



SUBMISSION OF COMMENTS ON VOLUME 9A

Please submit comments in editable document format (e.g. MS Word)

COMMENTS FROM the European Generic medicines Association, 50, rue d'Arlon, 1000 Brussels. Contact person: Suzette Kox skox@egagenerics.com

GENERAL COMMENTS

The EGA welcomes the opportunity to comment on the revised text of Volume 9a, particularly on Chapter I.4 “Requirements for Expedited Reporting of Individual Case Safety Reports”, and Chapter II.1 “Undertaking of Pharmacovigilance Activities by Competent Authorities in the Member States” to introduce modifications regarding the identification of biological medicinal products.

The proposed amendments have as their ultimate goal patient safety and therefore require the support of all stakeholders. Bearing this in mind, we have suggested some slight changes to avoid any possible ambiguity in the text.

The EGA’s proposed amendments are shown below in bold and underlined.

SPECIFIC COMMENTS ON TEXT

GUIDELINE SECTION TITLE

Line no. + paragraph no.	Comment and Rationale	Proposed change (if applicable)	Outcome of Review <i>[For EMEA/EC use only]</i>
Lines 2027-2030 under Paragraph 4.1	Article 1 point 20 of Directive 2001/83/EC, as amended, stipulates that the name of the medicinal product ‘ <i>may be either an invented name not liable to confusion with the common name, or a common name or scientific name accompanied by a trade mark</i> ’	<i>For adverse reaction reports relating to biological products, the definite identification of the product with regard to its manufacturing <u>site</u> is of particular importance. Therefore, Marketing Authorisation Holders should give advice to reporters to provide <u>at a minimum</u></i>	

¹ Examples of approved names for biosimilar medicines based on INN+ Trademark/MAH: Epoetin alfa Hexal, Filgrastim ratiopharm.

Submit all comments in editable document format by email to Peter.ARLETT@ec.europa.eu.

Deadline for comments: 2 May 2008

These comments and the identity of the sender may be published on the European Commission or EMEA websites unless a specific justified objection is received by the European Commission.

Date of transmission:

	<p><i>or the name of the marketing authorisation holder’.</i></p> <p>This article applies to all medicinal products in the EU, including biological products. This naming approach identifies without ambiguity any medicinal product. Biosimilar medicines could therefore also be named INN+ trademark or INN + MAH¹.</p> <p>Consequently no biological medicinal product is named by the International Non proprietary Name (INN) alone. When discussing the identification of biological medicinal products in the EU, it is important not to confuse or mix up EU naming practices for medicinal products with US naming practices for generic medicines² or UK practices for small molecule products.</p> <p>The terminology ‘invented’ in brackets in the Commission proposal is misleading, could be misinterpreted, and has the potential to lead to confusion amongst reporters and all other stakeholders, including industry and authorities. <u>The word invented in brackets should therefore be deleted.</u></p>	<p><i>the (invented) name of the medicinal product and the batch number and should follow up the report when this information is missing for completion.</i></p>	
<p>Lines 3834-3837 under Part II,</p>	<p>The same comments as above apply</p>	<p><i>For adverse reaction reports relating to biological products, the definite identification of the product with regard to its manufacturing</i></p>	

² The United States does have specific regulations on the naming of generic products. The generic product must use the USP name alone. If the product is not included in the USP, the generic product must use the same chemical name as used for the originator product (source: GPhA)

Chapter 1.3.2.		<p><i><u>site</u> is of particular importance. Therefore, Competent Authorities should give advice to reporters to provide at a minimum the (invented) name of the medicinal product and the batch number and should follow up the report when this information is missing for completion.</i></p>	

Please feel free to add more rows if needed.