

Certification of Substances Department

MDED/SPC

**PUBLIC DOCUMENT**  
(Level 1)

**PA/PH/CEP (15) 19, 2R**

Strasbourg, April 2026

**Certification of suitability to the Monographs of the European Pharmacopoeia**

## **COMPLAINTS PROCEDURE**

**Revision history of the document**

Revision N°	Date	Reason
2R	April 2026	updates of the process.

## **1. Purpose and scope**

The European Directorate for the Quality of Medicines & Healthcare (EDQM), through its Certification Department (DCEP), is committed to delivering high-quality services to applicants and users of Certificates of Suitability (CEPs).

Despite the existence of a robust Quality Management System designed to minimise errors, occasional issues may arise where the quality of products or services delivered by the DCEP does not meet expectations of stakeholders. In such cases, they may submit a complaint. Handling complaints enables the DCEP to clarify any misunderstandings, correct potential errors, prevent dissatisfaction, continuously improve its products and services, and build long-term trust with all stakeholders.

This procedure describes how complaints related to the implementation of the CEP procedure and its associated EDQM inspection programme are handled. All complaints are recorded and processed under the EDQM Quality Management System.

## **2. Definition of a complaint**

A complaint is a written report submitted by an external stakeholder highlighting a non-conformity or a discrepancy or any issue within the scope of the CEP procedure.

Complaints may concern, for example:

- the processing of CEP applications or revisions,
- the content of a CEP,
- the processing of EDQM inspections,
- information related to the CEP procedure published or communicated by the EDQM (e.g. website content).

## **3. Distinction between a complaint and a hearing**

Under Resolution AP-CSP (07) 1, applicants and CEP holders may request a hearing to seek reconsideration of an EDQM decision related to a CEP application or an issued CEP. In contrast to a complaint, a hearing is part of the **decision-making process**, as described in the EDQM policy “Suspension or withdrawal of a certificate of suitability, closure of an application” (PA/PH/CEP 08) 17, current version).

## **4. Who can submit a complaint**

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

## **5. How to submit a complaint?**

Complaints must be submitted **in writing**, preferably:

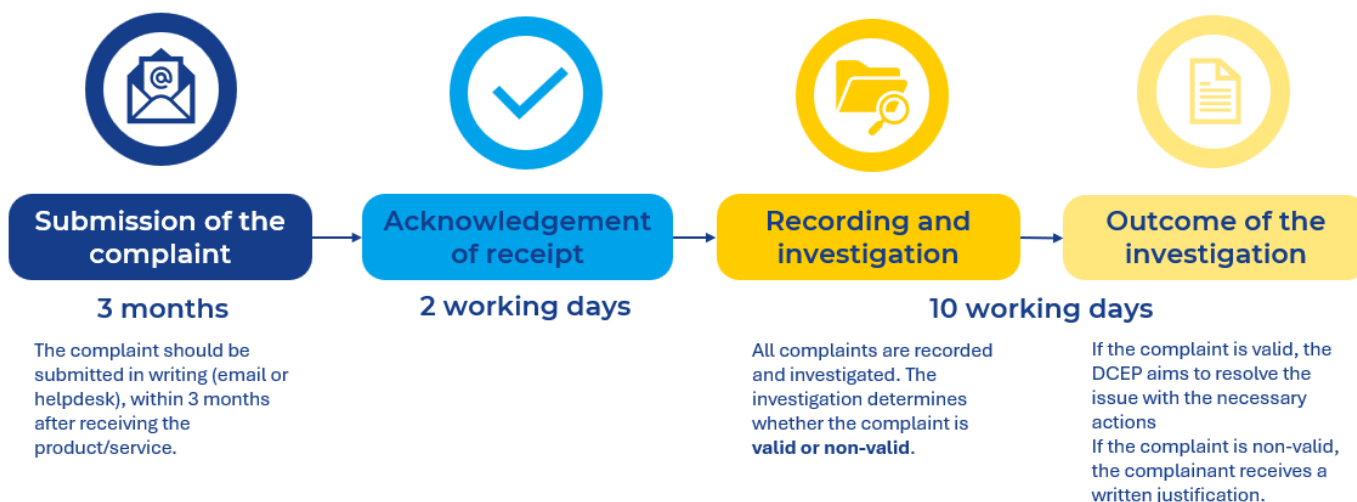
- via the dedicated email address provided to applicants and CEP holders
- via the [EDQM Helpdesk](#) on the EDQM website.

Only written complaints can be accepted.

To ensure rapid and efficient processing of the complaints, they should include as many relevant details as possible, including for example when applicable:

- The CEP number, and/or
- The references of any related EDQM inspection
- Details of the issue.

## 6. Timelines for submission and treatment of complaints



Complaints should be submitted within **3 months** of receiving the relevant EDQM product or service. After this period, the EDQM is not obliged to accept the complaint but will endeavor to resolve the issue where possible. If a correction to a CEP is requested after the 3-month period (e.g. editorial changes or address updates), the request will be treated as a [notification](#), and the corresponding [fee](#) will apply.

All complaints are recorded and investigated. Following receipt of a complaint, an acknowledgement of receipt is sent within 2 working days. The outcome of the investigation determines whether the complaint is **valid** or **non-valid**.

### If the complaint is valid

- The EDQM aims to resolve the issue as quickly as possible and **no later than 10 working days** after receipt (especially when a CEP revision is required).
- Corrective and/or preventive actions may be implemented to avoid recurrence and continuously improve services.

### If the complaint is non-valid

- The complainant receives written justification within **10 working days**, after which the case is closed.

### 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 which will be forwarded to the director of the EDQM who will, after investigation, decide on any further action, if necessary.

**Documents referenced:**

Resolution AP-CSP (07) 1 Certification of suitability to the Monographs of the European Pharmacopoeia

(PA/PH/CEP 08) 17 Suspension or withdrawal of a certificate of suitability, closure of an application