Delegated Act on the Principles and Guidelines of Good Manufacturing Practice for Active Substances in Medicinal Products for Human use

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COMMENTS FROM:

Name of Organisation or individual
Bundesministerium für Gesundheit (Germany) -Federal Ministry of Health-

The Federal Ministry for Health is pleased to comment on the consultation paper mentioned above:

The extension of the Directive 2003/94/EC on GMP for medicinal products to active substances could be agreed in principle as one possibility for the delegated act.

However we deem it advisable not to extend the existing Directive but to lay down the principles of GMP for active substances **in a separate Directive**. There are several reasons for this proposal:

Even if certain regulations of the existing Directive also apply to the manufacturing of active substances, a number of changes will still be necessary and might overload the existing Directive.

In addition manufacturing facilities for medicinal products and such for active substances are usually not in the same location / not operated by the same company. Insofar it would be more comfortable to them to have the regulations separated and not in the same Directive, because they have to follow either the regulations for manufacturing medicinal products or for manufacturing active substances.

Furthermore it is often not known at the time when an active substance is manufactured, whether it will end up in medicinal products or in another product.

Although understanding the Commissions´ approach, the German Federal Ministry of Health argues for laying down the principles and guidelines for the manufacture of active substances as starting material for medicinal products for human use in a separate directive.