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Using the CEP Procedure to elevate quality and drive trust

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CEP 2.0:
where do we stand today

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The Goals of the Project

- ★ Meet the needs of stakeholders: CEP holders/API manufacturers, DP manufacturers, regulatory agencies including quality assessors.
- ★ Increase the acceptance of CEPs
- ★ Ease the registration activities performed using CEPs
- ★ Offer enhanced user-friendliness and greater transparency of information without increasing regulatory burden related to revisions of CEPs.

Work areas

5 work areas

Review information to be stated on the CEP

Reduce revisions of CEPs and facilitate handling of changes

Enhance digital tools and public databases

Foster information sharing between CEP holders and medicines manufacturers

Train users on content and use of CEP

Some figures

- Between 01/09/2023 and 01/09/2025, out of 3680 granted CEPs
  - 2083 are in CEP 2.0 format (866 new, 415 renewed)
  - 1597 are in hybrid CEP format
- A number of CEP holders submitted a revision to switch to the CEP 2.0 which led to 802 CEPs in 2.0 format
- 98 major revision applications (out of 222) have been finalised without a CEP being issued.
- 31 renewal applications (out of 537) have been finalised without a CEP being issued.

Webinars

- Follow-up webinars were organised to get feedback from CEP users, holders and authorities, on benefits, difficulties and experience since the implementation of the CEP 2.0
- High participation (1734 attendees out of 2886 registered)
- 310 Questions received during the sessions

Questions related to the use of the CEP 2.0

- Appending specification to the CEP led to questions from CEP users;
  - Significant efforts in trainings and communication (webinars, FAQs, news etc)
  - EDQM policy document «How to read a CEP » revised to explain the specific features of the CEP 2.0 and hybrid CEP
  - EMA Q&A document on "How to use a CEP in the context of a MAA or a MAV"

Post implementation discussions

- Grades, micronisation and particle size distribution (PSD)
  - Cases of applicants claiming tens of grades with different PSD and methods, or few grades but with numerous alternative methods from their customers.
- Controls for microbial purity (TAMC, TYMC), bacterial endotoxins, specified micro-organisms / pathogens
  - Current agreement: only accepted if foreseen by individual monographs. The parameters are strictly related to the drug product and the companies are encouraged to address them in the MAA/MAV.
  - Further discussions may be needed since Ph. Eur. has changed their practice to remove microbial purity tests from the individual monographs and address this at the level of the general monographs.

Issues with SPOR OMS Id. mentioned on CEPs

- The initial idea was to replace administrative details of CEP holders and manufacturing sites (name and address) by SPOR OMS Org and Loc Id only.

- In 2023 at the launch of CEP 2.0, it was not possible nor realistic to use only the SPOR Loc Id. Stakeholders and databases were not ready and EU Variations guideline did not fit with reference only to Org and Loc Id.
  - Inclusion of Org and Loc Id in the CEP in addition to the full details (name and address) to prepare for the future

Issues with SPOR OMS Id. mentioned on CEPs

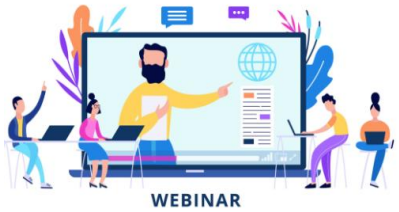
- Since the implementation, many issues encountered
  - Cases with differences between addresses declared by companies to EDQM and those registered in the SPOR OMS data.
  - Numerous requests to companies to flag these differences and request them to update SPOR OMS data (administrative burden)
  - Inconsistencies also within the data stored in SPOR OMS database and users highlight many issues (who is the owner of the data, data changed by others than the company itself, SPOR OMS uses information from local authorities for addresses and not what is declared by companies, etc).

Issues with SPOR OMS Id. mentioned on CEPs

- How can these issues be solved? Maybe another way to present the information on CEPs. e.g. only name of company, SPOR Org Id and “shorter” address with city, country and Loc Id
  - Deeper investigation is needed to get feedback from CEP holders, CEP users and authorities (EU and outside) and also specialists in data management on what are their needs and how are these data used for filing MAA
  - Exploration on creations of links between databases (latest details on companies names and addressed can be retrieved).

Authorities database

New features in addition to existing ones



- ★ EMA SPOR OMS ORG_ID and LOC_ID
- ★ CEP number and CEP document corresponding to each procedure (if any, instead of only the last one).
- ★ Extension of access to some regulatory authorities as part of worldwide acceptance of CEPs under suitable confidentiality agreements and MoU.
  - ★ Publication on the EDQM website of the list of competent authorities and organisations with a MoU or confidentiality agreement having access to assessment and inspection reports.

On-line Certification database

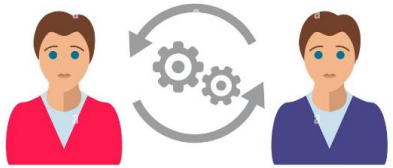
- New features in addition to current ones.
  - EMA SPOR OMS ORG_ID and LOC_ID for holders
  - **Renewal date for the CEP (where not yet renewed)**
  - Access to short history of finalised procedures (which can be downloaded as pdf) with:
    - ✓ type of procedure (e.g. minor revision, notification, major revision, renewal, monograph revision)
    - ✓ closure date of the last procedure, outcome (i.e. CEP revised, CEP remains valid)
    - ✓ corresponding CEP number, if any
- History available only for procedures opened as of 1 January 2020 (due to change of IT technology)

Information sharing between CEP holders & MAH

- CEP holder shall provide information to their customers in addition to the CEP.
- Reminder to CEP holders with the document “CEP holders' responsibilities towards their customers” on the EDQM website.
- Reinforcement of this responsibility with the CEP of 2.0:

Publication of history of procedures in the public certification database, so users are aware of changes and can ask details from the CEP holders

A specific sentence on this obligation in the CEP document



A commitment as part of the application form for a CEP

Effective sharing of information is checked during EDQM GMP inspections.

A specific sentence on this obligation in the CEP letter of access

Conclusion: did we reach our goals?

- Requirements and their impact on CEP dossiers better understood by CEP applicants. ✔
- Less questions raised during assessment in relation to CEP 2.0 aspects. ✔
- Positive feedback received during events EDQM staff attends, both from competent authorities and industry. ✔
- The transparency brought by appending the specification of the substances covered by the CEP is highly appreciated although some questions remain. ✔

Conclusion: did we reach our goals?

- 129 CEPs were not revised following major revisions/renewals reducing the unnecessary regulatory burden
- Administrative details (i.e. sites' addresses) are still having a relevant impact on the revisions
- « **Applicant's portal** » A dedicated space where applicants have access to information regarding their CEP applications

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