European Commission

Update: pilot project 'Market Launch Intentions of Centrally Authorised Products'

88th Pharmaceutical Committee
2 July 2020

Health and Food Safety

European Commission

Ad-hoc WG 'market launch of Centrally Authorised Products'

Issues of accessibility and availability of CAPs, due to:

- delayed market launches
- staggered roll-out of medicinal products
- decision to market in limited number of countries

Focus of ad-hoc WG:

- Marketing intentions – Are companies willing to provide information on their marketing intentions? How: Launch of pilot project on market launch intentions for some CAPs.

- Actual marketing - Can information transparency pressure MAHs to market their products in more countries? How: Creation of interim IT tool tracking marketing status information for all CAPs

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Pilot project 'Market Launch Intentions of Centrally Authorised Products'

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Targeted stakeholder consultation on the pilot project 'Market Launch Intentions of Centrally Authorised Products'

Period of consultation

22 June to 22 July 2020 (12.00 CET)

Targeted stakeholders

Marketing authorisation holders and companies/businesses involved in the application for marketing authorisation of centrally authorised medicinal products for human use (CAPs) to the European Medicines Agency. Comments from small and medium-sized enterprises (SMEs) are particularly welcome. Comments from any other interested party are welcome.

Objective of the consultation

In the EU, a medicinal product can be placed on the market after it has received a marketing authorisation. A centralized marketing authorisation granted by the European Commission is valid throughout the EU, allowing the marketing of the medicinal product in all Member States. However, in practice, there are still important differences as regards when (if at all) a newly (centrally) authorised medicine is made available in each EU Member State.

The lack of availability of medicinal products in many Member States, particularly in those with smaller population sizes, is a general concern that has also been highlighted in the roadmap of the recently published EU Pharmaceutical Strategy. It poses a particular challenge to the underlying principle of the centralised authorisation procedure. This procedure was designed to serve wide availability to patients and healthcare professionals throughout the EU by allowing marketing authorisation holders to commercialise authorised medicinal products in each Member State based on a single marketing authorisation.

Consultation document:
Pilot project description and template of 'Market Launch Intentions'

Period of consultation:
22 June – 22 July 2020

SANTE website
https://ec.europa.eu/health/medicinal_products/consultations/centrallyauthorisedproducts_en

EMA website
https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines

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Thank you.

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