Public consultation paper on the review of the variations guidelines

Joint Statement of the Federal Institute for Drugs and Medical Devices (BfArM), the Paul-Ehrlich-Institut (PEI) and the Federal Office of Consumer Protection and Food Safety (BVL)

The German competent authorities fully support the amendments proposed for the Classification Guideline in the public consultation paper. These changes reflect the current legislation and take into account the recommendations delivered in accordance with Article 5 of Regulation 1234/2008/EC as well as scientific and technical progress.

We would like to especially support the note introduced for classification category C.I.8.b referring to the Article 57 database. Owing to this note the workload of competent authorities (as well as applicants) will be extremely reduced due to a high decrease in administrative IA-notifications. It is therefore regarded as of a high importance for the German competent authorities.