PCPAES/12/01 – Public Consultation on PAES

Response from the Swedish Medical Products Agency (MPA)

DELEGATED ACT ON POST-AUTHORISATION EFFICACY STUDIES

Consultation item No 1: Do you think that a delegated act on the situations in which a post-authorisation efficacy study may be required will be of added value and that the Commission should consider bringing forward a draft delegated act? Please provide reasons for your opinion.

MPA answer to Q1:

No. We do not see any added value with a delegated act, since the competent authorities will still need to justify the imposition of a PAES on a case-by-case basis, taking into account the characteristics of the product concerned.

In addition, there is the disadvantage, i.e. the difficulty to react quickly to emerging situations which have not already been addressed in the act concerned, as such reactions may first require an amendment to cover the new situation.

Consultation item No 2: Do you have any comments on the above? Do you agree that generally speaking PAES should focus on generating efficacy data?

MPA answer to Q2:

Yes. Generally speaking PAES should focus on generating efficacy data. We agree that efficacy study of medicinal products in everyday medical practice are expected to be requested mainly when there is clear evidence that the benefits of the medicinal product as shown by RCTs might be significantly affected by the real-life conditions of use. It should be the exception rather than the rule.

Consultation item No 3: Please comment on the seven different situations described above. Do you agree that in these situations, a competent authority may ask for a PAES? Are there any other situations not covered in which it would also be justified to oblige a MAH to conduct an efficacy study? If this is the case, could you please elaborate on these situations and, if possible, give specific examples to underpin the need?

MPA answer to Q3:

Yes. We agree with the above specified seven different situations. Although not identified, there might be other situations where it would be justified for a PAES. However, we agree that as mentioned above, PAES would be imposed only in specific situations and therefore would apply only for a limited number of medicinal products.

Consultation item No 4: Do you have any comments on the above?

MPA answer to Q4:

We agree that interventional studies are preferred to obtain efficacy data. In certain specific circumstances however, other types of studies may be needed when interventional studies are not possible.

Regarding point 3 above, the methods for collection and analysis of data on the observational trials for regulatory purposes will have to be developed and their feasibility carefully considered. Special guidance on PAES methodology should accompany the guideline, perhaps as an annex.

Consultation item No 5: Please feel free to raise any other issues or make any comments which have not been addressed in the consultation items above.

MPA answer to Q5:

Regarding PAES studies that assess the efficacy of the medicinal products in everyday clinical practice (filling the "efficacy-effectiveness gap"), when there is common interest for more stakeholders, there might be an opportunity of liaison and scientific joint discussion with European health technology assessment (HTAs) bodies, MAHs, Research networks (e.g. EnCepp) as considered appropriate.