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EUROPEAN MEDICINES AGENCY

Revamp update

New PI review process, upcoming changes

Stakeholder Platform Meeting – Centralised Procedure

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15 June 2026

REVAMP programme

Assuring the Network's Sustainability

Throughout, collaboration with CHMP, CAT, PRAC, industry & internal EMA stakeholders

end 2022

- WORD versions of key documents in eCTD *Working Documents* folder
- Response template

Oct 2023

- New D80 clinical and non-clinical reports used by Assessors

end 2024

- Completed iMAA CHMP AR/Overview template
- Completed D80 quality report templates

Jan 2025

- Move to co-authoring on SharePoint between Rapp teams (after D82)
- Include quality templates in co-authoring pilot

Mar 2025

- Extension application template updated in line w/ iMAA overview

July 2025

- Quality reports revamped
- (Updated)overview

Nov 2023 => Jun 2026

(co-authoring) Pilot with industry completed

- Applicant completes D80 clinical and non-clinical reports

Enhanced PI review process

Upcoming

EoI template
Generic, hybrid & well-established use **=> enhanced template (with IRIS)**

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PI evolutionary process

Rationale

- No defined process for the review of product information
- **Several versions** circulated (D10, Rap and co-raps) needed to be consolidated
- **No uniform way** (applicant and assessors) on how to reflect and respond to feedback
- **Call for earlier focus** on the product information (especially SmPC)

REVAMP PI focus group formed

EMA Labelling, EMA Therapeutic areas, CHMP members and Other NCA representatives.

‘Evolutionary’ PI process

- **Only 1 ‘MASTER’ version** updated @ each key milestone (D10, D121, D181)

- Harmonised way of commenting for <u>all</u> (Agency and applicants) combining :
  - **Balloons/comment boxes and tracked changes** for self-standing comments
  - **Text boxes** for significant comments
  - **Cross-reference to list of questions/outstanding issues** for responses requiring extensive response/data (no duplication between documents)

- **Applicant’s responses follow the same format and justify non-implementation** of feedback in the ANNOTATED version
  - No separate justification document should be submitted.

Endorsed by CHMP in January 2026

Implemented for procedures starting on May 27th or restarting in May

- *Missed dose*
If the daily dose of Invented name is missed, resume dosing the next day at the prescribed dose.

- Special populations
-
Elderly
In Invented name phase 3 studies, 17 (20.2%) patients ≥65 years of age were treated with Invented name. No overall differences in safety or efficacy of Invented name have been observed between patients 65 years of age and older and younger adult patients. No dose adjustment is required based on age (see section 5.2).

- *Hepatic impairment*
No dose adjustment is required in patients with mild, moderate or severe hepatic impairment (see section 5.2).

Renal impairment
No dose adjustment is required in patients with mild, moderate or severe renal impairment (see section 5.2).

~~*Elderly population*~~
~~In Invented name Phase 3 studies, 17 (20.2%) participants ≥65 years of age were treated with Invented name. No overall differences in safety or efficacy of Invented name have been observed between participants 65 years of age and older and younger adult participants. No dose adjustments are required based on age.~~

Paediatric population
The safety and efficacy of Invented name in children aged below 18 years have not been established. No data are available.

Method of administration

Oral use.
~~Invented name~~This medicinal product ~~should be~~ swallowed whole with a glass of water, on an empty stomach, and at least 1 hour ~~before the~~prior to a ~~next~~ meal.

