Dear Madam/Sir,

Please find below our comments on the Consultation paper:

Consultation item no° 1: we agree with the approach. GMP for active ingredient is already part of ICH Q7 and of GMP (Part II). It is therefore important to align the European Directive laying down the corresponding principles.

Consultation item no° 2: Article 5 - Compliance with marketing authorisation of the Directive 2003/94/EC should also be listed under item 13. The finished product manufacturer can and should ensure compliance with the marketing authorisation. The active ingredient manufacturer does not have access to the MA dossier, but commits to inform the finished product manufacturer of any changes.

Consultation item no° 3: yes, we consider the list complete.

Consultation item n° 4: yes, we agree with specific item 16.

Consultation item n°5: We do not pronounce ourselves on this specific item.

With our best regards / Cordialement / Mit freundlichen Grüßen / Saludos / Cordiali saluti

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