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The place of the Certification Procedure In the global regulatory environment

Helen Robbins, RB, Regulatory Manager Post Approval Maintenance
On behalf of the Association of the European Self-Medication Industry (AESGP)

AESGP 

AESGP

- Founded in 1964
- Members:
 - 25 National Associations
 - 25 Member Companies
- Represents the manufacturers of non-prescription medicines of chemical and herbal origin
- Promotes responsible self-care

AESGP 

General remarks – In Scope

- The use of CEP's is a well understood and established process within the industry and is much appreciated as saves duplication and resources for both API and finished product manufacturers
- Substances described in monographs in the Ph. Eur. (Active substances, excipients, herbal drugs / herbal preparations) are in scope of the CEP procedure

General remarks – Out of Scope

- Out of scope of the CEP procedure:
 - Substances not included in Ph. Eur.
 - Biologicals
 - Human tissues derivatives, blood derivatives, vaccines
 - Homeopathics
 - Substances which do not comply with the Definition section of the monograph
 - Finished products

General remarks – Future Potential?

- Inclusion in the future scope of the CEP procedure for mother tinctures for homeopathic medicines?
 - Currently outside the scope of CEPs
 - A number of Ph. Eur. monographs exist for homeopathic preparations and mother tinctures
 - We recommend consideration of expanding CEP scope to mother tinctures

Observations on CEP changes – CEP holders view

- It is clear to CEP holders that they have to inform the EDQM of any change to the information provided in the initial application and precise the level of changes via a notification form
- It is unclear upfront as to whether the change will mean new CEP version (Rev. XX) or not...
 - Higher transparency on what triggers new CEP versions would be desirable

Observations on CEP changes – MA holders view

CEPs can seem to change quite often...

- It can be unclear what has changed

MA holders rely on CEP holders to inform them when CEPs are revised and what they have changed

- It would be desirable if MA holders could set up notifications for specific CEPs within the EDQM database so they receive notifications when these specific CEPs are under review and/or updated

Recognition of CEPs

- Some country observers to the EDQM are requesting more information on substance or sometimes even not recognising CEPs as a sufficient and reliable information for submission.
- This is an issue when seeking MA in these countries using existing dossiers containing CEPs
- Are there some discussions within EDQM with respect to such situations?

CEPs and GMP

- The aim of the EDQM inspection program is to “check compliance with GMP and the CEP application (and any updates) at the manufacturing and/or distribution sites covered by CEPs.”
- Many regulatory bodies do not recognize the GMP certification by EDQM and require additional GMP authorisation by another regulatory agency to confirm GMP compliance of the API Manufacturer

CEPs and Regulatory Optimisation Group

- Regulatory Optimisation Group (ROG)
 - small targeted authority-industry group within HMA
 - Mission: identify and deliver business cases aiming at optimising the operational practices and processes of the EU regulatory network
 - Reduce administrative burden and free up human resources for more scientific work
- 2017 ROG Workplan is focused on type IA variations, including several CEP-related variations

www.aesgp.eu | info@aesgp.eu