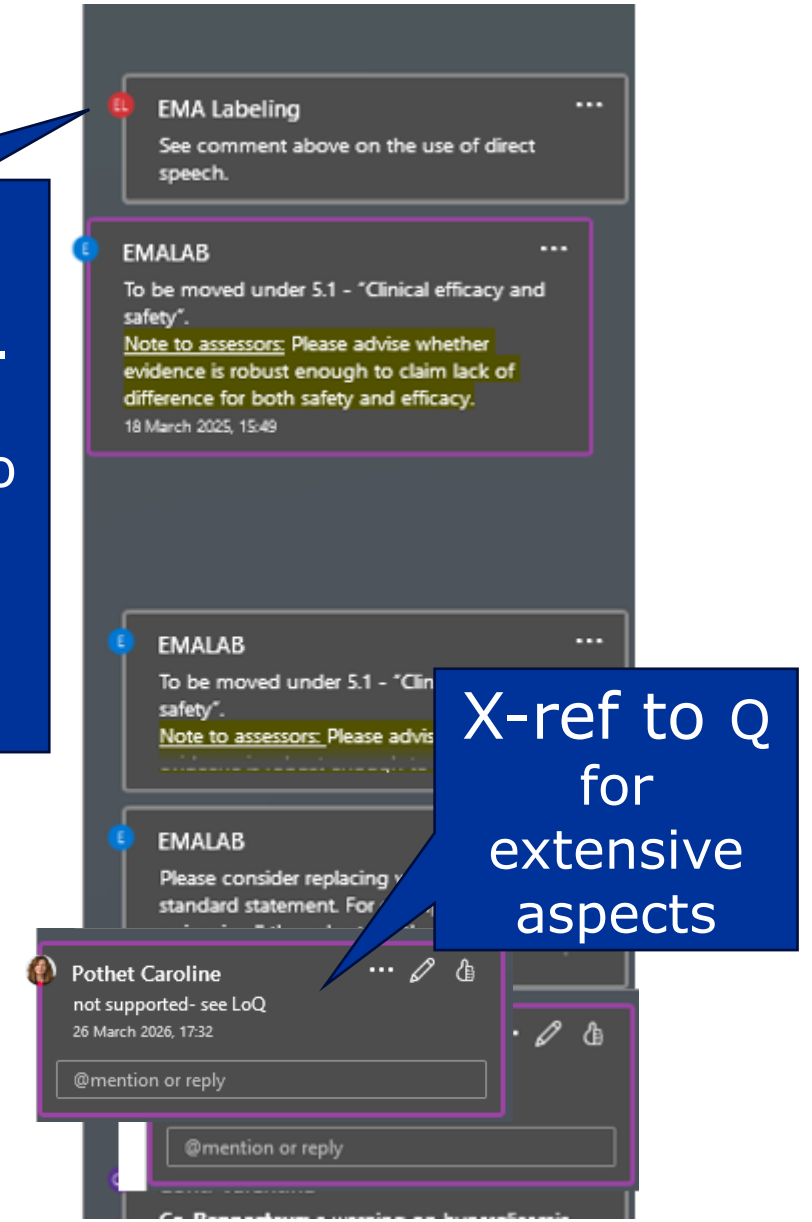
4.3 → Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 → Special warnings and precautions for use

‘comments’: 1. for small changes or 2. to communicate btn parties

Tracked changes for editorial matters



X-ref to Q for extensive aspects

6.3 → Shelf life

30 months

6.4 → Special precautions for storage

Store at or below 25°C.
Excursions permitted up to 30°C.

Co-rapp's comment

The information *"Store at or below 25°C"* cannot be accepted. The *qrd-appendix-template-iii-quality-review-documents-template-human-medicinal-products* does not allow the storage information by the MAH proposed.

The information can be one of the two following options:
a) "Store below 25°C" or
b) "Do not store above 25°C".

In addition, the information "Excursions permitted up to 30°C" is not allowed neither by the current QRD template nor by guidelines. Consequently, it should be deleted.

Heat induction sealed, white high-density polyethylene (HDPE) bottle with white child-resistant polypropylene (PP) closure.

Each bottle contains 60 film-coated tablets and a silica gel dessicant.
Each carton contains one bottle.

Co-rapp's comment

Taking into account that each bottle contains a silica gel dessicant, the following information, should be added:
"Keep the bottle tightly closed in order to protect from moisture"

Applicant's response:

We have implemented the proposed changes, with the addition to protect from light based on the photosensitivity data.

Tranchina Salvatore
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Tranchina Salvatore
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EL EMA Labeling
Not in line with the statements in Appendix III to the QRD template. Please check and amend accordingly.

'Boxes' for aspects requiring some justification (EMA, Rap, co-Raps, now with applicant's response)

NB: important to include the 'originator' of the comments.

