



## **Sixth Meeting of the CIOMS Working Group on MedDRA Labeling Groupings (MLG)-Virtual Meeting June 20th, 2023**

### **Contents**

#### **Report from the CIOMS Secretariat:**

Welcome: Ilona Große-Michaelis & Lembit Rägo:

Dr. Lembit Rägo welcomed the MLG Working Group participants to the call to the sixth CIOMS MLG EWG virtual meeting and provided an update on the seven CIOMS Expert Working Groups (EWGs) that are currently active.

Dr. Ilona Große-Michaelis invited participants to the agenda topics for 'today's meeting.

Tour de Table Introduction:

Participants briefly greeted everyone on the call.

#### **Open Topics Discussion:**

Dr. Ilona Große-Michaelis updated the CIOMS MLG EWG draft report status. Also, Dr. Ilona Große-Michaelis mentioned that the report writing sub-team wants to receive input and achieve consensus with the CIOMS MLG EWG on a few topics at this meeting.

The EWG discussed the MLG conventions in detail with MLG *Abdominal pain*, MLG *Insomnia*, and MLG *Renal impairment* example illustrations and achieved consensus on the interpretation of the conventions in grouping the MLGs with regards to differences in severity or because they represent different clinical entities. The EWG noted that these MLG examples should not be considered final and will only be presented in the report for illustration purposes.

A detailed discussion ensued on how the MLG EWG envisions the presentation of the MLGs in the product label as the PTs grouped are nearly synonymous terms, and hence, footnotes to provide the subtle distinction between the terms and further characterize the terms seem reasonable. The EWG agreed that the primary purpose of MLGs is to improve communication in the product label to achieve transparency and that the presentation of the safety information is as accessible as possible.

### **Future Considerations of CIOMS MLG EWG Draft Report:**

The EWG considered the next steps in finalizing the draft report and agreed to have an electronic version posted on the web. The broader CIOMS EWG engagement with review and comment of the EWG report was encouraged to ensure timely progression of the report and that the final product is representative of the views of the entire CIOMS EWG.

The goal of the EWG is to have the report complete by the end of 2023.

### **Date of next meeting**

To be determined.

## Participants

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### CIOMS

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Lembit Rägo	Secretary-General
Susanne Le Roux	Administrative Officer

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### Regulators

Scott Proestel	FDA, U.S.
Tomohiko Hara	PMDA , Japan
Tomohiro Hatta	PMDA , Japan
Yutaka Nagao	MedDRA, Japan (JMO)
Tomoka Narita	PMRJ, Japan
Lynn Macdonald	Independent
Aniello Santoro	European Medicines Agency (EMA)

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### Product R&D

Ilona Große-Michaelis	Bayer AG
Christiane Michel	Novartis Pharma AG
Radhika Rao	AbbVie
Silvia Bader-Weder	Roche

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