until further notice: eCTD format only via eSubmission Gateway or Web Client. Alternatively 1 DVD or CD-ROM with original signed cover letter is accepted until March 2014.	Dossier requirements for Centrally Authorised Products (CAPs)	File name for submissions via the Gateway or the Web Client: ESUBPXYZ_ESUBPROD_HC000999_Wonderpill_PSUR_0020.zip Submission Type (which is a mandatory field as per eCTD spec): PSUR
		CHMP, PRAC and CAT* Members + Alternates + * where relevant: CAT members, PRAC Independent Scientific experts and CHMP Co-Opted Members	*In case of submission to EMA via eSubmission Gateway or Web Client*: After the acknowledgement from EMA confirming the technical validation of the submission or the Validation Supplementary Information, send **one copy only** in eCTD format to the 'Dossier Delivery Address' of each National Competent Authority specifying the names of the relevant committee members (CHMP, PRAC, CAT - where relevant). *In case of CD/DVD submission to EMA*, send **one copy simultaneously** to the 'Dossier delivery address' of the Rapporteurs. After receipt of the EMA validation letter, send one copy only to all other members.	Dossier requirements for Centrally Authorised Products (CAPs)	

PSUR procedure type	Marketing Authorisation type of the products concerned	Addressees	Submission requirements	Reference document(s)	File name to be used when submitting to EMA
"**PSUSA**" PSUR single assessment of substances contained in centrally authorised product(s) **AND** nationally authorised products (including products authorised nationally in more than 1 Member States and through the mutual recognition and decentralised procedures)	CAP	EMA	eCTD format only via eSubmission Gateway or Web Client. Alternatively 1 DVD or CD-ROM with original signed cover letter is accepted until March 2014.	EURD list cover note, section 5	**See reference document in column E for more details on the file naming convention** File name for submissions via the Gateway or the Web Client: ESUBPXYZ_ESUBPROD_HCxxxxxx_Wonderpill_00000000_Substance_MAH_YYYYMM_psusa_00xx.zip Submission description field in the eCTD envelope for CAPs: substance, psusa/00000000/YYYYMM
	CAP	CHMP, PRAC Members + Alternates + where relevant: PRAC Independent Scientific experts and CHMP Co-Opted Members	*In case of submission to EMA via eSubmission Gateway or Web Client*: After the acknowledgement from EMA, confirming the technical validation of the submission or the Validation Supplementary Information, send **one copy only** in eCTD format to the 'Dossier Delivery Address' of each National Competent Authority specifying the names of the relevant committee members (CHMP, PRAC, CAT - where relevant). *In case of CD/DVD submission to EMA*, send **one copy simultaneously** to the 'Dossier delivery address' of the Rapporteurs. After receipt of the EMA validation letter, send one copy only to all other members.	Dossier requirements for Centrally Authorised Products (CAPs)	

PSUR procedure type	Marketing Authorisation type of the products concerned	Addressees	Submission requirements	Reference document(s)	File name to be used when submitting to EMA
"**PSUSA**" PSUR single assessment of substances contained in centrally authorised product(s) **AND** nationally authorised products (including products authorised nationally in more than 1 Member States and through the mutual recognition and decentralised procedures)	NAP	EMA	eCTD or NeeS format **only** via eSubmission Gateway or eSubmission Web Client.	EURD list cover note, section 5 http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/10/WC500133157.pdf	**Please refer to the reference document (see column E) for more details on the file naming convention** File name for submissions via the Gateway or the Web Client: ESUBPXYZ_ESUBPROD_00000000_substance_MAH_YYYYMM_psusa_00xx.zip Submission description field in the eCTD envelope for NAPs: MAH name, NAP Invented name
	NAP	CHMP, PRAC Members representing the Countries where the products are authorised + Alternates + PRAC rapporteur appointed for the procedure as identified in the EURD list Note: submission to the PRAC Independent Scientific experts and CHMP Co-Opted Members not required	1 submission package in accordance with the national requirements to the 'Dossier Delivery Address' of each National Competent Authority specifying the names of the relevant committee members (CHMP, PRAC, CAT - where relevant). *PSUR sent in eCTD format to EMA* : Send the package after acknowledgement from EMA *PSUR sent in NeeS format to EMA:* Send the package simultaneously	National Competent Authorities (NCAs) and European Medicines Agency (EMA) requirements for submission of PSUR during the transitional period	

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