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<Date>¶

Responses·to·<D90><D120><D180>·<list·of·questions><list·of·outstanding·issues>·-·<quality<-ASMF>>·<nonclinical>·<clinical>¶

*·more·granular·documents·e.g.·Efficacy,·Safety,·Product·Information·can·be·submitted,·but·at·minimum,·1·response·document·for·each·module·(i.e.·quality,·nonclinical·and·clinical).·Please·make·sure·the·title·of·the·document·is·very·clear·as·regards·the·contents.·Please·ensure·that·the·header·matches·this·title.¶

¶

<Product·name>¶

International·non-proprietary·name·or·common·name:·<INN>·or·<Common·name**>·¶

**eg·for·vaccines·and·some·ATMPs¶

¶

<Pharmaceutical·form·and·strength>¶

¶

Procedure·No.·<EMEA/H/C/XXXX/0000><IRIS·procedure·number>¶

¶

Applicant:¶

¶

Tick·boxes:¶

☐·The·applicant·confirms·that·all·questions·have·been·transferred·into·this·document·without·any·

Guidance in response template

[Prod name] – Responses to <D90><D120><D180> questions - <quality><non-clinical><clinical><etc>

Product information

This section is included to provide guidance on how to present response to questions and/or comments related to the Product Information (PI). However, no response should be reflected here:

*1) Any questions with impact on the PI included in **the quality, non-clinical, clinical, RMP sections of the LOQ/ LOI** should be addressed in these respective sections of this response document. In parallel, the Applicant should include a cross-reference to the relevant question/response number in the annotated version of the amended PI and introduce any consequent PI update proposals directly in both the clean- and annotated version of the amended PI.*

*2) Questions/ comments raised in **text boxes** throughout the PI should be responded to by the Applicant directly in the respective text box of the annotated version of the amended PI, stating "The Applicant´s response: ….". In parallel, the Applicant should introduce any consequent PI update proposals directly in both the clean- and annotated version of the amended PI.*

*3) Questions raised via **comment balloons** throughout the PI should be responded by the Applicant directly in response to the respective comment balloons. In parallel, the Applicant should introduce any consequent PI update proposals directly in both the clean- and annotated version of the amended PI. Any non-implementation or amende proposal should always be justified.*

The clean version and the annotated version (i.e. PI with tracked changes and completed text boxes + comment ballons) should be provided in eCTD module 1.3.1. as well as .doc working documents..

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Upcoming updates to the REVAMP template for initials (with IRIS)

Upcoming ‘REVAMP’ updates to templates

- Targeted sections for **generic/hybrid /well-established use**
- Updated guidance for the CMA/MA under EC section
- Shortened & **refined guidance**
- **Format optimized** (e.g. use of captions, for tables/figures/questions, fixed styles)

Upcoming update – Well-established use

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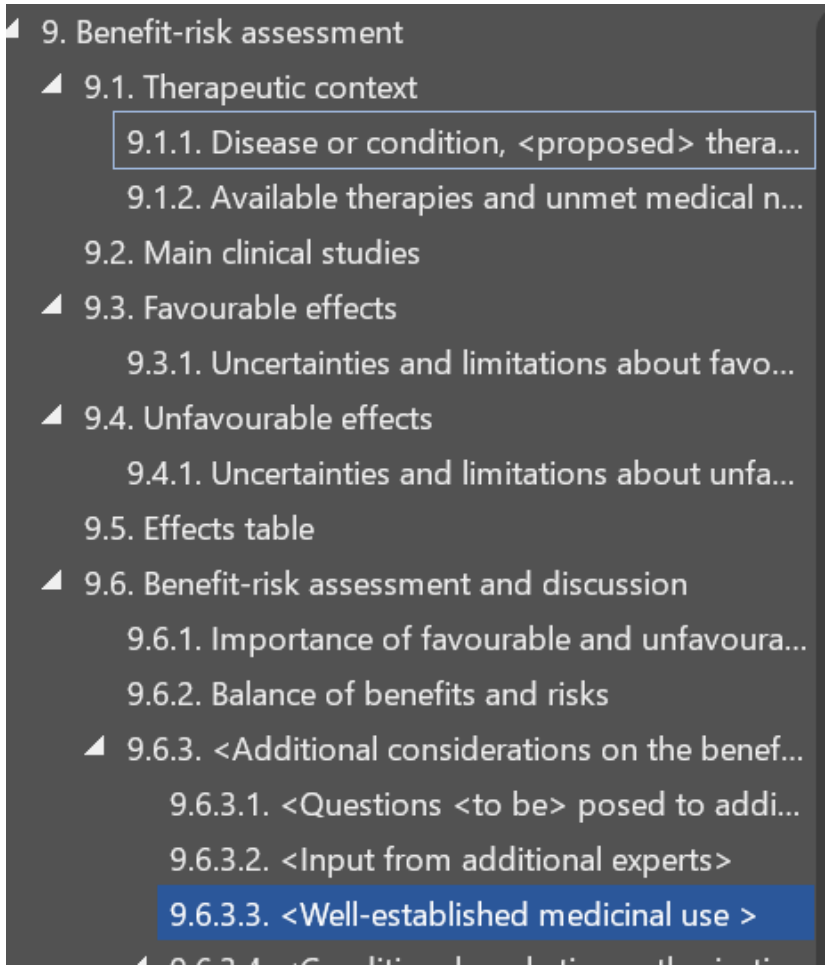


