Pilot project 'Market launch of CAPs'

Objective

To improve regulators' knowledge of market launch intentions and the reasons behind delayed market launch. Overall aim: increase patient access to medicines.

Approach

Since 25 March 2021, EMA invites **MAAs** for orphan and oncology medicines to make a → **declaration of market launch intentions** on a **voluntary** and **confidential basis**.

Action under the **Pharmaceutical Strategy** and supported by the Pharmaceutical Committee. Proposal for revision of pharmaceutical legislation end of 2022.

→ This an a **opportunity** for prospective marketing authorisation holders to give **direct feedback** on the issue.

Response rate

The response rate is low (7.8%). Only 6 responses have been received out of 76 products invited to participate in the survey.

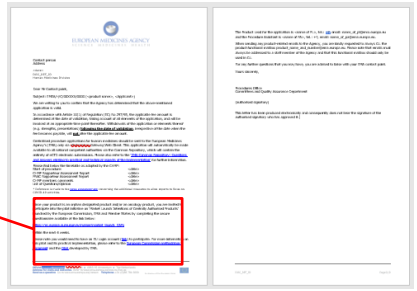
	Total products (n)	Responses (n)	%
Start of procedure	49	3	6.1%
Opinion	27	3	11,1 %
	76	6	7.8%

Invitation to participate

Since March 21, a link to a secure online questionnaire hosted by the EC (EU Survey1) is provided to the concerned applicants:

- at validation, as part of the EMA validation letter,
- at CHMP (positive) opinion stage, as part of the EMA letter to the MAH.

> Since your product is an orphan designated product and/or an oncology product, you are invited to participate into the pilot initiative on 'Market Launch Intentions of Centrally Authorised Products' launched by the European Commission, EMA and Member States by completing the secure questionnaire available at the link below:
>
> https://ec.europa.eu/eusurvey/runner/market_launch_CAPs
>
> within the next 4 weeks.
>
> Please note you would need to have an EU Login account (link) to participate. For more information on this pilot and its practical implementation, please refer to the European Commission methodology document and the Q&A developed by EMA.



Applicants are invited to complete the survey within 4 weeks.

More detailed instructions can be found in the Practical Q&A published on EMA website.