EMA
EUROPEAN MEDICINES AGENCY

# EMA regulatory update

# Rapid Fire Session

**Veronika Jekerle**
Head of Pharmaceutical Quality
Human Medicines
European Medicines Agency

swissmedic

# Notified Body Opinions: Findings & Handling by Swissmedic Quality Assessors

CMC Strategy Forum
Basel, 21 October 2025
**Rapid Fire Session with Regulatory Updates**

Ulla Grauschopf, Division Head Quality Assessment, Swissmedic

Dr. R.M. (Martijn) van der Plas
Senior beoordelaar Afd. Kwaliteit

CBG MEB
COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

SAHPRA
South African Health Products Regulatory Authority

# SAHPRA Rapid Fire Updates

CASSS-CMC strategy forum
Basel 20-22 October 2025

MPHAKO BRIGHTON RATLABYANA

MANAGER PHARMACEUTICAL EVALUATIONS
(PRE-REGISTRATION UNIT)

CMC strategy forum
Basel, 21 October 2025

# Rapid Fire Session with Regulatory updates

**Dr. Emmanuelle Charton, Head of Division B,**
**European Pharmacopeia Department**
**EDQM**

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

# EMA regulatory update

# Rapid Fire Session

**Veronika Jekerle**

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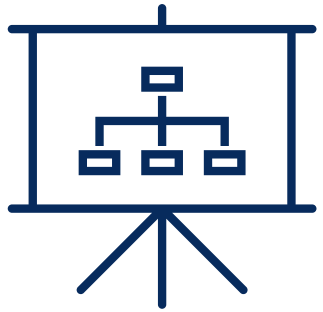
Human Medicines