IRIS automation planned: only appears for WEU

9.6.3.3. <Well-established medicinal use >

Only relevant for 10(a) applications relying on well-established medicinal use.

FACTUAL. This section is to be completed by the rapporteur. Co-rapporteur only to add in later stages of the procedure if in disagreement or major omission.

This application was submitted according to the article 10(a) of Directive 2001/83/EC related to well-established medicinal use supported by bibliographical literature. The below provides a summary of whether this application meet the requirements of article 10(a).

a) Factors taken into account to establish a "well established medicinal use":

- Time over which the substance has been used

<Text>. The CHMP therefore considers that it is established that this substance has <not> been used for more than 10 years in the Community.

- Quantitative aspects of use of the substance

<Text>. The CHMP considers that this requirement is <not> fulfilled.

- Degree of scientific interest in the use of the substance (reflected in the published literature)

<Text>.

- Coherence of scientific assessments.

<Text>.

b) The documentation submitted by the applicant does <not> cover all aspects of the safety assessment and include or refer to a review of the relevant literature. All documentation, both favourable and unfavourable have <not> been communicated. c) Particular attention has <not> been paid to <any> missing information and the CHMP considers that adequate justification has been provided by the applicant which demonstrate that an acceptable level of <safety> <and> <efficacy> can be supported although some studies are lacking.

