

Certification of Substances Department

MMAN/CB

PUBLIC DOCUMENT

(LEVEL 1)

PA/PH/CEP (15) 19, 1R

Strasbourg, February 2017

Certification of suitability to the Monographs of the European Pharmacopoeia

COMPLAINTS PROCEDURE

The European Directorate for the Quality of Medicines & Healthcare's Certification Department (DCEP) is committed to providing high quality services to applicants and users of certificates of suitability (CEPs).

Although the Certification procedure is run under an ISO 9001 certified Quality Management System which includes processes to avoid mistakes, human error cannot be entirely excluded and it may happen that the products and services delivered by the DCEP do not have the expected quality. In such a situation, a complaint may be submitted to the EDQM. These complaints allow the DCEP to clarify misunderstandings, to correct potential errors, to avoid any dissatisfaction, to further improve products and services, and to establish a long-term relationship of trust with all stakeholders.

This document describes the processing of complaints on any issues arising from the implementation of the CEP procedure and its related EDQM inspection programme.

All complaints received are recorded and treated under the EDQM Quality Management System.

What is a complaint?

A complaint is a report made by an external party of a non-conformity or divergence between expected quality and the results for a product/service received within the scope of the CEP procedure. Complaints may be of different nature and may be related to the treatment of a CEP application or its revision, to the content of a CEP, to inspections carried out by EDQM, or to information communicated by the EDQM (e.g. on the EDQM website).

What is the difference between a complaint and a hearing?

Resolution AP-CSP (07) 1 provides an opportunity for applicants and CEP holders to ask for a hearing in order to ask for re-consideration of a decision taken by EDQM on a CEP application or on CEPs. In contrast to a complaint, the hearing procedure is an integral part of the decision-making process and is described in the EDQM policy document "Suspension of withdrawal of a certificate of suitability, closure of an application" (PA/PH/CEP 08) 17, current version).

Who can submit a complaint?

All applicants and users of certificates of suitability can submit a complaint.

How to make a complaint?

The complaint should be sent to the EDQM in writing, preferably to the email address provided to applicants and CEP holders, or by using the Helpdesk on the EDQM website (<https://www.edqm.eu/en/EDQM-FAQ-and-Helpdesk-List-630.html>). Only written complaints can be accepted.

In order to speed up the investigation and corrective action, complaints should include as many details as possible, and when applicable the CEP number or the reference of an EDQM inspection should be given.

In order to ensure a timely and efficient treatment of complaints, they should be submitted to EDQM within 3 months of the date of delivery of the products/services. After this timeline, the EDQM is not obliged to accept a complaint, but will do its best to resolve the issue. In particular, if a correction of a CEP is requested (e.g. editorial changes to addresses), and the 3-months period has elapsed, this shall be in the form of a notification (with the corresponding fee).

How are complaints treated by EDQM?

An acknowledgement of receipt is sent to the complainant by the DCEP within 2 working days following receipt of a complaint.

All complaints are recorded and subject to an investigation which will conclude whether the complaint is founded or unfounded.

If the complaint is founded, the EDQM aims to resolve the problem as soon as possible, and not later than 10 working days after receipt (in particular if the CEP should be revised). In addition to the immediate treatment, corrective and preventive actions may also be identified in order to prevent the problem from recurring and to improve the services in the future.

If the complaint is unfounded, the complainant is informed in writing within 10 working days of the non-validity of the complaint, supported by suitable explanations, and the complaint case is closed.

What to do if there is still dissatisfaction after the treatment of a complaint?

If the complainant does not agree or is dissatisfied with the treatment of a complaint, they may express their dissatisfaction by sending a letter to the director of the EDQM who will, after investigation, decide on any further action, if necessary.