Update from CMDh
June 2015 – August 2015

PCWP/HCWP joint meeting 17
September 2017
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1. European Reference Product

- Concept introduced in the Directive in 2004 to support the availability of medicines in the Member States
- To be used as a basis for a generic application if the reference medicinal product is not authorised in the MS where the application is submitted, thus allowing the availability of the generic even if the originator is not authorised in that MS
- The definition of the reference medicinal product is based on active substance, strength and marketing authorisation holder
- Some MS had some difficulties accepting a European Reference Product if they had another reference product authorised in their MS (e.g. interchangeability issues)
- On the basis of the same principles and interpretation used by the European Commission and applied by EMA and majority of MS, during CMDh discussions it was agreed that using a ERP is not case for invalidating an application. CMDh will publish necessary guidance on this topic.

2. Update on guidance on QR code

The CMDh discussed questions on QR codes brought forward by a Member State.
It was agreed that the QR code could be placed on the primary packaging in case a product does not have secondary packaging.
The CMDh was in favour to allow the possibility to include the QR code on the primary packaging even in cases when there is secondary packaging. The content has to be in line with the agreed principles and should not have a negative impact on the legibility. All the legally required information still has to be present on the packaging.

3. PSUSA outcomes at CMDh

- During the last quarter, the first Periodic Safety Update Report Single Assessment (PSUSA) outcomes being agreed at CMDh for nationally authorised medicinal products – procedure going well.

- Further information regarding the above-mentioned PSUSA procedures, including information on the implementation, are published on the EMA website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000620.jsp&mid=WC0b01ac0580902b8d

CMDh
Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human

Thank you!!