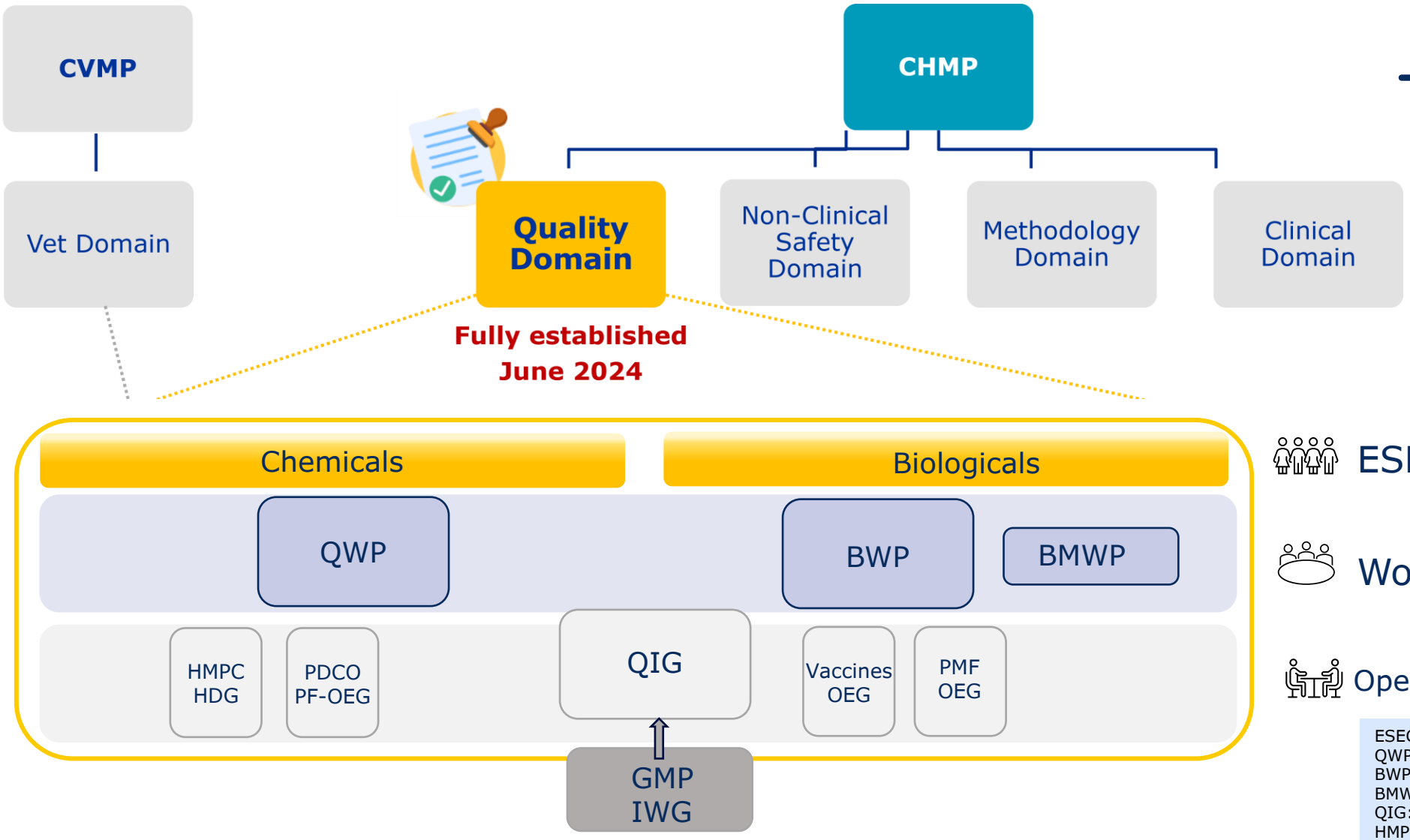
European Medicines Agency

**CASSS-CMC strategy forum**

Basel 20-22 October 2025

# EMA's Quality Domain





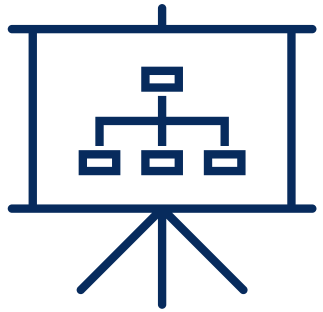

ESEC

Working parties

Operational expert groups

ESEC: European Specialised expert community
QWP: Quality working party
BWP: Biological working party
BMWP: Biosimilar working party
QIG: Quality Innovation Group
HMPC-HDG: Herbal Medicines Drafting group
PDCO-PF-OEG: Paediatric Formulation OEG
PMF OEG: Plasma Master File OEG
GMP IWG: Inspector working group

# EMA's Quality Domain



EU National Competent Authorities

assessment expertise — knowledge — harmonisation

EMA Quality Domain

governance

Chemicals

Biologicals

QWP

knowledge

BWP

BMWP

HMPC HDG

PDCO PF-OEG

QIG

Vaccines OEG

PMF OEG

GMP IWG

ESEC

Working parties

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international observers

ESEC: European Specialised expert community
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# EU pharmaceutical legislation

## New pharmaceutical legislation


**Enabling mechanisms for innovation/CMC**
e.g.
Master files
Personalised medicines
Platform approaches
Decentralised manufacturing
Regulatory sandbox

Variation framework & Annex II
Strengthened pre-submission support

## What will the pharmaceutical sector reform change?

| | |
|---|---|
| **Single Market** | creating a Single Market for medicines |
| **Regulatory framework** | reducing the administrative burden for medicines to reach patients faster |
| **Medicines for all** | ensuring better access to affordable medicines |
| **Medicine supply** | addressing shortages of medicines and ensuring security of supply |
| **Innovation** | promoting innovation and competitiveness |
| **Environmentally friendly** | making medicines more environmentally sustainable |
| **Saving lives** | tackling antimicrobial resistance (AMR) |
| **Transparency** | informing better about public funding used to develop medicines |

# Quality Innovation Group

Share

The Quality Innovation Group (QIG) is an operational expert group set up to support the translation of innovative approaches to the design, manufacture and quality control of medicines, to bring new therapies and help improve the supply of existing medicines to patients.

| | |
|---|---|
| **1st LLFG**<br>**13 March 2023** | Decentralised manufacturing<br>Continuous manufacturing of biologicals or end-to-end continuous manufacturing |
| **2nd LLFG**<br>**12 Oct 2023** | Digitalisation and automation of manufacturing and control |
| **3rd LLFG**<br>**5 June 2024** | **Process models** |
| **4th LLFG**<br>**19-20 Nov 2024** | **Platform manufacturing technologies** |
| **5th LLFG**<br>**8-9 April 2025** | **Personalised medicines** |
| **6th LLFG**<br>**3-5 Mar 2026** | **Innovative technologies to advance sustainability goals in pharmaceutical manufacturing** |

Published meeting reports : case studies, challenges, possible solutions + concrete actions that QIG will take to address the challenges

# Pharmaceutical Process Models

- **Listen & learn focus group (4/5 June 2024)**
- Case studies (diverse models in pharmaceutical manufacturing)

**Discussion points:**

- Model agnostic regulatory framework
- Risk-based consideration → regulatory requirements
- Model classification (low/**medium**/high)
- Model validation
- Documentation
- Lifecycle
  - Preliminary QIG considerations on pharmaceutical process models
  - **QIG breakout session: 18 Nov 2025**

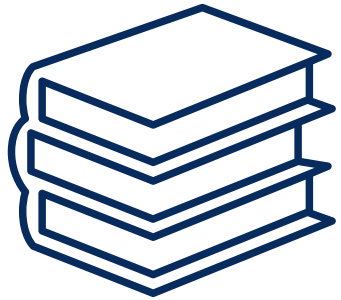

# Platforms

- Listen & learn focus group (19-20 November 2024)
- **Regulators' considerations**: prior knowledge/platform approaches
- **Industry examples**: vaccines, mRNA, gene therapy, continuous direct compression, oligonucleotides


**Discussion points:**

- **Benefits of the platform**: streamlined development, data utility, acceleration
- **Prerequisites:** definition, documentation, data maturity, reproducibility
- Modular approach versus end-to-end
- Product experience & ideal product class
- Lifecycle management

