First meeting of the CIOMS Expert Working Group on MedDRA Labelling Groupings (MLG)

3–4 April 2019

CIOMS offices, Ecumenical Centre, 150 Route de Ferney, 1218 Geneva, Switzerland

Report from the CIOMS Secretariat

Dr Lembit Rägo welcomed the participants and provided an overview of CIOMS, including its history, significant and recent activities and contributions of CIOMS. To increase transparency and stimulate comments, CIOMS has started to publish high-level web versions of Working Group (WG) meeting minutes on the web. Comprehensive and up-to-date information about CIOMS is available (https://cioms.ch/).

L Rägo shared his vision for MedDRA Labeling Groupings (MLG), Expert Working Group (EWG). L Rägo also updated the group about his interactions with MedDRA Management Committee (MMC)/International Council for Harmonization (ICH) and shared the concept paper and one pager from MMC/ICH that was developed during the ICH meeting held in Charlotte, U.S., in the week of 10 November 2018.

MedDRA Labelling Groupings (MLGs)

An overview about the MLG initiative was given. The Expert Working Group (EWG) has been informed that a presentation on the CIOMS activity for MLGs has taken place on the last Annual Meeting of the International Society of Pharmacovigilance (ISOP) meeting (Geneva; Nov 13, 2018).

The group reviewed the regulatory guidances supporting adverse drug reaction presentation in product label, ISOP presentation, one pager and concept paper. The group also reviewed the document titled “Questions and Points for Clarification” from ICH, regarding the proposed MLG concepts.
This review enabled a detailed discussion on the concept of MLGs, which led to the agreement that there is a need to develop core principles of MLGs to attain harmonization. The group discussed the overall purpose of MLGs.

The group agreed that there is a need to simplify and standardize labeling to serve as a communication tool of medical concepts to primary stakeholders (e.g. HCPs, industry) and not primarily as a regulatory document. The group postulated that development of MLG principles such as inclusion and exclusion criteria, would help achieve consistency in adverse event presentation in labels.

The group delved into additional topics such as goals and limitations of MLGs for standardization. One such limitation discussed was that the granular nature of MedDRA does not necessarily support the need to serve as a communication tool for external facing stakeholders. Overall, the group agreed that one of the central precepts for MLGs is to improve communication, likely for practitioners and possibly for patients.

The Group explored the impact of MLGs, given the legal nature of a label, specifically pertaining to expedited reporting or expectedness, Reference Safety Information (RSI) for Investigator Brochure, Company Core Data Sheet (CCDS) and other labeling documents.

The group suggested that further work towards delineating general principles for MLGs is likely to help clarify the scope of MLGs. The group postulated that these principles for MLGs potentially may have voluntary usage, be explicit (potential application to commercially available/marketed products), easily accessible, and widely available.

The participants agreed that feasibility of MLGs could be explored through a review of examples of MLGs used for adverse event representation with Preferred Terms (PTs) in labels in different jurisdictions.

Review of the Principles of MLG in development and in production

The group considered some challenges of implementing MLGs such as identification of scope of MLGs not only in terms of stakeholders for MLGs but also the impact on various legal and regulatory documents. A proposed roadmap was to consider regulatory/Health Care Providers first, then consumer in a stepwise fashion.

The group also reviewed few examples of MLGs presented, including the principles in their creation and discussed the challenges for maintenance and versioning of MLGs at the time of MedDRA updates.

The group proposed MLGs should be voluntary in nature with guidance with established principles.

Participants agreed to develop a roadmap with following next steps, in order of priority:

1. Develop a mission statement
2. Prepare a presentation at the DIA in San Diego (June 2019), entitled “The elephant in the room-meaningful communication of near synonyms as suspected ADRs”, in order to seek input to the initiative from various stakeholders

3. Identify current examples of MLG in the labels to better illustrate/define the problem statement
4. Clearly outline the principles of MLG.

Date of next meeting

The date of the next meeting was tentatively scheduled for middle of September 2019 (23 September 2019).

Participants

CIOMS		
	Lembit Rägo	Secretary-General
	Susanne Le Roux	Administrative assistant
Regulators, MedDRA JMO		
	Sonja Brajovic	FDA, U.S.
	Mari Kobayashi	PMDA, Japan
	Omi Watanabe	PMDA, Japan
	Yutaka Nagao	MedDRA JMO
	Lynn Macdonald	Health Canada (By Phone)
	Norbert Paeschke	BfArM, Germany
	Aniello Santoro	European Medicines Agency (EMA)
Product R&D		
	Silvia Bader-Weder	Roche
	Brian S Dillman	Eli Lilly
	Bill Gregory	Pfizer
	Debbra Scotti	Pfizer
	Ilona Große-Michaelis	Bayer
	Judith Jones	PharmaLex
	Diane Farkas	Sanofi Aventis
	Jill Robinson	Amgen
	Radhika Rao	AbbVie
	Hitomi Takeshita	Chugai Pharmaceutical