

Certification of Substances Department

PPR-HDE-HB/CB

**PUBLIC DOCUMENT**

(Level 1)

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

**Communication on the implementation of the CEP 2.0**

### ***What is the CEP 2.0?***

The CEP 2.0 (new name of the CEP of the future) is a “new-look” CEP that will better meet the current needs of stakeholders and offer both enhanced user-friendliness and greater transparency of the information conveyed without, however, increasing the regulatory burden related to revisions of CEPs.

### ***CEP 2.0: what will change?***

In the context of the project of the CEP of the future, the EDQM organised in late 2020 a wide public consultation with its stakeholders. This was followed in 2022 by targeted consultations in order to define the design of the CEP and discuss specific questions.

Based on the feedback received during these discussions the Certification Steering Committee decided on the future design of CEPs for which the deployment is expected for 2023. This will have impacts on CEP applicants, CEP holders and users of CEPs.

The changes linked to its implementation cover the following 9 areas and will be further detailed within the next months:

- Area 1: CEPs and information reported
- Area 2: Changes regarding assessment of CEP applications
- Area 3: On-line public certification database
- Area 4: Authorities database
- Area 5: Fostering information sharing between CEP holders & MAH
- Area 6: Reduction of revisions of CEPs
- Area 7: Impact of changes and their implementation
- Area 8: Trainings for CEP holders and CEP users
- Area 9: Revising documents available on the EDQM website

At any time, stakeholders may contact the Certification Department via the EDQM helpdesk to get more information: <https://www.edqm.eu/en/faq-helpdesk-certification-and-ceps>. Please choose CEP-Certificates of suitability then the choice CEP 2.0.



## Area 1: CEPs and information reported

The CEP becomes an electronic document with a digital signature, downloadable as a pdf or printed by CEP holders to share with their customers, for inclusion in Marketing Authorisation Applications (MAA).

Its numbering system will change due to a change in the renewal procedure for CEPs (see area 6). The declaration of access box on the CEP document will be replaced by a letter of access for which a template will be available on the EDQM website.

The company details (name and address) will be completed by the EMA SPOR/OMS Organisation (Org) and Location (Loc) ID (more information on EMA Website). These validated organisation data will become mandatory for the submission of CEP applications.

Information reported on the CEP for chemical purity, Herbal Drug/Herbal Drug preparations and related to the quality of the substance will be revised. The main changes to the content are:

“Technical” information (such as additional controls for impurities or solvents) will be replaced by annexing the specification applied by the CEP holder (section 3.2.S.4.1) and the additional methods needed to control the quality of the substance (not those which are alternative to the Ph. Eur. ones) as approved during the assessment of the CEP dossier. The recommendations on how to present these data will follow soon.

The quality of water used in the last steps of the synthesis of the substance will be reported on the CEP.



## Area 2: Changes regarding assessment of CEP applications

Some changes will be introduced regarding the content of the CEP and the associated assessment, which apply to CEPs for chemical purity and Herbal Drugs/Herbal Drug preparations.

The process description and the specification sections of the CEP dossier should contain only information corresponding to the quality claimed (data on micronisation, particle size, microbiological controls, etc. should not be included in the dossier if no corresponding specific grade is requested).

The CEP dossier, the assessment performed and the approved specifications will be fully aligned. As a result, any information not approved will have to be deleted from the dossier.

The applicants will be encouraged to claim a re-test period and to include stability data in their CEP applications. In addition, there will be an extension of the assessment of stability data by proposing the option to submit data referencing to other additional climatic zones (III and IV).



## Area 3: On-line public certification database

The public CEP database available on the EDQM website will include new features in addition to current ones:

The EMA SPOR/OMS Org and Loc ID will be mentioned for the CEP holder and the history of the finalised procedures for each CEP application will be available. This means that the type of procedure without any details on the exact changes introduced in the CEP dossier (e.g. minor revision, notification, major revision, renewal, update of the dossier following a monograph revision), the end/finalisation date, the outcome (i.e. CEP revised, CEP remains valid etc) and the corresponding CEP number if any will be transparent for any user of the database.



## Area 4: Authorities database

The Authorities database is currently intended for the licensing authorities of the member states of the Ph. Eur. convention. It contains confidential information related to the lifecycle of CEP applications as well as copies of the current CEPs and CEP assessment reports. It is aimed to ease the decision making process during the review of the marketing applications for medicinal products where a CEP is included.

There will be new features in this database in addition to current ones. The EMA SPOR/OMS Org and Loc ID will be mentioned for CEP holders and manufacturing sites. The CEP number and CEP document corresponding to each procedure of a dossier (if any) will be available.

