Is it possible to apply for a CEP for biological substances?

Answer:

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 general or individual monograph has been adopted by the European Pharmacopoeia Commission. The procedure does not apply to gene products (e.g. proteins) or products obtained from human tissues, vaccines and blood products and preparations.

In light of the discussions held at the level concerning the classification of biological products, the products classified by the Co-ordination group for Mutual recognition and Decentralised procedures - Human (CMDh) as 'other biological substances' are excluded from the scope of the CEP procedure. A list is available on the Heads of Medicines Agencies website.

The reasoning behind this decision is that the characterisation 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.

This means that the EDQM does not accept new applications for CEPs for these biological substances.

However, for historical reasons, there are a number of valid CEPs for such substances. These existing CEPs for biological substances may be included in the marketing authorisation application (MAA) but should not be used to replace the relevant data in the corresponding sections of Module 3 (for more information, see the procedural announcement on Submission of full data on Module 3 of dossiers of biological substances of non-recombinant origin, included in the monthly report of the plenary meeting of CHMP, November 2009: EMEA/CHMP/745639/2009). CEP holders must provide their customers with full data to be included in Module 3, and the marketing authorisation holder will then submit them in their MAA.