PHARMIG
Verband der pharmazeutischen Industrie Österreichs

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PHARMIG response to the European Commission Draft: Guidelines on the Principles of Good Distribution Practices for Active Substances for Medicinal Products for Human Use

PHARMIG, the association of the Austrian pharmaceutical industry, would like to thank the European Commission for the opportunity to comment on the Draft Guidelines on the Principles of Good Distribution Practices for Active Substances for Medicinal Products for Human Use.

Please find following our comments.

Storage

In order to point out the whole purpose of appropriate storage we recommend amending number 18 as follows. It also should be pointed out that the review of records can be done by any appropriate quality personnel:

18. *Active substances should normally be stored* ***in a way to avoid the risk of mixing-up and of unauthorised access*** ~~*apart from other goods and*~~ *under the conditions specified by the manufacturer (e.g. controlled temperature and humidity when necessary).* ***This can be achieved by separate storage and conspicuous labelling or electronic methods.*** ~~*These*~~ ***The*** *conditions should be monitored periodically and records maintained. The records should be reviewed regularly by* ***a trained quality function*** ~~*the person responsible for the quality system*~~*.*

For number 20 we suggest to use another word instead of “attack” which would better meet the intended statement:

20. The storage facilities should be clean and free from litter, dust and pests. Adequate precautions should be taken against spillage or breakage, ~~attack~~ ***infestation*** *by micro-organisms and cross contamination.*

To enhance comprehensibility we suggest to rewrite number 23 as follows:

23. ~~Shortages that requires registered importers to notify relevant customers of any interruption to supply that the importer or distributor becomes aware of.~~
Shortages the registered importer or distributor becomes aware of require notifying relevant customers of any interruption in supply.

Returns

Number 35 shall clearly point out that all four subitems (a-d) have to be fulfilled in case of a return of active substances to saleable stock:

35. Active substances which have left the care of the distributor, should only be returned to saleable stock if ***all of the following conditions are met****:*
a) the active substance is in the original unopened container(s) and in good condition;
b) it is demonstrated that the active substance have been stored and handled under proper conditions;
c) the remaining shelf life period is acceptable;
d) they have been examined and assessed by a person authorised to do so.