From: Jenny Walsh]
To: SANCO PHARMACEUTICALS D5
Subject: PCPD/12/01 - Public Consultation on Paediatric Report

Please find below my responses to Consultation on Paediatric Report.

I am a Limited Company (pharmaceutical consultancy) which falls within the EU definition of an SME.

1. I agree that in general, the Paediatric Regulation has made paediatric development part of the overall product development of medicines in the EU. This is especially true for large and medium sized companies based in the EU. I do not think all small companies are fully aware. In addition, I have noticed that some small US based companies are not aware of EU requirements which has led to challenges when they have tried to develop global products.

2. I agree with the assessment.

3. I agree that the PUMA concept is a disappointment. I think this is because there are not sufficient incentives in place. There is no protection for a company that submits a PIP for an off-patent product – writing and submitting a PIP itself is time-consuming and incurs costs. Generic manufacturers are not interested in PUMAs as their business model is to develop products as quickly and cheaply as possible. It is left to SMEs and academia to develop off-patent products and the costs associated with this can be prohibitive, especially as there is a risk that there will be insufficient ROI. It seems that only potentially profitable off-patent paediatric products will be developed. There is also concern about competition from Specials in the UK. e.g. even though a licensed product is available, similar Specials products are often still available. I do not think that PUMA will become more attractive, although I think there will be a few more PUMA applications.

4. Generally speaking there is no impact on adult development timelines, although there is a huge impact on resource requirements. In the current economic climate, I am not sure if this could indirectly lead to projects being cancelled due to insufficient resources. (I am aware of instances where projects have been stopped to save money).

5. No comments.

6. I agree. The challenge is that many compounds do not reach the market and hence will not be subject to the SPC extension reward, although resources will have been spent.

7. I agree that arts 45/46 have been a successful tool. The lack of interest in updating SmPCs is likely due to cost and resource implications with little perceived benefit to the company.

8. I agree that HCPs may not be receptive to new information on paediatric products and tend to prescribe what they have used previously. It seems that there is a lack of awareness of new products amongst Drs. This should be driven an national level. In the UK, the process for adding a new product to a formulary appears to be time-consuming and laborious.

9. No specific comments, although the use of modelling should be encouraged.

10. I think that end of Phase 1 is too early to submit a PIP as many compounds will not progress any further and writing and submitting a PIP will not be a valuable use of resource for the company or EMA. In addition, such an early PIP will have little information and will require many subsequent modifications. It would make more sense to submit the PIP at Ph2a once the compound has been tested in patients. Companies should start developing their internal paediatric development strategies at end of phase one and then this should drive the PIP. This should also facilitate paediatric development to fit smoothly within the overall programme.

11. I agree.

12. No comment – implementation reflects my initial understanding.

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