# Resources

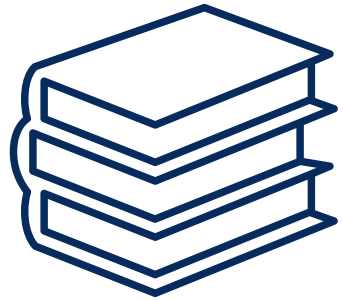


## CHMP/BWP guidance

- Guideline on quality aspects of **RNA vaccines** *(revision for finalisation in 2026)*
- Reflection Paper on tailored clinical approaches for **biosimilar developments** *(revision for finalisation in 2026)*
- Guideline on the development and manufacture of human medicinal products specifically designed for **phage therapy** *(draft in public consultation)*
- Revision of Guideline on **Radiopharmaceuticals Based on Monoclonal Antibody Derivatives** *(awaiting finalisation)*
- Revision of Guideline on **epidemiological data on blood transmissible infections)** *(draft in preparation)*
- QIG Preliminary Considerations on **Pharmaceutical Process Models** *(draft)*
- Guidance to support **new variations framework** (i.e. complex manufacturing, PACMP, PLCM, other)

- **Questions and Answers on BWP learnings**

- ICH Guidance (Q1/Q5C; Q3; Q6; M4Q; Upcoming: Biosimilars, Cell&Gene therapies discussion group, SPQS)



nature reviews drug discovery

nature › nature reviews drug discovery › biobusiness briefs › article

**BIOBUSINESS BRIEFS** | 15 March 2024

# Genome-editing medicinal products: the EMA perspective

By Anna Tavridou, Dolça Rogers, Giada Farinelli, Iordanis Gravanis & Veronika Jekerle

Genome editing technologies such as CRISPR–Cas9 are being developed as therapeutic platforms, especially for monogenic diseases that could be treated by targeting the associated mutations. The first CRISPR–Cas9-based medicinal product, Casgevy (exagamglogene autotemcel), has recently been granted marketing authorization in the European Union for sickle cell disease and β-thalassemia, and a substantial number of other genome-editing medicinal products (GEMPs) are in development.

Nevertheless, the field of GEMPs is still nascent, with very limited scientific guidance available to developers to fit these complex products into existing regulatory frameworks. A recent horizon scanning report by the EU Innovation Network includes initial regulatory considerations, socioeconomical aspects and recommendations to help better understand general challenges and opportunities of genome editing. Developers seeking to market their products in Europe should also make use of tailored support from national competent authorities and the European Medicines Agency (EMA): that is, Innovation Task Force (ITF) meetings, PRIority MEdicines (PRIME) designation and scientific advice (SA). SA – recommendations from the EMA that may aid developers on aspects of the medicine development supporting a marketing

*vaccines*

MDPI

*Opinion*

# Scientific and Regulatory Lessons Learnt on Building a Chemistry, Manufacturing, and Controls (CMC) Package for COVID-19 Variant Vaccine Updates in the EU—A Regulator's Perspective

**Ragini Shivji [1,*], Elena Grabski [2,†] and Veronika Jekerle [1]**

[1] European Medicines Agency, Human Division, Domenico Scarlattilaan 6, 1083 HS Amsterdam, The Netherlands; veronika.jekerle@ema.europa.eu
[2] Division of Infectology, Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, Paul-Ehrlich-Straße 51-59, 63225 Langen, Germany; elena.grabski@pei.de
* Correspondence: ragini.shivji@ema.europa.eu
† EMA Biologics Working Party member.

**Abstract:** During the COVID-19 pandemic, eight COVID-19 vaccines were authorised in the European Union (EU); as a result of emerging SARS-CoV-2 variants and waning immunity, some of these have been adapted to broaden the immunity against circulating variants. The pace at which variants emerge challenges the technical feasibility to make adapted vaccines available in a suitable timeframe and in sufficient quantities. Despite the current absence of a clear-cut seasonal spread for COVID-19, the EU regulatory approach thus far is a pragmatic approach following a pathway similar to that of seasonal influenza. This approach currently requires chemistry, manufacturing, and controls (CMC—the design, development and consistent manufacture of a specified medicinal product of good quality) and non-clinical data (from product laboratory and animal studies), as well as demonstrating that updated vaccines induce an immune response that can predict clinical efficacy and safety in humans. For CMC data, COVID-19 mRNA vaccine adaptations generally made use of the same formulation, control strategy, manufacturing process, and inclusion of registered manufacturing sites for the drug product; therefore assessment was generally streamlined. The experience gained from the vaccine adaptations, combined with a continuous early regulator-developer scientific discussion, permits increasingly greater predictability for timing and positive regulatory outcomes. Here, we review key aspects of the quality control and manufacture of updating COVID-19 vaccines to protect against new variants. Although most experience has been gained with mRNA vaccines, we note that investment in the streamlining of manufacturing processes for recombinant protein vaccines would facilitate future strain updates/adaptations thereby safeguarding availability of different COVID-19 vaccine types, which is considered of value for public health. We also reflect on the challenges and opportunities in establishing more predictable regulatory mechanisms for future COVID-19 vaccine adaptions and more widely for future vaccines containing rapidly evolving pathogens with the potential to cause health threats.

