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Medicines for Europe's Contribution to WHO's Biological Qualifier (BQ) Developments 18 October 2016

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Vision 2020 - Our 5 pillars

Medicines for Europe
VISION


PATIENTS


QUALITY


VALUE


SUSTAINABILITY


PARTNERSHIP

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Presentation Outline

1. Update on EU & International developments relevant for the INN expert committee identification debate

- New EMA Good Pharmacovigilance Practice (GVP) Module for Biologicals
- Falsified Medicines Directive implementation
- ISO Identification of Medicinal Products (ISO IDMP) standards implementation

2. Biosimilar Medicines Group questions on BQ pilot scheme project for ToR

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NEW EMA Good Pharmacovigilance Practice (EU-GVP) Chapter for Biologicals

(AUG 2016)

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Pharmacovigilance aspects specific to biologicals

HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 August 2016
EMA/168402/2014

Guideline on good pharmacovigilance practices (GVP)
Product- or Population-Specific Considerations II: Biological medicinal products

Draft finalised by the Agency in collaboration with Member States	17 November 2015
Draft agreed by the European Risk Management Strategy Facilitation Group (ERMS FG)	24 November 2015
Draft adopted by Executive Director	8 December 2015
Start of public consultation	15 December 2015
End of consultation (deadline for comments)	29 February 2016
Revised draft finalised by the Agency in collaboration with Member States	9 June 2016
Revised draft agreed by ERMS FG	26 July 2016
Revised draft adopted by Executive Director as final	4 August 2016
Date for coming into effect	16 August 2016

- Immunogenicity
- Manufacturing variability
  - ….potential for serious new risks (safety or efficacy) to emerge at **any time point in the product life-cycle** due to **changes** in product quality or characteristics
- Stability and cold chain
- Product traceability
  - When reporting suspected adverse reactions, CAs and MAHs shall provide all available information on each individual case, including the **product name and batch number**

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EU Falsified Medicines Directive (FMD) - Implementation

EU Falsified Medicines Directive (FMD) in implementation phase

- **Data-Matrix code, developed to ISO-standards: powerful unique identifier**
- **Key data elements:**
  - Product code (GTIN/NTIN or PPN)
  - Randomized unique serial number
  - Expiry date
  - Batch number
  - National health number (where necessary)

Making each product unique

Facilitating Pharmacovigilance

Product #:	09876543210982
Batch:	A1C2E3G4I5
Expiry:	140531
S/N:	12345AZRQF1234567890

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ISO IDMP Standards - Implementation

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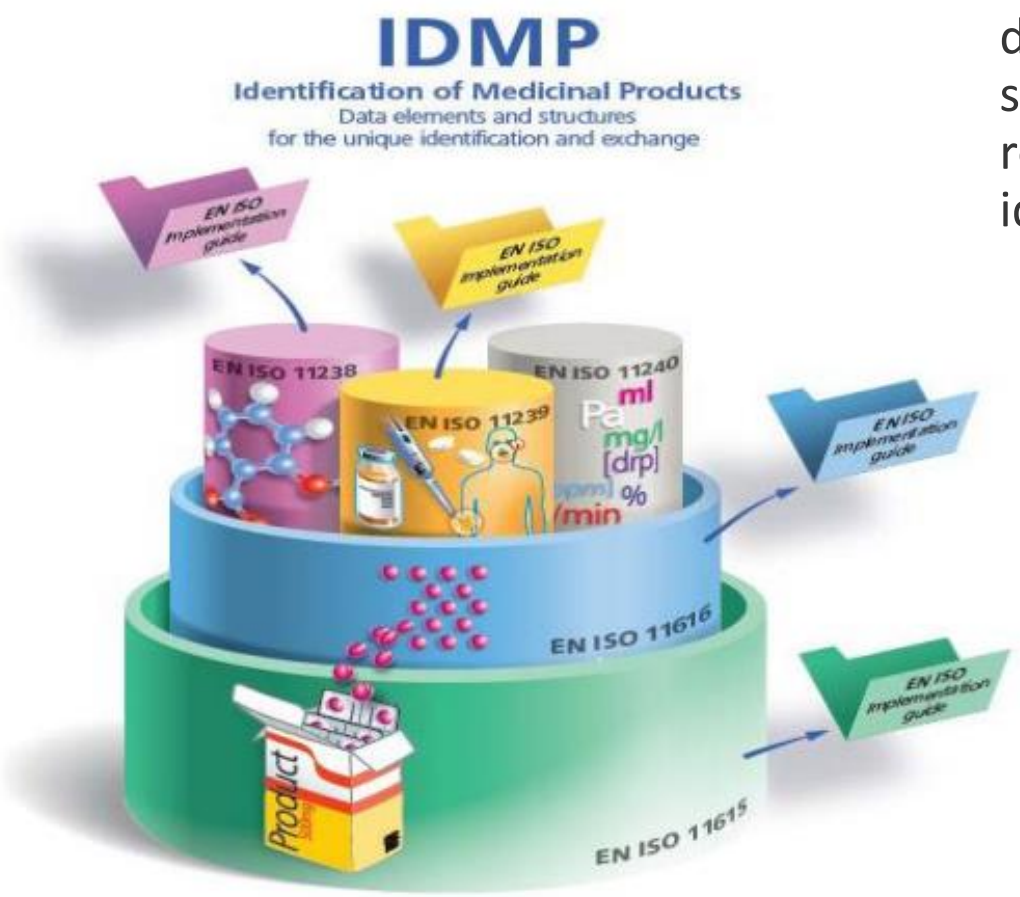
ISO IDMP standards EU implementation ongoing



