

Certification of Substances Division

Title:	The EDQM position on CEP Applications for Biological Substances
Reference Document:	PA/PH/CEP (09) 152 rev 01 (EN)

According to Resolution AP-CSP (07)1, the procedure for ‘Certification of Suitability to the Monographs of the European Pharmacopoeia’ (CEPs) is intended for substances for which a monograph, either general or specific, has been adopted by the European Pharmacopoeia Commission. The procedure does not apply for direct gene products (i.e. proteins), products obtained from human tissues, vaccines and blood products and preparations.

In light of the discussions held at the European level concerning the classification of biological products, the EDQM has decided to exclude from the scope of the procedure those products that have been classified, by the Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMD(h)), as “other biological substances”. A list is available from the website of the Heads of Medicines Agencies http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Compilation_Biological_Active_Substance_non-recombinant_origin.pdf.

The reasoning behind this decision is as follows: the characterization and determination of biological substances require not only a combination of physico-chemical and biological testing, but also extensive knowledge of the production process and its control.

The EDQM, therefore, will not accept any new application for CEPs for these biological substances.

Existing CEPs are not affected by this decision.