EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH
AND FOOD SAFETY

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Pilot project 'Market Launch of Centrally Authorised Products'

1. Context and objectives

The Pharmaceutical Strategy for Europe[1] highlights the importance of patients' access to medicines. Innovative and promising therapies do not always reach the patient, so patients in the EU still have different levels of access to medicines.

Companies are not obliged to market a medicine in all EU countries; they may decide not to market their medicines in one or more countries. This can be due to various factors, such as national pricing and reimbursement policies, size of the population, the organisation of health systems and national administrative procedures resulting in smaller and less wealthy markets in particular facing these problems. Furthermore, due to operational limitations, smaller pharmaceutical companies may be unable to launch a newly authorised medicinal product in all Member States.

It is a particular challenge to the underlying principle of the centralised authorisation procedure. This procedure allows marketing authorisation holders to market medicinal products and make them available to patients and healthcare professionals throughout the EU based on a single marketing authorisation.

While Member States are mostly concerned by the issue, both the European Commission and the European Medicines Agency (EMA) have an important stake in this discussion due their role in the marketing authorisation process for centrally authorised products and the link to certain provisions in the EU legislation.

In the Pharmaceutical Strategy, the Commission has committed to initiate a pilot together with the EMA and Member States, with the engagement of future marketing authorisation holders, to better understand the root causes of deferred market launches for centrally authorised products. This action is supported by the Human Pharmaceutical Committee.[2]

The pilot's overall objective is to **improve regulators' knowledge of the planned marketing of centrally authorised medicinal products (CAPs) and on the reasons behind delayed market launch by engaging with prospective marketing authorisation holders**

[1] Pharmaceutical Strategy for Europe, COM/2020/761 final
https://ec.europa.eu/health/sites/health/files/human-use/docs/pharmastrategy_com2020-761_en.pdf
[2] 86th meeting of the Pharmaceutical Committee, 12 March 2020
https://ec.europa.eu/health/sites/health/files/files/committee/ev_20200312_sr_en.pdf

through voluntary sharing of their marketing intentions for specific types of CAPs in the pre-authorisation phase.

Prospective marketing authorisation holders participating in this pilot will be sharing this information on a confidential basis. The Commission and the EMA took the adequate steps to ensure that the information collected will be well secured and used for the purpose of the pilot project only.

The pilot is based on a voluntary declaration of market launch intentions and on the engagement of stakeholders from the public and private sector to address the long-standing problem of unequal availability and delayed market launches of medicines. The decision to make a medicinal product available in each country is not only dependent on marketing authorisation holders' marketing intentions or ability to market. It is also affected by other factors, namely:

> Therapeutic area: Not all therapeutic areas are conducive for an EU wide launch. For instance, the specificities of ATMPs, as cell and gene therapies, target often areas of lower disease prevalence, and require specialised medical staff and infrastructure, which may not always be available in all Member States or may need to be established first.
>
> Introduction into the health system, pricing and reimbursement decisions: The heterogeneity of pricing and reimbursement procedures in each Member State are reported as factors having an impact on companies' commercial decision-making and operational restrictions.

While fully acknowledging these factors, there is value in collecting data on companies' market launch intentions to better understand the root causes and contextual factors influencing the uneven market launch and availability of medicinal products in the Member States.

Results may inform other actions under the Pharmaceutical Strategy for Europe.

2. Method

Requesting marketing authorisation applicants for CAPs covered by the pilot to declare, on a voluntary basis, their planned market launch intentions will provide further knowledge base to DG SANTE, the European Medicines Agency and national competent authorities on the planned rollout of the medicinal products undergoing a marketing authorisation application. It will also allow comparing the intended market launch, as provided by the applicant, with the actual marketing situation in the Member States. Information provided by companies on a voluntary basis about the reasons for the non- or delayed launches would help analyse the situation and understand the impacts of such decisions on the one hand for companies and on the other hand on the Member States' markets.

3. Medicinal products covered

The medicinal products covered by the pilot concern **orphan and oncology medicines in the context of newly submitted centralised applications, as well as centralised applications under assessment.** These products were identified given their link to unmet needs in the EU and to areas of high public health interest.

4. Definitions

Market launch - the placing of the medicinal product on the market of the declared Member State.

Placing on the market - the date of release into the distribution chain in the course of a commercial activity[3] (e.g. products provided under compassionate use or a named-patient basis are not considered to be placed on the market).

5. Key questions and outcome measures

i) Are companies willing to provide information to the competent authorities on their marketing intentions for the relevant products?
Outcome measure: submission of template of 'Market Launch Intentions': Yes / No

ii) What is the average intended EU market coverage declared by the participating companies?
Outcome measure: average number of countries where the MAH intends to market the medicinal product concerned.

iii) What is the average time of market launch declared by the companies?
Outcome measure: average time between granting of marketing authorisation and declared intended market launch in all MSs or in individual Member States.

iv) What is the underlying reasoning behind the company's intention to not market or delay the launch of a medicinal product in specific countries?
Outcome measure: qualitative analysis of the free text entry "Remarks on market launch intentions" included in the template.

v) To what extent do the intended launch plans correspond to the actual marketing in the Member States?
Outcome measure: comparison between declared marketing intentions and actual marketing as reported to EMA according to Art 13(4) of Regulation (EC) No 726/2004.

