EIPG COMMENTS on Sanco.ddg1.d.6(2012)73176

Extension of the Directive on GMP for medicinal products to active substances

Consultation Item No 1: Do you agree with this appraisal and approach?

Yes, we agree with this appraisal and approach.

Adaptation of regulatory requirements of Directive 2003/94/EC to active substances

Consultation Item No 2: Are there other aspects which should be considered?

We agree that the provisions in Directive 2003/94/EC would not apply to active substances, as specified in the list at point 13.

However, we would like to take this opportunity to emphasize the need to reconsider a few specific differences which exist today between the detailed guidelines on good manufacturing practices for medicinal products (EudraLex-Volume 4, Part I) and the corresponding guidelines for active substances (EudraLex-Volume 4, Part II).

In fact, in the light of a broad application of these principles for a better quality management of the manufacturing processes involved in the preparation of medicinal products, it seems to us reasonable to revise the guidelines on good manufacturing practices for active substances by introducing two fundamental requirements, namely the presence of a "Qualified Person" and the "Manufacturing Authorization".
This would make the two guidelines identical in terms of quality responsibility and management, though they would maintain their specific difference in terms of the manufacturing processes.

The assignment of a personal responsibility and the issue of a formal authorization for a manufacturing site would improve the reliability in active substances manufacture. Taking into account that this revision would also be applied to non EU manufacturers, a positive impact would be expected on the control of the supply chain, possibly reducing the risk of falsified active substances.

We realize that this revision will require a long process to achieve an agreement by all parties involved.

Provisions in Directive 2003/94/EC that would need to be amended

Consultation Item No 3: Do you consider this list complete ?

Yes, we consider the list complete

Other provisions on active substances that could be added to Directive 2003/94/EC

Consultation Item No 4: Do you agree with this specific point? Do you consider that other provisions specific to active substances should be added?

Yes, we agree on this specific point. We do not consider the need for other provisions specific to active substances

Other issues

Consultation Item No. 5: Please comment on section 3.

No comments

JN/PI/April 2012