European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Department

NF/CB

WORKING DOCUMENT, WITH NO LEGALLY BINDING STATUS,
intended exclusively for the addressees
and their associates, under the responsibility of
the addresses (Level 4)
English only/Anglais seulement

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Certification of suitability to the Monographs of the European Pharmacopoeia

Public consultation on the CEP of the future

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1. Content of the survey

1.1. Introduction

The content and layout of the current Certificate of Suitability (CEP) remains very similar to the original created in 1992. The EDQM is nonetheless well aware of the far-reaching effects that globalisation, the rise of digital technology and many other major regulatory and scientific developments have had on the pharmaceutical industry and competent authorities over the last three decades and, in response, is launching a project to design the CEP of the future. The aim is to develop a "new-look" CEP that will better fit the emerging needs of stakeholders and offer both enhanced user-friendliness and greater transparency of the information conveyed without, however, increasing the administrative regulatory burden related to their revision.

Since this is a major change, the EDQM believes that it is crucial to first gather feedback from all stakeholders with regard to the content, layout, format and use of CEPs.

You are invited to take part in this important survey which will give you a unique opportunity to help shape and influence the different aspects of the future "new-look" CEP.

Please feel free to provide as much information (your opinions, comments, needs and feedback) as you feel appropriate; everything you give us will be analysed and used wherever possible to re-design CEPs and enhance their usability for the benefit of all stakeholders, from both industry and National Competent Authorities worldwide.

There are 24 questions in total. It will take you about 1 hour to reply to all of them and there is space to provide additional feedback at the end. We recommend that you read the entire list of questions before starting to respond. Answers should be returned to us by 31 December 2020.

All the information you provide will be handled anonymously and kept for a period of 5 years by the EDQM. You will be informed about the outcome of this consultation and the new design of CEP in due time.

Please note that you are welcome to share this survey widely with any other relevant and interested partners

Thank you in advance for your valuable input and for accepting to help us design the CEP of the future!

1.2. Questions

Participant's profile

1. You are part of

Choose one of the following answers

- a Ph. Eur. competent authority
- a non-Ph. Eur. competent authority
- a CEP holder company
- a MA holder company
- an industry association
- Other:

Content of the CEP

2. A CEP is granted for a substance without knowing its final use since this information is not available at the time of the submission of the CEP application. Do you encounter any difficulties with respect to this aspect of the procedure? If so, is there anything you think the EDQM should change to address these difficulties? Please explain and elaborate.

3. What kind of information do you require concerning the sites involved in the manufacture and control of the substance covered by the CEP? Are the details currently available in Annex 1 of the CEP appropriate with respect to the manufacturing sites and their roles? In your opinion, what information is missing and why? Do you have any suggestions?

4. Which elements/information should be presented on the CEP concerning the quality of the substance it covers? A CEP currently only specifies information on controls which are required in addition to those of the Ph. Eur. monograph (e.g. impurities, solvents, use of water, methods). In your opinion, is this appropriate or is there a need for more information? Please explain and elaborate.

5. Is the current information on grades and subtitles clear? Do you have any suggestions on how to optimise the information about grades and subtitles on CEPs? Please explain and elaborate.

6. Do you consider the information reported concerning the container closure system appropriate? Do you have any suggestions as to how it could be improved? Please explain and elaborate.

7. What information is needed with respect to the stability and re-test period of the substance covered by the CEP and why? Please explain and elaborate.

8. What information should be included on Chemical CEPs with respect to sterile substances? Please explain and elaborate.

9. What additional information, currently NOT mentioned on chemical CEPs, should be included? Please explain and elaborate.

10. What additional information, currently NOT available, should be included on TSE CEPs? Please explain and elaborate.

11. What additional information, currently NOT available, should be included on Herbal CEPs? Please explain and elaborate.

12. How useful do you find the information currently provided on CEPs? Is there information currently mentioned on a CEP which could be omitted or which is not important for the regulatory process? Please explain and elaborate.

Layout of the CEP

13. What should the future CEP look like? Do you have any suggestions for the layout? How useful are the numbering of the lines, numbering of annexes and pages, etc.? Please explain and elaborate.

14. Is the current CEP numbering system RX-CEP xxxx-xxx-Rev XX meaningful as regards the lifecycle of a CEP application (e.g. transparency of renewal with the credential RX and revisions with the credential Rev XX)? What difficulties, if any, do you encounter with this numbering system? Do you have any suggestions as to how it could be improved? Please explain and elaborate.

Format of the CEP

15. The current CEP is a paper document. Do you encounter any difficulties when using this document in marketing authorisation applications (MAAs) due to its format? If so, please explain.

16. Do you have any suggestions to change the format of the CEP (e.g. paper document, electronic document, addition of a QR code)? Please explain and elaborate.

17. If you could only receive an electronically signed CEP (qualified electronic signature), what potential risks and issues would this pose for your company/organisation/country? How would you recommend addressing these issues?

Use and distribution of the CEP

18. How useful is the current "certification database" (available on the EDQM website)? Should the database include additional information or have additional features to make it more useful to you (which ones and why)?

19. Access of the finished product manufacturer/marketing authorisation holder to relevant information on the manufacture and control of substances covered by a CEP they use is a recurring issue. Manufacturing authorisation holders of finished products are legally obliged to audit their suppliers, and CEP holders are bound by their commitment to inform their customers of any changes they make to the manufacture and control of their products.

However, recent incidents have shown that the current system does not entirely fulfil its purpose. While the EDQM only interacts with the CEP applicant/holder, and information exchanges between the CEP holder and their customers should be covered by a quality agreement, do you think there is anything the EDQM could do to further encourage CEP holders to increase transparency and share information? Please explain and elaborate.

20. Following up on the previous question, in your opinion, is there anything the EDQM should change on the CEP itself or in the certification database to further encourage CEP holders to inform their customers of changes made to the manufacture or control of their substance that have been approved by the EDQM? Please explain and elaborate.

21. What could be changed in the current CEP document and the certification database in order to reduce the number of administrative variations in MA applications linked to changes/revisions of the CEP? Please explain and elaborate.

22. How convenient and user-friendly is the “declaration of access” box on the CEP? Should it be replaced by something else (e.g. “letter of access” as for ASMF)? Do you have any proposals? Please explain and elaborate.

23. Is there a need to check that a CEP is authentic and/or complete? If yes, do you have any proposals? Would a QR code be appropriate to verify the authenticity? Please explain and elaborate.

Miscellaneous

24. Please use this space to add any other comments or suggestions on the CEP and its use.

1.3. End message

Thank you for having taken the time to respond to this survey. As stated above, you will be kept informed about the outcome in due course.

If you have any additional information you would like to share with the EDQM on this topic (a letter or other document), you may submit them directly by e-mail to the address cep@edqm.eu.

If you are interested in receiving regular updates on EDQM news and CEP activities, you can register to receive our eNewsletter.