**Keywords:** COVID-19 vaccine; chemistry, manufacturing, and controls; regulatory approvals;

check for updates

**Citation:** Shivji, R.; Grabski, E.; Jekerle, V. Scientific and Regulatory Lessons Learnt on Building a Chemistry, Manufacturing, and Controls (CMC) Package for COVID-19 Variant Vaccine Updates in the EU—A Regulator's Perspective. *Vaccines* **2024**, *12*, 1234. https://doi.org/10.3390/vaccines12111234

Academic Editor: Giuseppe La Torre

Received: 27 June 2024

Drug Discovery Today • Volume 30, Number 9 • September 2025 REVIEWS

ELSEVIER

# Learning from the EMA experience: common CMC deficiencies in marketing authorisation applications over the past decade

**Dolores Hernán Pérez de la Ossa*, Friederike Haas, Robert N. Bream, Evangelos Kotzagiorgis, Klara Tiitso, Veronika Jekerle**

European Medicines Agency, Pharmaceutical Quality Office, Human Division, Amsterdam, the Netherlands

**Here, we present an analysis of major objections (MOs) raised on quality aspects during review of marketing authorisation applications (MAAs) for new medicines via the centralised procedure in the European Union (EU). The review covers a 10-year period by analysing data from 2013, 2018, and 2023. We identify common deficiencies, which should help developers prepare dossiers aligned with EU and global standards and avoid delays to approval of medicines, thereby improving patient access to medicines. The most common deficiencies are correlated with specific product types, recent public health crises, new legal frameworks, and the publication or revision of guidance.**

**Keywords: medicines; marketing authorisation; major objection; quality; deficiencies**

POST-SCREEN (GREY)



EMA

# Reflection paper on a tailored clinical approach in biosimilar development

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 February 2025
EMA/CHMP/BMWP/60916/2025
Committee for Medicinal Products for Human Use (CHMP)

Reflection paper on a tailored clinical approach in biosimilar development

| | |
|---|---|
| Draft for internal consultation agreed by Biosimilar Medicines Working Party[1] | 21 October 2024 |
| Consultation with MWP, BWP and SAWP | 17 January 2025 |
| Adopted by CHMP for release for consultation | <DD Month 2025> |

| | |
|---|---|
| Draft agreed by Biosimilar Medicines Working Party[3] | 12 February 2025 |
| Adopted by CHMP for release for consultation | <DD Month 2025> |
| Start of public consultation | <DD Month 2025>[2] |
| End of consultation (deadline for comments) | <DD Month 2025>[3] |
| Agreed by <Working Party>[3] | <Month YYYY> |
| Adopted by <Committee> | <DD Month YYYY> |

Comments should be provided using this EUSurvey form *(add the link to the form)*. For any technical issues, please contact the EUSurvey Support.

| | |
|---|---|
| Keywords | Reflection Paper, Biosimilar, Comparative Efficacy Study, Tailored clinical approach [4] |

**Scope:** This Reflection Paper discusses the **necessity of CES for demonstration of biosimilarity**. In order to place those reflections into context, the Reflection Paper first considers the current practice with respect to analytical comparability exercises, including *in vitro* pharmacology, and consider their predictive value.

Subsequently, some reflections will be provided with regard to the contribution of CES, and other human in vivo studies, especially PK/PD studies, and to the assessment of immunogenicity.

This Reflection Paper is **not intended to replace current guidance** or current practice with regard to analytical comparability exercises.

 Personal views only - evolving field – may not reflect final view of EMA/CHMP

# Workshop @ EMA 22nd September

## Take home messages

- *Broad support for the principles and main conclusion of the RP*
- *Maintaining high scientific standards while considering a tailored approach is key*
- *To be further reflected upon (either update of RP or subsequent guidance):*
  - *Contents of similarity assessment protocol*
  - *Impurities (esp. process related)*
  - *Statistical approaches for CQAs*
  - *PK studies*
  - *Immunogenicity assessment*

Personal views only - evolving field – may not reflect final view of EMA/CHMP

swissmedic

# Notified Body Opinions: Findings & Handling by Swissmedic Quality Assessors

CMC Strategy Forum

Basel, 21 October 2025

**Rapid Fire Session with Regulatory Updates**

Ulla Grauschopf, Division Head Quality Assessment, Swissmedic

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

Hallerstrasse 7, 3012 Bern
www.swissmedic.ch

# Notified Body Opinions - Status at Swissmedic

- Swissmedic has aligned its authorisation requirements for non-separable (integral and co-packaged) combination products with the revised provisions of the EU-MDR.
- In keeping with Article 117 EU-MDR, a **Notified Body Opinion** must be submitted for **integral medical device components** for which the involvement of a designated conformity assessment body (“Notified Body”) would be required if the device component were to be marketed separately as a CE-marked medical device.

https://www.news-medical.net/drugs/Enspryng.aspx


https://www.enbrel.com/-/media/Themes/Amgen/Enbrel-com/Enbrel-com/Documents/USA-916-83999_ENBREL_SureClick_Injection_Overview.pdf

….. Autoinjectors and pre-filled syringes as „bread and butter“ devices for SC administered parenterals.

