Fact sheet

The Certification procedure (CEP procedure)

What is the Certification procedure?

The Certification of suitability to the monographs of the European Pharmacopoeia, or so-called CEP procedure, is one out of three alternative options that can be used by a manufacturer to demonstrate that the quality of their substance is suitably controlled by the respective monograph of the European Pharmacopoeia (Ph. Eur.), and is in compliance with the current regulatory requirements. Alternatively, for an active substance, the same data can be filed either in an Active Substance Master File (ASMF), to be submitted to each competent authority, or in the relevant part of the quality dossier of the marketing authorisation application (MAA).

How is a CEP granted?

To obtain a certificate, the manufacturer may submit an application to the European Directorate for the Quality of Medicines & HealthCare (EDQM) describing the manufacturing process for the substance and the methods applied for the quality control, including for the control of impurities. The data are assessed by a network of experienced quality assessors nominated by National Competent Authorities and the EDQM. Following a positive conclusion of the assessors, the EDQM grants a CEP. A copy of the CEP can then be used in any MAA for a medicinal product in which the active substance from this specific source is included.

Who accepts CEPs?

CEPs – which are referred to in European Union (EU) pharmaceutical legislation – are recognised by the European Pharmacopoeia member states and by a number of other countries, such as Australia, Canada, New Zealand, Saudi Arabia, Singapore, South Africa, Taiwan, etc. An increasing number of licensing authorities worldwide accept CEPs to support (fully or partially) the data related to the quality of active substances used in medicinal products.

Added benefits of the Certification procedure

The procedure centralises the evaluation of the quality of pharmaceutical substances for the benefit of regulatory authorities and industry alike, thus saving time and resources and ensuring harmonisation in the assessment of the data. It also provides the Ph. Eur. with information on the quality of the substances on the European market, thus helping to identify whether or not a revision of specific monograph is needed.

The inspection programme

The EDQM inspection programme is an integral part of the Certification procedure and is carried out under the mandate given to the EDQM by the European Commission in application of Directives 2001/83/EC and 2001/82/EC, which set out the EU code relating to medicinal products for human use and veterinary use, respectively.

Inspections of manufacturing and/or distribution sites of active substances covered by CEPs are scheduled on the basis of a risk assessment; they ensure that GMP (Good Manufacturing Practice) is applied and that the information supplied in the CEP application is accurate.

The inspection programme is drawn up based on priorities recommended by the competent authorities of member states and is adopted by the Certification Steering Committee. The inspections are jointly carried out by GMP inspectors from the competent authorities in the European Economic Area (EEA)[1] or in countries which have a mutual recognition agreement (MRA) with the EU in the GMP sector and by EDQM inspectors having the same qualifications.

About 40 on-site inspections are carried out each year, mainly in Asia. For several years, the vast majority of inspected sites have been outside the EEA, as the production of substances for pharmaceutical use has largely shifted to non-European countries.

1. The European Economic Area is an economic union consisting of 31 European states: the 28 member states of the European Union and three of the four member states of the European Free Trade Association (EFTA): Iceland, Liechtenstein and Norway.