One- year industry experience – *Support to PRIME medicines*

PRIME Workshop, London/EMA

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EuropaBio®
The European Association for Bioindustries

Vaccines Europe
An industry for healthy lives

This is a joint industry presentation on behalf of the trade associations shown

ebe
european biopharmaceutical enterprises

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PRIME Industry Experience

Introduction

- Provide industry reflections on experience with the PRIME scheme
  - Continuing efforts in collecting industry experience through a survey of EU Trade Association member companies
  - The expanded survey, conducted in April 2016, collected the following information:
    - » General information / baseline
    - » Eligibility request
    - » Guidance
    - » Kick-off meeting*
    - » Overall experience / feedback*
- This presentation focuses on support following PRIME eligibility (n=8 eligible applications).
  - Based on survey results, supplemented with experience from individual member companies

*New survey questions following the April 2016 survey

Kick-off meeting

Process

Characteristic	May 2017
Kick – off meeting took place	5/8
[...If yes,]	
Received guidance about the content, preparation and topics for the kick-off meeting	5/5
Guidance was helpful	3/5
Assignment of dedicated EMA contact is beneficial to overall process	5/5
Assignment of Rapporteur took place shortly after entry into the PRIME scheme was confirmed	5/5
Following assignment of Rapporteur, did there remain the opportunity for continued informal dialogue with Rapporteur or other national agencies outside the centralised advice procedure?	**2/5***

Specific comments:

* There was no opportunity to continue informal dialogue with the Rapporteur. These informal discussions with the applicant are crucial to be able to identify what topics really do need to go through scientific advice.

Kick-off meeting

Support

Characteristic	May 2017
What were the team expectations?	Meeting with Rapp Presentation product (development) Discussion on strategic key questions Scientific advice Milestones definition/scenario planning
Were the expectations met?	**4/5***
How would you qualify the information provided during the meeting?	Clear (4) Concise (4) **Contradictory (1)**
Were the recommendations feasible and realistic?	5/5
Type of impact on product development and/or strategy	Potential accelerated registration path (1) Addition of development steps (1) Additional study (non)clinical or CMC (2) Strategy to use Real World Data (1) Addition of registry (2) Protocol design (1) Orphan assessment (1)

Specific comments:
*only partially met expectations as it turned out there were no possibility for informal meetings with Rapporteur outside of a scientific advice procedure.

Kick-off meeting

Most useful elements

- Attendees:
  - Rapporteurs‘ assessment team,
  - the EMA senior representation with high level of knowledge,
  - multidisciplinary group of experts.
- Feedback
  - on key procedural, legal and scientific issues/questions encompassing all aspects of the dossier (quality, non-clinical, clinical and administrative),
  - by flagging potential issues to be resolved prior to filing,
  - on application dossier welcomed,
  - SME office supporting and assessing early eligibility appreciated,
  - quick interactive procedure.
- **Informal dialogue** is welcomed and expected.

Kick-off meeting

Key learnings / experiences

- Logistics
  - Resource intensive, tense preparation,
  - Meeting not long enough,
  - Not all relevant stakeholders were present.
- Discussion
  - Greater understanding of the Rapporteur and CHMP expectations,
  - Very relevant dialogue in case of innovative product with limited experience – knowledge/capacity building,
  - Dedication of EMA and Rapporteur/assessment team to allow for potential accelerated registration pathway through innovative approaches e.g. rolling submission,
  - Responses to scientific questions to be covered in scientific advice.

Support within PRIME scheme

Overall experience

Characteristic	May 2017
Timetable was followed	8/8
Were the interactions with the EMA team useful?	**7/8***
Were there (or are there plans) to include additional stakeholders involved during SA's within PRIME?	HTA (1) WHO (1)

Specific comments:

*In one case, a pre-PRIME submission meeting with the SME office was very helpful in providing a preliminary view on PRIME eligibility. The company did not proceed with the PRIME submission.

*Additional clarification questions from the EMA during the review process provided an insight into the EMA evaluation.

Support within PRIME scheme

Proposals for improvement

- Kick-off meeting
  - time for discussion: longer to cover all items of development,
  - flexibility around the meeting date (not limited to CHMP week), location (National agency of the Rapporteur),
  - timelines for availability of final minutes,
  - Possibility of follow-up clarification meeting.
- Regulatory interactions
  - Support to define the planned frequency and timing for EMA and Rapporteur interactions,
  - Flexibility for national scientific advice interactions, where appropriate
    - To optimise the use of specific expertise within the EU system.
- Other key regulatory actors
  - Transfer of knowledge from EMA PRIME Co-ordinator to EMA Product Lead
    - Specific plans within PRIME to address this?

PRIME Scheme

Further suggestions

- Request for PRIME eligibility early in the development independent of the size of the company.
- Open PRIME scheme for products already licensed in the EEA that could address unmet medical need (e.g. new indications).
- Flexible scientific advice tailored to the PRIME scheme
  - Potential for a more rapid process.
- Stronger link between the PRIME scheme and the involvement of HTA bodies into the early discussions.
- Automatic accelerated assessment
  - if the product remains in the PRIME scheme and the applicant desires accelerated assessment.

Questions