**Quality Assessors have to rely on the Notified Body Opinion report during their assessment.**

# Findings

- Late coming NBOs due to limited NB capacity
- **Significant heterogeneity** in the delivered content of NBOs
  - 11 pages versus 120 pages!→ quantity is not everything…but!
  - Unclear descriptions of the device components assessed by the NBO with no/minimalistic link to the submitted drug-device combination product
  - GSPR compliance declared despite obvious data gaps.
  - Biocompatibility, usability and transport validation data missing, incomplete or not applicable to the final version of the device…….
- In some cases, NBO did not cover the **intended use scenario**, eg peninjector required to have a small volume up-titration with device not capable to stay within the required dose delivery limits but NB issued positive opinion because of compliance with ISO11608

**Swissmedic has noticed that in some cases critical deficiencies in the content of the NBO limits its usefulness for the marketing authorisation assessment.**

# How to move forward to improve the situation?

- Sharing of our findings with EMA colleagues, NBs and industry stakeholders
  - Team NB incl. Art 117 working group
  - Planned publication at Swissmedic homepage

- Introduction of a checklist for Swissmedic quality assessors to facilitate the handling of a Notified Body Opinion Report

- Issuing of questions within LoQ to applicants
  - e.g. if scope and clear description of device components in the NBO are missing: "*Please confirm that all device components of the drug-device combination product have been addressed in the NBOp. Please explain and justify any deviations in Module 3. Please request from the NB to include such information in future versions of this NBOp.*"

**→ Industry colleagues to check NBOs prior submission- ask yourself the same questions as we do in Quality Assessment**

Thank You!

# CMC strategy forum
# Basel, 21 October 2025
# Rapid Fire Session with Regulatory updates

**Dr. Emmanuelle Charton, Head of Division B,**
**European Pharmacopeia Department**
**EDQM**

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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# European Directorate for the Quality of Medicines & HealthCare, EDQM

- ★ Part of the Council of Europe
- ★ Founded in **1964**
- ★ European Pharmacopoeia: Partial agreement
  (39 members states & the EU
  + 33 observers)
- ★ Contributes to **public health and access to good quality medicines and healthcare in Europe**
- ★ Wide scope of activities


* EU: European Union; TFDA: Taiwan Food and Drug Administration; WHO: World Health Organization

## Our vision

**Together for better health, for all**

## Our mission

To contribute to public health protection by engaging with an international community of experts and stakeholders

# New Pyrogenicity Strategy
# Suppression of the Rabbit Pyrogen Test

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# Phasing out the Rabbit Pyrogen Test - Communication to stakeholders

Project started, with announcement of the timelines

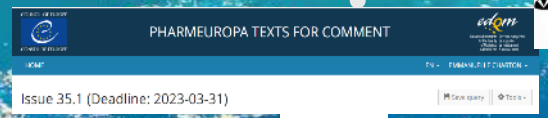
**Strategy paper**

**EDQM 11th edition Conference** EDQM, Strasbourg **(19-21/09)**

**EPAA/EDQM Conference** EU Commission, Brussels **(14-16/02/23)**


**RPT deleted from 57 texts**

2021 | June | 2022 | Sep | 2023 | Jan | Feb | Novem-ber | 2024 | June | November | 2025 | May | 1 July | 1 January 2026


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

**EMA Q&A**

**Chapter 2.6.9 deletedf from Ph. Eur.**

# Save the date! Follow-up EPAA/EDQM event

## 25-26 February 2026 Brussels

https://www.edqm.eu/en/-/save-the-date-joint-edqm-epaa-symposium-pyrogen-testing-2.0-ethical-evolving-and-eco-friendly-implementing-safe-rapid-state-of-the-art-and-sustainable-non-animal-approaches-worldwide-25-26-february-2026

epaa
The European Partnership
for Alternative Approaches to Animal Testing

# Rapid Microbiological Methods

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# Exploring a certification system for rapid microbiological methods

**Identification** of
- ★ Benefits
- ★ Challenges
- ★ Questions re. stakeholder needs (what would be acceptable/not acceptable)