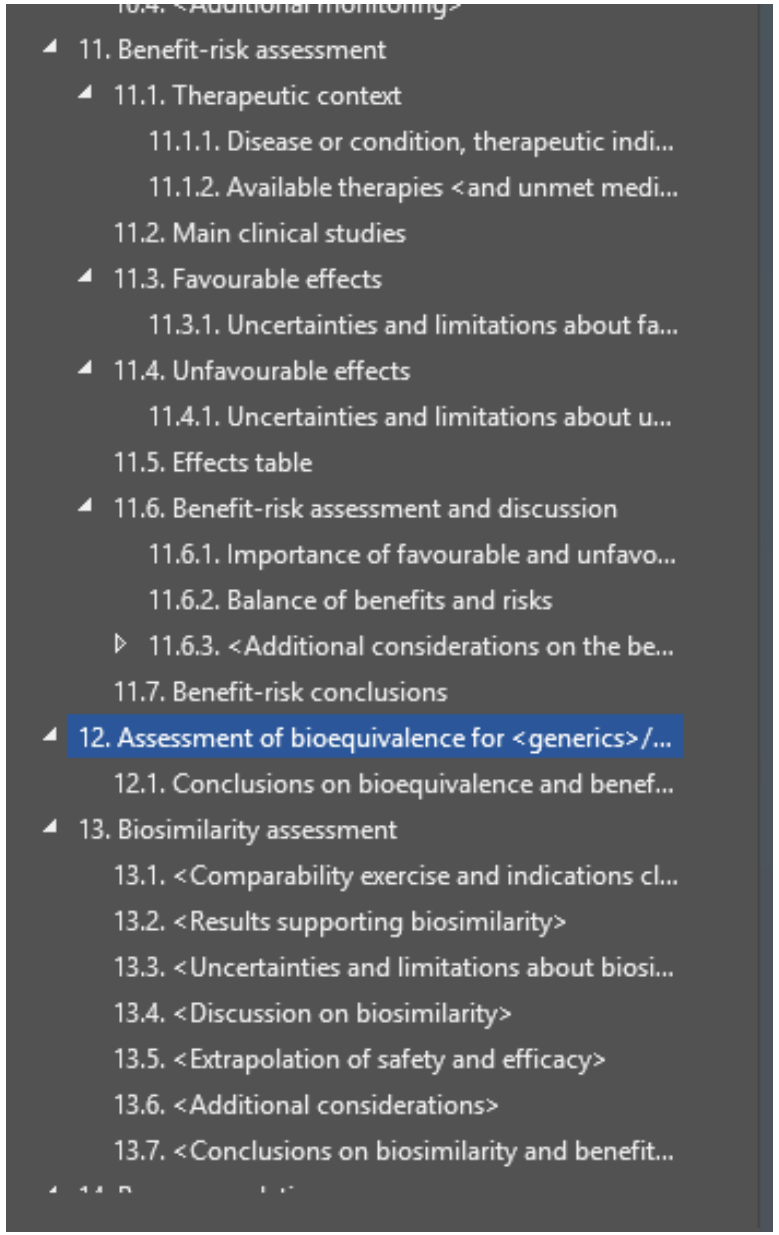
d) The applicant explained the relevance of data submitted concerning the product reviewed in the literature being different from the product intended for marketing.

<Text>.

e) The applicant emphasized that there is post-marketing experience with this active substance as <text>

The requirements for an Article 10(a) application are <not> considered met by the CHMP.

Upcoming update – Generics and hybrids



- Introduction of a new section for assessment of BE replacing B/R section (= biosimilars)

- Inclusion of specific guidance and wording relevant for generics/hybrids

- Adjustment of other sections equally relevant for generic/hybrids (e.g. aspects of development merged with product development, non-clinical aspects, new section for generic/hybrids

IRIS automation planned based on legal basis

Upcoming update – CMA and MAUEC sections

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- No structural change to the REVAMP template, i.e. current standalone sections maintained (applicant's, rationale, conclusion).

- Updated points to consider incorporated as **guidance** (= assessment aid).

- **Re-focus on uncertainties leading to non-comprehensiveness**, i.e. why data are deemed non-comprehensive **and how they are being addressed**.
  => Section title updated to '*discussion on **non-**comprehensiveness*' and standard wording as follows:

In·regards·to·the·request·for·conditional·marketing·authorisation·the·CHMP·considers·that·the·following·uncertainties·also·described·in·the·'uncertainties·and·limitations·sections'·result·in·non-comprehensiveness·of·the·dataset:¶

Other updates

MODIFIED

- **Recommendations** moved to the end of the report (filled in by EMA at opinion)
- **B/R guidance text condensed** to 3-4 bullet points & duplication removed
- Format of effects table (refs column removed)
- **ADR and RMP (final) outcome introduced**

REMOVED

- Executive summary
- **User testing section** (separate report)
- **Repeated sections for questions**
- ‘Co-rapporteur’ effects table
- Reason for quality questions
- **Separate SmPC justification section**
- General instructions moved to internal manuals

CLARIFIED

- How to capture key remaining uncertainties:
  - ‘Which’ in the ‘uncertainties and limitations’ sections
  - ‘How’ (mitigation) in the importance and/or balance sections.

Upcoming REVAMP template for extension of indication (end of Q2-26)

Key features of the EoI template

- No change to the case and procedural management (IRIS)
- ‘Evolutionary’ template developed in line with the REVAMP template for initials & and extension applications
  - Formatting and content guidance
  - Assessment of questions managed in separate reports
- Flexibility maintained for quality and nonclinical
  => ‘light’ Type II template approach
- New guidance for paediatric ‘extrapolation’ approaches

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Thank you

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