EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update of CHMP Guideline on Accelerated Assessment(AA)

Overview of changes proposed and comments received during public consultation

Presented by Sonia Ribeiro on 20 October 2015 at 3rd STAMP meeting
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An agency of the European Union

Overview

Revision in parallel to the Guideline on Conditional Marketing Authorisation:

- Discussions at 1st and 2nd STAMP meeting
- Updated guideline released for public consultation in July 2015
- Commenting period finished 30 September 2015

Next steps:

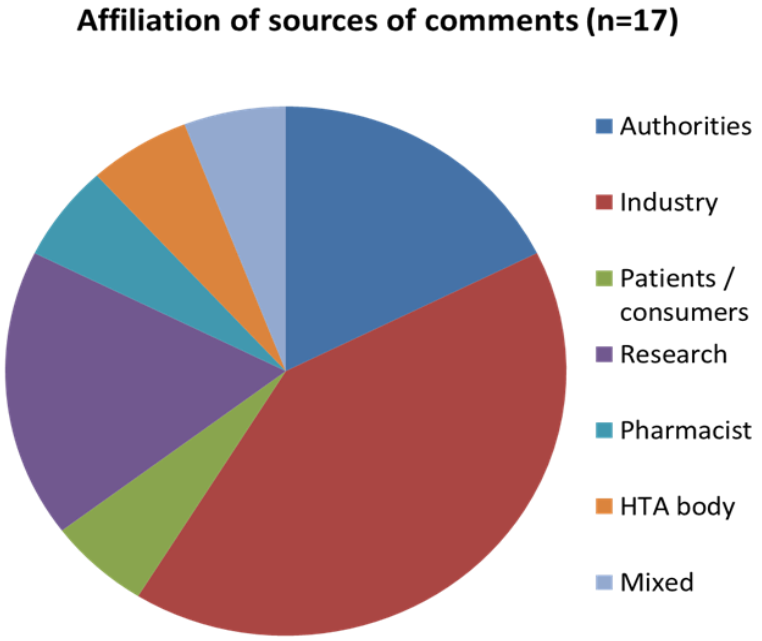
- Today's exchange at the 3rd STAMP meeting
- Finalisation of CHMP guideline expected in Q4 2015

Changes to the Guideline for public consultation

- Introduction of more detailed guidance how to justify major public health interest based on the existing three key elements (existing methods, unmet medical need, and strength of evidence)
- Acknowledgment that comprehensive clinical data may not be available in certain situations, allowing accelerated assessment in the context of a conditional marketing authorisation for example
- Stressing the importance of proactive early dialogue to advise on MAA submission strategy
- Optimisation of the assessment timetable by better balancing evaluation phases to reach a CHMP opinion within 150 days

17 stakeholders were contributing to the public consultation

Stakeholder
Alexion Pharma GmbH
ANSM French Products Safety Agency
The European Consumer Organisation - BEUC
BIO Deutschland e.V. – the German Biotech Industry Association
BioMarin Europe Limited
Cancer Research UK
EFPIA
European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
EuropaBio - the European Association for Bioindustries
Health Action International (HAI), the International Society of Drug Bulletins (ISDB) and Medicines in Europe Forum (MiEF)
International Plasma Fractionation Association (IPFA)
Medicines Evaluation Board, The Netherlands
Centre for Health Technology Evaluation, National Institute for Health and Care Excellence (NICE)
Norwegian Medicines Agency – NOMA
Pharmaceutical Group Of the European Union (PGEU)
REGenableMED - United Kingdom Economic and Social Research Council (ESRC)-
IABS-EU as a member of the IMI – Zoonoses Anticipation and Preparedness Initiative



Overall, the comments were supportive of the proposed revisions in terms of receiving additional guidance on the scientific justification and procedural optimisation.

Examples of comments received

At a minimum, clarification meetings with applicants on the responses to CHMP adopted questions during the evaluation within the centralised procedure should be explicitly allowed as a possibility. To facilitate maintenance of the accelerated assessment timetable, both regulators and applicants would benefit from having more flexibility in this approach. For instance, meetings before the adoption of the list of questions may be particularly important to retain an accelerated clock. EFPIA

We strongly support the principle of early dialog between applicant and EMA/national regulatory agencies. More AA-procedures will obviously stress the assessment teams and we need to plan for resources as early as possible. NOMA

We support initiatives to increase access to medicines and thereby improving patient care. However, we would like to stress that patient safety and product effectiveness should not be compromised in any way, and that any shortening of assessment period should not come at the cost of less robust assessment procedures. PGEU

After discussion with the applicant, the new timetable will be communicated to the applicant. In any case, the CHMP will explain the reasons for the change to the assessment timetable, including how the impact on the previously agreed major public health interest of the accelerated assessment has been considered in making this change." . EFPIA

Selected comments for STAMP discussions

"Major public health interest" vs "Unmet medical need"

The current text focusses on the justification to be provided to support a claim that a medicinal product addresses an "unmet medical need". This may be perceived and interpreted as too restrictive as there may be situations where a medical product while not addressing an "unmet medical need" can still be of "major public health interest". The guideline should not a priori exclude aspects other than purely medical ones (e.g. significant cost savings for public health systems, addressing emerging or anticipated drug shortages, etc.). EFPIA

The guideline focuses on the positive risk benefit balance for individual medicines. When considering the public health importance of these medicines, which is one of the explanations for this regulatory route being made available, it is vital that further precision is provided on what justification is required to demonstrate 'public health unmet need'. We note that this is not included in the legal provisions. NICE

Selected comments for STAMP discussions

Introducing the principles of rolling review

It would be useful if some concepts of the rolling review prior to the start of the evaluation procedure as applicable in the US on Expedited Programs can be included. EFPIA

Orphan designation as an element to consider for requesting AA

EFPIA seeks clarification that an Orphan Medicinal Product will be eligible for an accelerated assessment. The maintenance of the Orphan drug designation (i.e Maintenance report) could serve as basis for requesting the AA procedure. EFPIA

Selected comments for STAMP discussions

Opportunity for shortening the EC decision phase

EFPIA flags the importance of Accelerated decision making by the European Commission to reduce the timeline from max. 67 days to max. 30 days to reflect the public health importance of the product evaluated under accelerated assessment.

Particular focus should be given to the reduction of the Standing Committee procedure to significantly less than 22 days (max. 5 days for situations where there is a high public health interest and which stipulate an 'urgency' or 'extreme urgency'. (ref. Rules of Procedures for the Standing Committee on Medicinal Products for Human Use (SANCO/D/3/PB/SF/ddg.1.d.3 (2011)1118442), in particular Art 3(2) and 8).

Thank you for your attention

Further information

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