**From:** Rothwell, Jeff
**To:** SANCO PHARMACEUTICALS D5
**Subject:** Public consultation on post-authorisation efficacy studies - PCPAES/12/01

Dear Sirs,

All the comments below are made with reference to marketing authorisations for generic products as this is Rosemont's area of expertise and operation. Furthermore the PVG legislation is heavily slanted towards new chemical entities without much regard for older products. Whilst the burdens are obviously necessarily high for new chemical entities, regulators often apply similar requirements to generics, presumably because of their interpretation of the guidelines.

**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.**

Yes it would be helpful for generic drug companies to know where a PAES may be required as the requirement to carry out such a study could easily mean that the company will not market the product in question as the costs incurred could outweigh the profit. Some degree of certainty will enable the company to make an earlier decision on whether an application to market a product will be made. It is important that regulators know when and where a PAES should be demanded. Placing the burden of a PAES on one generic company would create unfair competition and making all generic companies do a PAES on one common product would cause duplication of effort with no corresponding benefit.

**Consultation item No 2: Do you have any comments on the above? Do you agree that generally speaking post-authorisation efficacy studies should focus on generating efficacy data?**

Effectiveness is the true measure of success for a product. The efficacy for generic products has been established in the licensing process, but the effectiveness may depend on the dosage form which may be different to the originator product. It also may be different in different patient populations. In general effectiveness studies should not be necessary for generic products.

I do not see a place for efficacy studies for generic products.

**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 postauthorisation efficacy study? Are there any other situations not covered by points 5.1 to 5.7 in which it would also be justified to oblige a marketing authorisation holder 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?**

5.1 No comment

**5.2 Studies on combination with other products should not be required for generic products as they have been on the market for more than 10 years. The burden of these studies should be on the new chemical entity being studied in combination with the older products**

**5.3 Studies in sub populations should not be required as the SmPC for the generic is based on the originator product.**

**5.4 Studies in the context of European medical care should not be required generics are licensed using European comparators which have been on the market for more than 10 years.**

**5.5 Studies where the understanding of the treatment of a disease etc may change could potentially be relevant but the cost of carrying out such studies may mean the generic could be discontinued to avoid doing the study.**

**5.6Long term efficacy should already have been determined for generic products. The burden should be on the originator.**

**5.7Studies in everyday practice should not be required for generic products as they are based on products that have been available for more than 10 years.**

**No further comment**

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

**Study design has to be determined by the reasons for carrying out the study. Regulators need to be careful to be pragmatic about the usefulness of the data that will be generated. If the number of patients enrolled on the study is likely to be small, then it may not be practical to carry out the study at all even if there is a need to understand more about a product.**

**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.**

**Regulators need clear guidance on the added value to patients and the public health from requiring PAES to be carried out. As stated the commitment to carry out a PAES should not be a route for premature licensing. In the case of generics the need to do a PAES should be the rare exception rather than the rule and regulators should be guided to that principle.**

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