BfArM
Federal Institute for Drugs and Medical Devices

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Response to Public consultation on draft guidance

HARMONISED REQUIREMENTS FOR NON INVESTIGATIONAL MEDICINAL PRODUCTS IN CTA SUBMISSIONS

SANCO/C/8/SF/dn D(2010) 326199

The document lists detailed requirements for NIMP dossiers dealing with different circumstances concerning the origin and the regulatory status of the medicinal products used as NIMP.

But it leaves out the most important question, as well as the CT1 guideline does.
What are the consequences if the NIMPs do not comply with the guideline? Do same consequences apply like for IMPs?

What if applicants do not comply with the ranking list?
For example use of a third country medicinal product although there is an equivalent medicinal product available in the concerned member state?

What if a NIMP has an insufficient pharmaceutical quality?
May the competent authority prohibit complete clinical trial? .. or the use of the NIMP?

We would suggest clarification of these questions within the guidance.

In addition, we would like to take your attention to the fact, that neither this guidance nor the CT1 or CT3 guidance covers the notification of unexpected serious adverse events related to NIMPs. With regard to CT3 only adverse reactions related to a NIMP with interaction with an IMP is regarded as SUSAR. We would like to suggest including a reporting requirement in case of unexpected serious adverse events related to non-approved NIMPs.