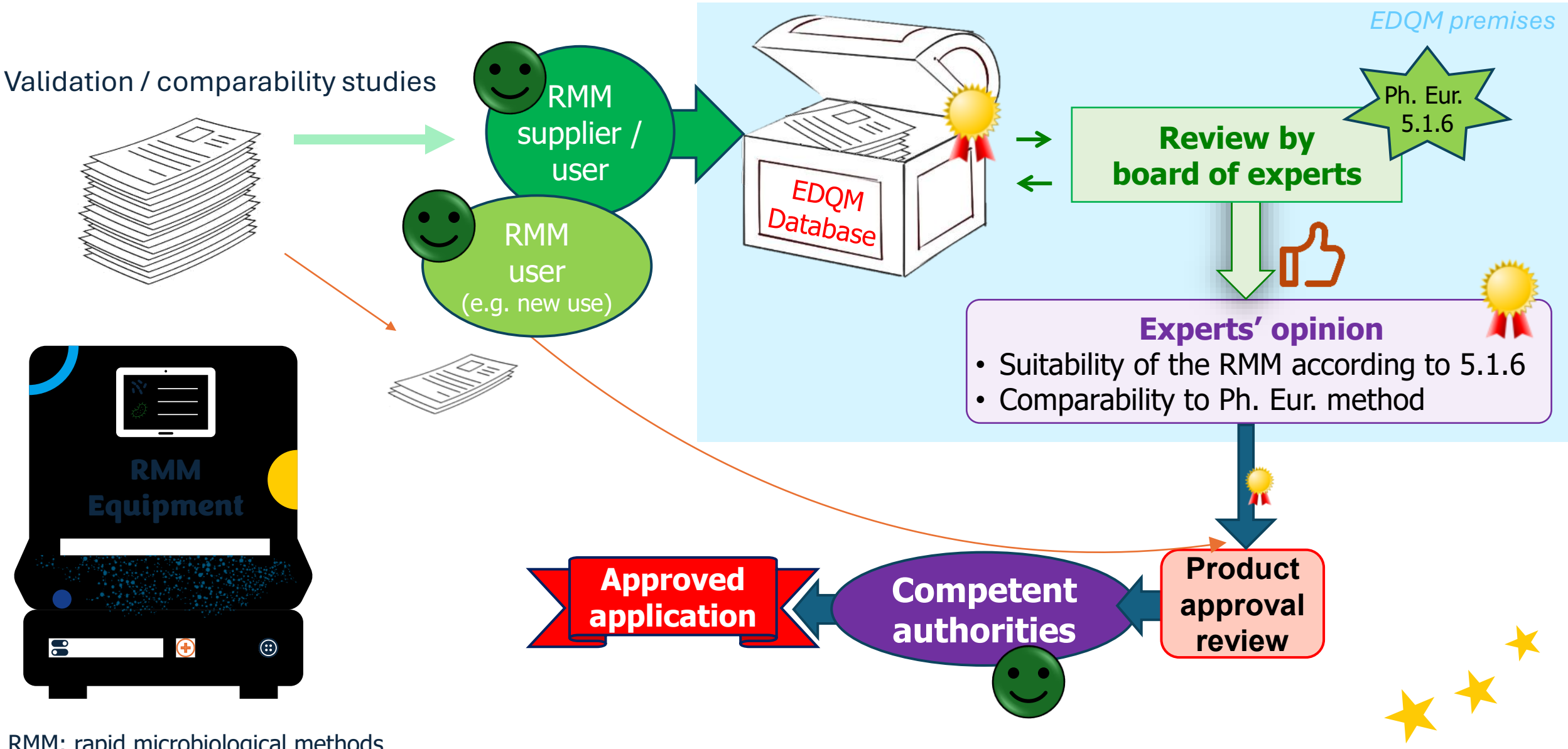
**Concept stage**:
Still lots of questions to address

**Stakeholders feedback**
- ★ Needs
- ★ Embark
- ★ Shape the system

***Regulator workshop***

***Public workshop***

# Exploring a certification system for the validation and comparability of RMM




RMM: rapid microbiological methods

# Take away message: The EDQM is…

- …participating in the establishment of **innovative approaches to QC** of medicines in Europe
- … **listening** to its **stakeholders** to help shaping up these approaches
- …facilitating the **regulatory framework** in Europe **and beyond** by the establishement of standardised approaches
- …. promoting **globalisation** of these approaches

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SAHPRA
South African
Health Products
Regulatory Authority

# SAHPRA Rapid Fire Updates

## CASSS-CMC strategy forum
## Basel 20-22 October 2025


MPHAKO BRIGHTON RATLABYANA

MANAGER PHARMACEUTICAL EVALUATIONS
(PRE-REGISTRATION UNIT)

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# South African Health Products Regulatory Authority (SAHPRA)

- Population ~ 62 million
- HQ in Pretoria-Capital city
- 2 Regional offices (Durban and Cape-Town)
- ~400 staff members


SAHPRA
South African
Health Products
Regulatory Authority

# Background information

- Work sharing initiative in SADC (medicines assessments and GMP inspections)
- Founded in October 2013 by 4 countries


- SAHPRA joined the initiative in 2016
- Triggered by common challenges
  - -Huge backlogs & Long registration times
  - -High staff turnover
  - -Limited capacity to assess certain types of products e.g biologicals
  - -Inadequate financial resources

SAHPRA
South African Health Products Regulatory Authority

OCTOBER 2023

# 10 years on…Where are we?

Since 2013

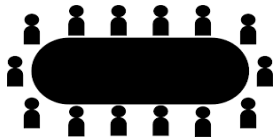
2| meetings/Year of Heads of Agencies (HOA)

≠17

Training Sessions

31 (face to face) + 13 (virtual sessions)=44

# of Assessment Sessions: 4|year



74

Manufacturers inspected for GMP compliance: 4 schedules |year

11| Average # of products per session

ZAZIBONA

56% vs 20% vs 24%

Positive | Negative | Withdrawn

409 Products.

SAHPRA South African Health Products Regulatory Authority

# AFRICAN MEDICINES AGENCY

AMA a Specialized Agency of the African Union (AU) dedicated to improving access to quality, safe and efficacious medical products in Africa through regulatory harmonisation and systems strengthening.

