European Directorate for the
Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

The Director

Unit SANCO/D/3
BREY 10/114
BE-1049 Brussels

RZ/PH/2012-03089L
SK/rhe

Strasbourg, 26/04/2012

RE: EDQM comment on the consultation paper on the detailed rules for a unique identifier for medicinal products for human use, and its verification

Dear Sir/Madam,

Please find enclosed our answer to the public consultation launched on 18 November 2011 on the Delegated acts on the detailed rules for a unique identifier for medicinal products for human use, and its verification.

The answers given here to the consultation reflect the expertise and knowledge acquired in this field by the European Directorate for the Quality of Medicines and HealthCare (EDQM) as an inter-governmental organisation and a directorate of the Council of Europe (CoE).

The EDQM is a leading organisation that protects public health by:

- enabling the development,
- supporting the implementation, and
- monitoring the application

of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopoeia is legally binding in European member states.

Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantations and consumer health issues.

Yours sincerely,

Dr Susanne KEITEL
Director

cc: FXL, HJB

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