It is also foreseen to grant access to regulatory authorities beyond Ph. Eur. which accept CEPs under suitable confidentiality agreements or Memorandum of Understanding (MoU). The EDQM website will describe the list of authorities which have access to the Authorities database. The CEP holder's declarations as part of the CEP application form will be updated to cover this aspect.



## Area 5: Fostering information sharing between CEP holders & MAH

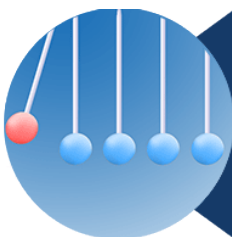
As published in January 2022 on EDQM website, CEP holders have responsibilities towards their customers. They shall namely provide suitable information to their customers in addition to the CEP and it is up to the CEP holder and the marketing authorization holder (MAH) to agree on the information shared and its format. To raise awareness, CEP applicants will have to provide a commitment to share information with their customers as part of the application form for a CEP. In addition, a specific sentence on this obligation will be part of the CEP document and compliance with these requirements will be enforced and checked during GMP inspections. The history of procedures for CEP dossiers will be transparent in the public certification database, so the users will be aware of changes and could ask for the details they need from the CEP holders (see area 3).



## Area 6: Reduction of revisions of CEPs

The CEPs will no longer be revised if their content is not changed. This means that the approval of changes (even major ones) not impacting the CEP content, will not result in the granting of a revised CEP.

The renewal process is kept but a “renewed” CEP will no longer be issued following the renewal procedure, unless changes are introduced at renewal, which impact the content of the CEP. The CEP numbering is impacted by this change and the part of the numbering related to renewal will be removed, for example the new numbering will be **R0** CEP 20YY-XXX-Rev 00.



## Area 7: Impact of changes and their implementation

The project will have a major impact for all users therefore a stepwise approach is foreseen for its implementation. The major repercussion is linked to the fact that the specifications of the substance applied by the CEP holder will be appended to the CEP. To implement the CEP 2.0 smoothly, there is a need to have an appropriate balance between updating the existing CEPs to the “new look” and the burden generated for the holders, the EDQM and the other users.

The “new look” corresponds to the CEP 2.0. with the specifications (3.2.S.4.1) and additional methods appended. These CEPs have the new numbering, SPOR/OMS Loc ID, the declaration of access removed and an e-signature and are issued as an electronic document.

The “new look” CEPs will be issued for any new CEP granted and after the renewal procedures. For the on-going new and renewal files, some updates of dossiers will be requested if needed before the CEP is granted (information not approved will have to be deleted and sections 3.2.S.4.1 and 3.2.S.4.2 will reflect what has been approved during the assessment of the dossier).

The “hybrid look” CEP will be granted after approval of revision applications and notifications for existing CEPs when the content of the CEP is impacted, but the company’s specifications will not be appended to the CEP (since this may require additional assessment not linked to the request for revision and notification). The “hybrid look” CEP will have the new numbering, SPOR/OMS Loc ID, the declaration of access removed and an e-signature and will be issued as an electronic document.

During the initial phase of the implementation of the CEP 2.0, the CEP holders will not be pushed to switch to the “new look” CEP for their existing CEPs except at renewal, after which the specification of the substance will be appended to the CEP. There will however be a special type of CEP revision request to switch to the “new look” CEP for the convenience of CEP holders.

The “old look” corresponds to CEPs as granted till the implementation of CEP 2.0 meaning that no CEP will be granted with the “old look” after the implementation of the CEP 2.0 but CEPs granted before this date will still be valid until they get revised.

Training material will be provided to address the “old”, “new” and “hybrid” looks of CEP and to explain what they are and in which case which one is issued.

“Old look”, “hybrid look” and “new look” CEPs will coexist for some time and experience will show whether additional measures should be taken in the future.



## Area 8: Trainings for CEP holders and CEP users

Some webinars will be organised at the time of the implementation of the CEP 2.0 and after some months of experience.

These will be organised in May 2023 to present an overview of the changes linked to the implementation and after some months of implementation.

Training and guidance will be given for CEP holders and users on the changes to the content of CEP dossiers and also on the content of CEPs at any occasion during conferences and events where EDQM is involved.



## Area 9: Revising documents available on the EDQM website

Most of the documents published on the EDQM website under “Certification policy documents and guidelines” are impacted (applications forms, content of the dossier for chemical purity and microbiological quality, EDQM guideline on requirements for Revisions/Renewal of Certificates of Suitability to the European Pharmacopoeia Monographs,...). These will be revised progressively in line with the different changes and in the meantime information will be shared via news and specific documents.