The AMA Treaty was adopted by the AU Assembly on 11 February 2019 and came into force on **5th Nov 2021.**

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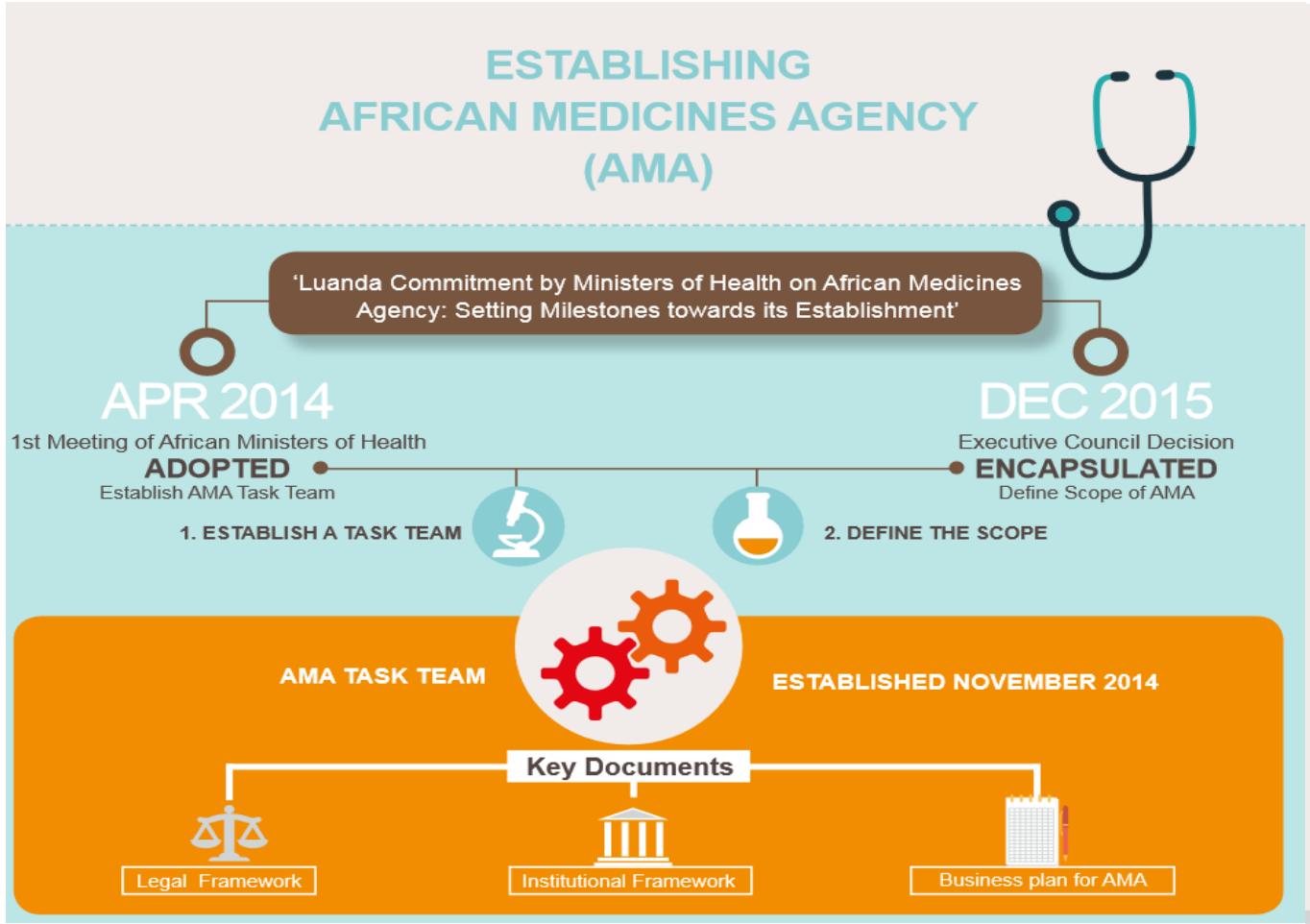
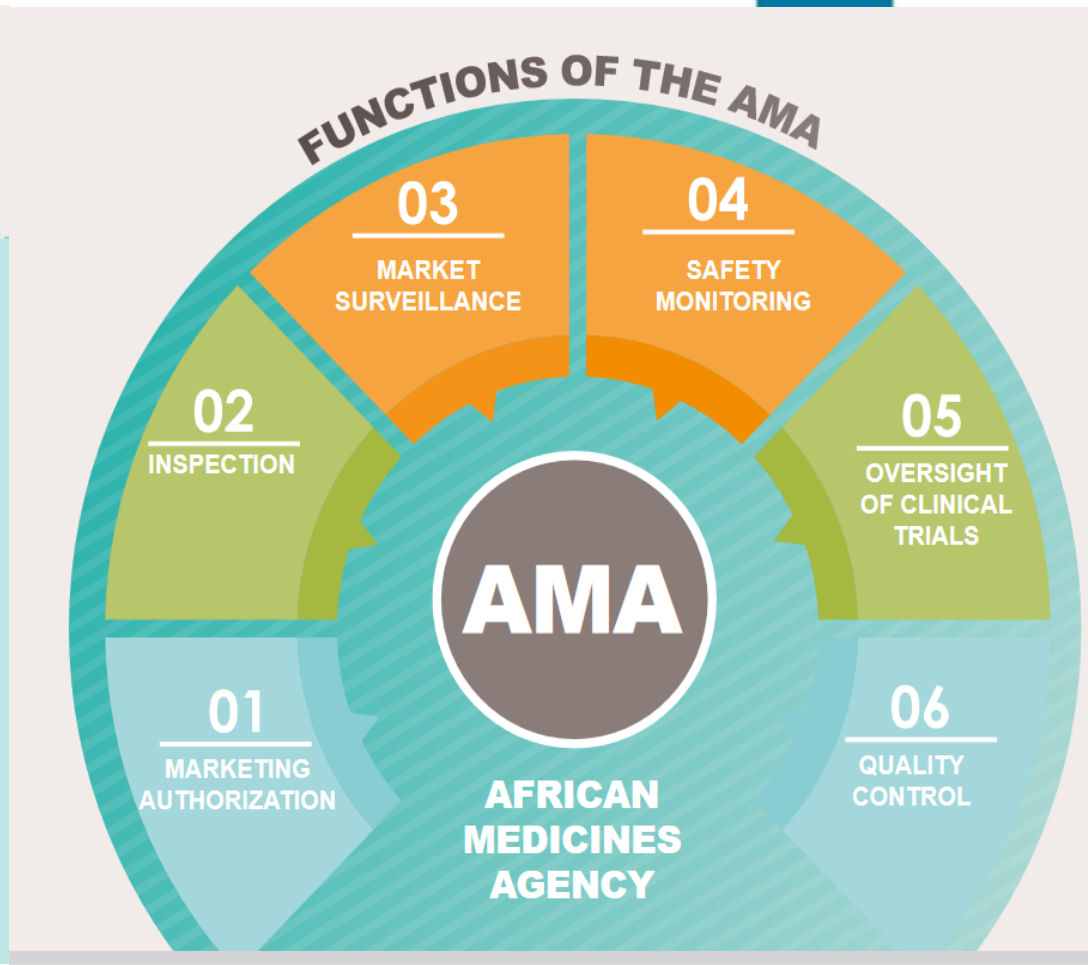
South African Health Products Regulatory Authority