- The ISO IDMP standards establish definitions and concepts and describe data elements and their structural relationships that are required for the unique identification of:
  - Units of measurement (UCUM) -ISO 11240
  - Pharmaceutical dose forms, units of presentation, routes of administration and packaging -ISO 11239
  - **Substances (Substance ID) -ISO 11238**
  - Pharmaceutical product information (PHPID) -ISO 11616
  - Medicinal product information (MPID/PCID) -ISO 11615

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Biosimilar Medicines Group's questions on WHO BQ pilot scheme project

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Open Questions* to the INN Expert Group and WHO Management

*Selection of

Only prospective application planned

- How can a prospective approach provide sufficient data to evaluate the usefulness of the BQ for the intended purposes?
- When will the retrospective application be addressed in order to provide a level playing field for biosimilar medicines and a competitive neutrality is achieved?

Random countries to be selected for BQ pilot

- How will the features of the pharmacovigilance system be taken into account in the ToR?
- What role will WHO play in the local implementation into local pharmacovigilance and healthcare communities' databases?

Interoperability of BQ with other systems

- Given that the BQ is not ISO standard, how will the pilot scheme ensure interoperability amongst international agencies and healthcare communities?

International developments and alignment

- How can the FDA be included in the pilot since the FDA suffix is NOT equivalent to the WHO BQ?

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Open Questions* to the INN Expert Group and WHO Management

*Selection of

BQ impact on access to medicines

- What are the criteria/key performance indicators for evaluating the impact on access to medicines within the scope of prospective implementation?

Kick off date for pilot

- How does WHO coordinate the convergence of national frameworks to accommodate the BQ?
- Will there be one kick off date of the pilot?

Added value of the BQ over other existing validated systems

- How is the added value evaluated?

Summary conclusion and recommendations

- **Countries to implement ISO IDMP standards**
  - *"*ISO IDMP (IDentification of Medicinal Products) standards have been developed and published in 2012 to establish a lasting international framework which allows exchange of medicinal product information in a robust and reliable manner…..
- **Implementation of the proposed BQ scheme and impact study to be decoupled**
- **The development of any additional identifier to be preceded in every "BQ volunteering country " by a rigorous assessment** of the need for such an identifier, its legal basis, and an evaluation of potential alternatives and impacts, such as benefits, burdens and cost-effectiveness, in line with the October 2016 WHO Draft: Good Regulatory practices: guidelines for national regulatory authorities for medicinal products (QAS/16.686)
  - In particular in the interest of patients, it must be ensured that the BQ does not lead to any confusion or medical errors in the global health care arena.

Call for a Moratorium of the provisional BQ implementation scheme

- Given that no single WHO Member Country has undertaken a formal and public regulatory impact analysis (RIA) regarding the WHO BQ scheme, we urgently call for **a moratorium** of the provisional implementation of the BQ scheme and call for further international exchange and dialogue

- Implementing without a prior RIA will contribute to the proliferation of different national identifiers, in particular in case the scheme is dropped, and goes against the primary purpose of the BQ proposal.

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Looking forward to contributing to further discussions
THANK YOU!
ANY QUESTION?