Second Meeting of the CIOMS Working Group on MedDRA Labeling Groupings (MLG)

25–26 September 2019

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

Contents

Report from the MLG EWG meeting

Dr Lembit Rägo welcomed participants of the MedDRA Labeling Groupings (MLG), Expert Working Group (EWG) second meeting. Introduction and Tour de Table was completed.

The group reviewed minutes from the MLG EWG first meeting. The group also reviewed a draft mission statement and the problem statement that focuses on the 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.

All Presentations including the outcome of DIA presentation, and round table at DIA San Diego June 2019, were reviewed.

The group discussed the document titled “Questions and Points for Clarification” from ICH, regarding the proposed MLG concepts and European Commission Clinical trials regulation EU No 536 question and answers. Following this review a detailed discussion ensued on the preliminary work on development of principles and concept of MLGs to achieve consistency in adverse event presentation in labels.

Review of the Principles of MLG in Development

The MLG EWG proposed draft concepts for principles of MLGs. Examples of MedDRA Preferred Term groupings and potential principles for groupings were presented and reviewed.

Various aspects of MLGs were considered and it was agreed that the principles for MLG should be clearly delineated to appropriately capture the medical concept and maintain important safety information.
The group proposed that MLGs should be voluntary in nature with guidance from established principles, in a manner that is consistent with existing regulatory frameworks.

Participants agreed with the following next steps, in order of priority:

1. Continue to develop concepts for principles of MLGs
2. Prepare a presentation at the DIA 2020 in Washington/USA, round table/forum at World Drug Safety Congress Americas 2020, in Boston/USA in order to seek input for the initiative from various stakeholders
3. Address the document "Questions and Points for Clarification" from ICH
4. Work towards potential future publication

Date of next meeting

The date of the next meeting was tentatively scheduled for 13 and 14 May 2020.

Participants

CIOMS		
	Lembit Rägo	Secretary-General
	Susanne Le Roux	Administrative assistant
Regulators		
	Scott Proestel	FDA, U.S.
	Kanae 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		
	Brian S Dillman	Eli Lilly (By Phone)
	Debbra Scotti	Pfizer
	Ilona Große-Michaelis	Bayer
	Judith Jones	PharmaLex
	Diane Farkas	Sanofi Aventis
	Jill Robinson	Amgen
	Radhika Rao	AbbVie
	Andrea Brown	Gilead