6. Timelines and data collection methodology

In the framework of the usual application process, marketing authorisation applicants will be requested to submit information on the planned market launch by means of the EU Survey tool, in the following two timelines, as applicable:

- For new marketing authorisation applications – at time of submission of the application
- For ongoing applications – at time of CHMP opinion.

Additional practical guidance on how and to whom to submit the information will be provided to applicants, before the pilot is initiated.

[3] Consistent with Article 2(1) of Regulation (EC) No 765/2008 which clarifies that "making available on the market' shall mean any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge."

The template of 'Market Launch Intentions'[4] (Annex 1) includes the following information elements to be provided by marketing authorisation applicants:

a) Identification of the marketing authorisation applicant;
b) Identification of the medicinal product and its active substance;
c) Member States in which the company intends to market the product;
d) The envisioned timing of market launch per country; and
e) Remarks on market launch intentions.

7. Duration

The pilot project shall run for a total period of 18 months, from 25 March 2021.

8. Analysis and reporting

Upon completion of the data collection and analysis, the results and lessons learnt from the pilot project will be published by the European Commission, based on aggregated data and fully respecting the confidentiality principle.

9. Confidentiality

The European Commission and the European Medicines Agency will respect the confidentiality of information and data obtained in carrying out this pilot in order to protect any commercially confidential information that might be received. The information is collected for the sole purpose of the pilot project 'Market Launch of Centrally authorised products.' The European Commission together with the EMA have implemented the required data governance procedures to ensure confidentiality of the data shared by prospective Marketing Authorisation Holders. The information will not be publicly disclosed but may be published in aggregated form as regards the results of the pilot, without reference to individual products or companies. Member States will be informed through the Human Pharmaceutical Committee about interim and final results of the pilot.

The information provided in the context of this pilot project is without prejudice to the legal obligation of marketing authorisation holders under Article 13(4) of Regulation (EC) 726/2004.

[4] The template was programmed in EU Survey for the purpose of the pilot project. Note: there are slight formatting changes in the online version of the template.

Annex 1

Centralised Marketing Authorisation Application

Market Launch Intentions

Name of Company applying for marketing authorisation:

Applying on behalf of an SME: Yes or No
Active substance (INN):

Proposed (invented) name of the medicinal product:
Oncology medicinal product ☐ Orphan medicinal product ☐

EMA application number:

Stage of marketing authorisation application:
Initial submission ☐ CHMP opinion ☐

1. The applicant is asked to outline its market launch intention in the EU/EEA as regards the above-mentioned medicinal product.

EU Member State / EEA Country	**Market launch is intended**		**Year of intended market launch**	**Launch intended in 1st or 2nd half of the year**	
	Yes	**No**		**1st half**	**2nd half**
Austria	☐	☐	Choose year	☐	☐
Belgium	☐	☐	Choose year	☐	☐
Bulgaria	☐	☐	Choose year	☐	☐
Croatia	☐	☐	Choose year	☐	☐
Republic of Cyprus	☐	☐	Choose year	☐	☐
Czech Republic	☐	☐	Choose year	☐	☐

Denmark	☐	☐	Choose year	☐	☐
Estonia	☐	☐	Choose year	☐	☐
Finland	☐	☐	Choose year	☐	☐
France	☐	☐	Choose year	☐	☐
Germany	☐	☐	Choose year	☐	☐
Greece	☐	☐	Choose year	☐	☐
Hungary	☐	☐	Choose year	☐	☐
Iceland	☐	☐	Choose year	☐	☐
Ireland	☐	☐	Choose year	☐	☐
Italy	☐	☐	Choose year	☐	☐
Latvia	☐	☐	Choose year	☐	☐
Liechtenstein	☐	☐	Choose year	☐	☐
Lithuania	☐	☐	Choose year	☐	☐
Luxembourg	☐	☐	Choose year	☐	☐
Malta	☐	☐	Choose year	☐	☐

Netherlands	☐	☐	Choose year	☐	☐
Norway	☐	☐	Choose year	☐	☐
Poland	☐	☐	Choose year	☐	☐
Portugal	☐	☐	Choose year	☐	☐
Romania	☐	☐	Choose year	☐	☐
Slovakia	☐	☐	Choose year	☐	☐
Slovenia	☐	☐	Choose year	☐	☐
Spain	☐	☐	Choose year	☐	☐
Sweden	☐	☐	Choose year	☐	☐

2. In case you have selected “Market launch is NOT intended” or “After 2025” at least once, please state the potential barriers to launching medicinal products, preferably in order of importance, mentioning the countries for which they apply.

(Max 800 characteres)

3. From a policy perspective, please provide feedback on how market launch can be improved and what would be helpful for regulators to further consider.

(Max 800 characteres)

4. Please state the name and surname of the person filling in the template. [text box]

I hereby declare that the information provided is truthful to the extent of the applicant's knowledge at the time of submission. [check box]

Confidentiality of the information provided

The European Commission and the European Medicines Agency will respect the confidentiality of information and data obtained in carrying out this pilot in order to protect any commercially confidential information that might be received. The information is collected for the sole purpose of the pilot project 'Market Launch Intentions of Centrally authorised products. The information collected will be handled as described in the pilot project description.

Although the information will not be publicly disclosed, it may be published in aggregated form in a report summarising the results of the pilot, without reference to individual products or companies.

The information provided herein is without prejudice to the legal obligation of marketing authorisation holders under Article 13(4) of Regulation (EC) 726/2004.