



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# 5-year review of the PRIME scheme

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Update on the surveys and next steps

Industry stakeholder platform on research and development support, 4 June 2021

Presented by: Sonia Ribeiro, Head of Product Portfolio Office, EMA





## Background – Follow-up to previous platform meeting

- Discussion on the enhancement of the PRIME scheme & planned 5-year analysis ([5th Industry Stakeholder Platform on R&D support 16.11.20 - highlight report](#))
- Agreement to engage with sponsors in the context of 5-year analysis
- Questionnaires to survey developers on PRIME developed in consultation with steering group of trade associations



## Update on Surveys to developers on PRIME

- Surveys to developers on PRIME are an integral part of the review of the performance of the scheme after 5 years
- Aim to collect feedback on developers' experience with PRIME designated medicinal products (**product specific**), complemented by general questionnaire to gather broader Industry's views on the PRIME scheme (**Company specific**)
- EMA questionnaire specific to stage of development (PRIME, MAA submitted or PRIME, no MAA)
- Input highly encouraged to inform the review of the performance of the scheme, including any future adaptation of its scope and features, if applicable.



# Surveys on PRIME



Aim

Capture experience from PRIME-designated and/or products' sponsors

What to do

Complete the questionnaire sent by EMA to the **product contact person**

*A **single response** for **each** PRIME product*

Aim

Capture industry's general views and feedback on PRIME, also from companies without PRIME experience

What to do

Complete the questionnaire sent by trade-association via the relevant group

*A **single response** reflecting the overall company views*



## Methodological aspects on EMA PRIME Survey

- EMA will send the PRIME survey to the contact point for each PRIME designated product, using EU Survey tool
- A single reply is expected for each PRIME product
- EMA will not collect or process personal data with this survey -> answers will be collected and evaluated in an **aggregate** and **anonymous** manner
- For any questions on the EMA survey, please contact [prime@ema.europa.eu](mailto:prime@ema.europa.eu)



## Timelines & next steps

- **7 June 2021:** Launch of both surveys to Industry stakeholders
- **30 June 2021:** Closure of surveys
- **Q3 2021:** Analysis of the results
- **Q4 2021:** 5 year analysis of PRIME & discussion at the R&D platform

		June 2021				
Mon	Tue	Wed	Thu	Fri	Sat	Sun
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30				



## Take home messages

- Unique opportunity to provide feedback on experience with PRIME after 5 years of launch of the scheme
- Surveys cover experience with the support offered by EMA and Rapporteur's team during development
- Surveys seeks to understand impact of PRIME designation for products that have received a MA



# Any questions?

## Further information

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