Pilot project 'Market Launch Intentions of Centrally Authorised Products'

1. Context and objectives

There are still significant differences in the timing of availability of new medicines among EU/EEA Member States and inequalities in access to (innovative) medicines.

The lack of availability of medicinal products in several Member States, particularly those with smaller population size, is a concern in general that has also been highlighted in the roadmap of the recently published EU Pharmaceutical Strategy. 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.

In order to increase availability of centrally authorised medicinal products (CAPs), the Human Pharmaceutical Committee has welcomed the consideration of actions, which could help improve company engagement for a wider roll-out of CAPs. In this context, the Pharmaceutical Committee agreed to initiate a 'pilot project' on Market Launch Intensions of Centrally Authorised Products.'

The pilot's overall objective is to improve regulators' knowledge of the planned marketing of CAPs and on the mechanism behind delayed market launch by engaging with prospective marketing authorisation holders 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.

There is value in collecting data on companies' market launch intentions to better understand the root causes and contextual factors influencing the uneven availability of medicinal products in the Member States. To illustrate this with an example, it is possible that a smaller pharmaceutical company is unable to launch its newly authorised medicinal product in all Member States due to operational restrictions. It is equally possible that the specific therapeutic area where the medicine is used is not conducive to an EU wide launch. As a result, those companies' market launch strategies must be adapted accordingly. In addition, 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 also relies on the pricing and the reimbursement negotiation processes in each Member State. Nonetheless, this pilot project aims to capture the companies' market launch intentions knowing that other decision-makers will still influence the final marketing outcome.

The pilot project aims to collect structured data through a template of 'Market Launch Intentions' to provide a better understanding of the issue to decision-makers. Results may inform other actions under the Pharmaceutical Strategy for Europe.

2. Objective

Requesting marketing authorisation applicants for CAPs 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 roll-out of the medicinal products undergoing a marketing authorisation application. It will also allow to compare the intended market launch, as provided by the applicant, with the actual marketing situation in the Member States.

3. Definitions

Market launch means the placing of the medicinal product on the market of the declared Member State. **Placing on the market** means the date of release into the distribution chain for value[1] (e.g. the product is not just provided to patients in need under compassionate use programmes but instead sold to hospitals, pharmacies and distributors in exchange for a price).

4. Medicinal products covered

The medicinal products covered by the pilot concern newly submitted applications for Centrally Authorised Products (CAPs), as well as centralised applications under assessment, for orphan and oncology medicines. These products were chosen for their link to unmet needs in the EU and to areas of high public health interest.

5. Pilot project questions and outcome measures

The pilot will assess the following main questions:

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 degree of 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: declaration to launch in 1st or 2nd half of the year.

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', incl. 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.

[1] 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."

6. Timing and method of data collection

In the framework of the usual application process, marketing authorisation applicants will be requested to submit the template of 'Market Launch Intentions' in one of the following two timelines:

- 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 will be initiated.

The template of 'Market Launch Intentions'[2] (see below) 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) The 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 (starting in Q3-2020 - tbc).

8. Analysis and reporting

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

9. Confidentiality

The information collected in the pilot project 'Market Launch Intentions of Centrally Authorised Products' will be shared in confidentiality with the European Commission, the European Medicines Agency, and with National Competent Authorities (NCAs). The information will not be publicly disclosed but 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 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.

[2] The template was endorsed by the Human Pharmaceutical Committee at its meeting of 12 March 2020.

Marketing Authorisation Application for CAPs

Market Launch Intentions

Name of Company applying for marketing authorisation:

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 ☐

Date of completion of the form:

The applicant is asked to outline its marketing intention in the EU/EEA of 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	☐	☐

Remarks on market launch intentions:

Confidentiality of the information provided

This information is collected in confidentiality with the European Commission, the European Medicines Agency, and with National Competent Authorities (NCAs) for the purpose of the pilot project 'Market Launch Intentions of Centrally Authorised Products.' 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.