Report from the WHO workshop on IDMP, WHO HQ, Geneva, Sep 11-12, 2019

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Aim of the workshop

A clear articulation of the benefits and challenges of the maintenance of global PhPID

Initial considerations for the necessary policy, processes, training and resources for scale-up of IDMP in different geographic and resource settings

Consensus to establish a working group and initiate the development of a plan for the maintenance of global PhPIDs

Elements of a framework for further outreach and collaboration in the global implementation of the IDMP standards

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Participants

US-FDA

EMA

PMDA

Health Canada

WHO

UMC

Brazil

Morocco

Nigeria

Thailand

IFPMA

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Use cases identified for IDMP and global PhPID

Pharmacovigilance including signal detection, medication errors & pharmacoepidemiological studies

Reimbursement and purchasing

- Comparing for example price differences between countries

Stock-outs and shortages

- Identify comparable products to be used

Cross-border prescriptions

Support information sharing in-between authorities

- Identify products with the same ingredients in drug submissions and evaluations

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IDMP and implementation of global PhPID

There is a risk for disharmony in the implementation of global PhPID with local solutions:

- Local assignment for substance IDs
- Local controlled vocabularies
- Local variations of PhPID algorithms to fit local use case that can not be mapped to a global PhPID

There is a need to adopt a proactive approach that will limit unnecessary local variations in the data

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A need of global control vocabularies to ensure consistency of global PhPID.

A global PhPID needs global control vocabularies according to ISO 11238, ISO 11239 and ISO 11240

- **Identified problem with dosage form according to ISO 11239**
  - Need for adaptations of EDQM to ensure global use
- **A global substance ID is a prerequisite for a global PhPID**

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Use and maintenance of Global PhPID

WHO proposal:

The WHO collaborating centre, the Uppsala Monitoring Centre (UMC), take on the responsibility for the day-to-day operations of the global PhPIDs

- WHO-UMC maintained global PhPIDs use global substance IDs, dose forms, strength and reference strength according to ISO standards
- All users (regulators and industry) are able to use and request global PhPID
- Users understand the different components of IDMP and use or map to global dose forms, strength and reference strength

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Use and maintenance of Global Substance ID

WHO proposal:

To form a working group to investigate the requirements for global substance registration. The group should define best practise for how to identify/validate new substances and the level of granularity needed for global substance registration

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Need for promotion of global consistency of IDMP

Find out needs from different stakeholders regarding training, promoting and awareness

- What investment is needed for each regulatory authority to start using IDMP?

The following ideas were suggested regarding awareness and promotion:

- Learn from what has been done already (e.g. FDA for G-SRS, EMA for EU-SRS)
- Circulate information about webinars, e.g. FDA and EMA are broadcasting regularly
- Create training material
- Use IPRP to raise awareness of IDMP

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Nest steps: Global PhPID

Work group for global PhPID:

- **to have frequent meetings to update on progress and discuss implementation approaches**
- **to agree on next steps for global PhPID, including possible pilot and business case for WHO-UMC maintained global PhPID to give the background and value of the initiative**
- **to elaborate on the use cases for global PhPID**
- **investigate the feasibility of incorporating veterinary medicines into WHO-UMC maintained global PhPID**

Development of the global PhPID service should follow the pace of the development and implementation of IDMP in a stepwise and pragmatic approach

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Nest steps: Global Substance ID

A separate group should define the objective, expertise and membership needed to form a working group for creation and maintenance of global substance IDs

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Nest steps: communication

Present update at IPRP meeting in October and discuss possible collaboration with ISO/WHO.

Developed communication material including work group minutes to be published on IPRP homepage

No efforts should be duplicated, interact with other groups working with IDMP (ISO, IPRP etc)

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