# AFRICAN MEDICINES AGENCY

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South African Health Products Regulatory Authority

https://www.nepad.org/publication/ama-inforaphics

# TYPES OF APPLICATIONs IN THE CONTINENTAL PILOT

- 09 Biological Products (3 Vaccines)
- 2 New Chemical Entities
- 10 Multisource Products manufactured in the Continent

3 of the Biological products were withdrawn thus proceeded with 21 applications

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# CURRENT STATUS/ KEY ACHIEVEMENTS

- From the 21 applications
- 10 Continentally Listed as of July 2025
- All remaining applications are in the final cycle 3

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# Role of SAHPRA

- Chair AMRH Steering committee
- Chair GMP Technical Committee
- Chair EMP Technical committee of biological and vaccines
- Participate actively in EMP TC.
- Participate actively in BABE TWG.
- Participate actively in other supporting TC’s.
- Contribute to pool of continental assessors and GMP inspectors.

SAHPRA
South African
Health Products
Regulatory Authority

# Panel discussion

Dr. R.M. (Martijn) van der Plas
Senior beoordelaar Afd. Kwaliteit

CBG MEB
COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Ulla Grauschopf, Division Head Quality Assessment, Swissmedic

Schweizerisches Heilmittelinstitut
Institut suisse des produits thérapeutiques
Istituto svizzero per gli agenti terapeutici
Swiss Agency for Therapeutic Products

Hallerstrasse 7, 3012 Bern
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Thank You!

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

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Acknowledgement to:
Zanele Xaba-Zazibona Focal person
Aseza Matolengwe-AMA focal person
Alex Juma Ismail-AUDA NEPAD RSS

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MANAGER PHARMACEUTICAL EVALUATIONS
(PRE-REGISTRATION UNIT)

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Dr. Emmanuelle Charton, Head of Division B,
European Pharmacopeia Department
EDQM

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# Revised variation classification GL: main changes

## Procedural part

- **Operational details shifted** to EMA/CMDh guidance for **easiest updates** in the future.
- **Change the current code system (numbering)** to facilitate the implementation of the new framework

## A. Administrative variations

- Reduction/simplification list from 8 to 5 scopes.

## B. Quality variations

**Review of all categories:**

- **Downgrade** certain scopes when scientifically justified (risk/based approach).
- **Removed conditions of biological** medicinal products in certain circumstances allowing a Type IA variations.
- **Implementation of PACMP** as Type IB or Type IA also for BIO.
- **Alignment** and **consistency** between Chemicals and Biologics where appropriate
- New section on **In-house reference preparations.**
- New scopes for **Medical devices** in line with MDR.

## C. Safety, Efficacy, PhV variations

- **Deletion** of scopes (C.I.9, C.I.10, as now done via Art. 57 database).
- C.I.3 **expanded to include** implementation of **PRAC signals** and **joint recommendations of EU authorities.**
- New scope for submission of **results** of assessments carried out on **target patient groups**.

## D. PMF

- Reduction/simplification list from 23 to 16 scopes.

entry into force 15 Jan 2026

# Questions and answers for biological medicinal products

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## Page contents



*Updated on 16 June 2025:*
*'Raw materials and media components (3.2.S.2.3)' section*

This question and answer page is developed and maintained by the CHMP Biologics Working Party (BWP) and provides agreed positions by the Biologics Working Party position on issues that can be subject to different interpretation or require clarification, typically arising from discussions or correspondence during assessment procedures of biological human medicinal products.

In order to obtain information on a topic, please click on the topics/questions. Please note that this page has been produced to provide transparency and additional information, and should be read in conjunction with the European Pharmacopoeia, CHMP guidelines on quality and other guidance documents.

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