# Optimizing the regulatory procedures

## factsheet

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better access. better health.

# Optimizing the regulatory procedures

factsheet

## Problem Statement

Each medicine, before reaching the patient, needs to be approved by competent authorities. The regulatory framework of Marketing Authorisation (MA) is critical to achieve the twin objectives of timely patient access to medicines and assuring the sustainable long term development of the industry to meet patient needs in the future. The current system of MA is built on two main pillars: the Centralised Procedure (CP) when the assessment is led/ coordinated by the EMA; the Decentralised Procedure (DCP) when the assessment is led by the Reference Member State (RMS).

## Issues

From the perspective of 50 years of pharmaceutical legislation, enormous progress has been made to achieve better quality, safety and efficacy of medicinal products. Significant effort has been made to build a strong European regulatory structure and harmonised European standards. However, the **current regulatory systems and their implementation do not always support the objectives of timely access and operational efficiency**. The weakness of the current system has been recognised and the revision of the MA framework has been announced in the Pharmaceutical Strategy:
*A study[1] on the authorisation and monitoring of medicines for human use will inform the evaluation of the regulatory framework to simplify and streamline procedures and reduce costs.*

Although the outcome of the study is pending (to be published in 2021), Medicines for Europe recommends some improvements to the operational aspects of EU marketing authorisation procedures to facilitate timely access to generic and biosimilar medicines[2].

(1) Study on the experience acquired as a result of the procedures for authorisation and monitoring of medicinal products for human use – to be published in 2021.
(2) For deeper diagnosis of the current MA system, its weak and strong points and several detailed proposals for improvement, please refer to Medicines for Europe Regulatory Efficiency Report

# Policy recommendations

## Centralised MA procedure

**The Centralised Procedure (CP) was not designed with generic and biosimilar medicines in mind, leading to some cumbersome and constraining steps for those medicines** (i.e. duplicate MAs due to use patents, naming policy, eligibility etc) This has limited the use of the CP by generic manufacturers compared to DCP applications. While the CP procedure is mandatory for biosimilar medicines and optional for generic medicines, these constraints have limited the appeal and therefore the optimal use of the CP for patient access.

### Recommendations to remove the limitations of the Centralised Procedure for generic and biosimilar medicines

- Reinterpret the eligibility criteria to broaden access to generic medicines.
- Address the inflexibilities that have limited generic medicine applications fully utilising the Centralised Procedure.
- Address the issue of brand naming of duplicates agreed on use patent grounds to allow patient access to medicines in the cross-border healthcare setting and to avoid market hurdles at the expiry of patents.

## Decentralised Procedure (DCP)

The Decentralised Procedure is the main route for registering generic medicines in Europe. Over 85% of the medicines being registered in Europe through DCP every year are generic medicines. Therefore it is crucial to focus efforts on further improving this route to make these important medicines more widely and quickly available to patients and providing the value which sustains the EU healthcare systems.
Several suggestions have been made to **optimise the Decentralised** procedure for the regulatory approval of new generic medicines[3]. The objectives of the proposed solutions are to **streamline procedures, eliminate unnecessary duplications** of approvals and enable rapid **reaction to patients' needs in new countries**. These improvements would more closely reflect the operation of the generic medicines industry and more importantly give the possibility to respond faster to patient and market needs.

(3) For detailed proposals on simplification of the DCP, please refer to Medicines for Europe Regulatory Efficiency Report

## Recommendations to address weak points of the DCP (i.e. Repeat Use Procedures (RUP) in extending MA to new countries and meeting patient needs. timelines, duplications and inefficiency etc)

Refreshing the Decentralised Procedure by introducing "Backbone DCP"- inspired by the Centralised Procedure, where there would be a single harmonised assessment involving a rapporteur and co-rapporteur, endorsed by CMD(h).

Another option: "Basket DCP" - Member State assessing a "full package/basket" of elements for a given product; with the Marketing Authorisation Holder choosing a tailored option for MA in each Member State.

**Other areas for simplifications:**

- Variations (addressed in the Pharma Strategy separately as an area for improvement and digitalisation)
- Assessment of the documentation for the active substance, used by multiple manufacturers of the finished medicinal products (addressed in the Pharma Strategy separately as an area for improvement)
- Further optimisation of the pharmacovigilance

  The digitalisation of the MA processes - switching from a document-based processes towards the submission, management and evaluation of structured data via a two-way common EU Regulatory submission gateway. Regulator data submitted once, as structured data and in one format only and reused by the authorities for various purposes