Council for International Organizations of Medical Sciences

9th meeting of the CIOMS Working Group on Recommended Standards of Education and Training for Health Professionals Participating in Medicines Development

Geneva, 29-30 October 2024

Meeting Minutes

Participants:

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Regrets: Priya Bahri, Barbara Bierer, Malcolm Brown, Matthew Farmer, Sophia Goodison, Stuart Jones, Kenneth Katin, Katarina Kelin, Nilima Kshirsagar, Michelle Limoli, Simon Maxwell, Min Soo Park, Honorio Silva, Ena Singh, Peter Stonier, Ichiro Uchida, Haruko Yamamoto.

Secretariat: Lembit Rägo

The following definitions were proposed:

Product development

Medical product scientific development includes all processes and activities necessary to generate, assess and communicate data with the aim of bringing the product to the market and supporting its safe and effective use through its lifeline.

Health professional

Health professionals maintain health in humans through the application of the principles and procedures of evidence-based medicine and caring. They diagnose, treat, prevent and document human illness, injury and other physical and mental impairments in accordance with the needs of the populations they serve. They also conduct and assess non-clinical and clinical research and improve or develop concepts, theories and operational methods to advance evidence-based health care.

[To be fine-tuned based on the below:

Health professionals *maintain health in humans through the application of the principles and procedures of evidence-based medicine and caring. Health professionals study, diagnose, treat and prevent human illness, injury and other physical and mental impairments in accordance with the needs of the populations they serve. They advise on or apply preventive and curative measures, and promote health with the ultimate goal of meeting the health needs and expectations of individuals and populations, and improving population health outcomes. They also conduct research and improve or develop concepts, theories and operational methods to advance evidence-based health care. Their duties may include the supervision of other health workers. (source: Transforming and scaling up health professionals' education and training. WHO 2013 - adapted from ILO 2008; WHO 2010; Gupta 2011)*]

The following TABLE OF CONTENTS was proposed:

ACKNOWLEDGEMENTS

TABLE OF CONTENTS

LIST OF FIGURES, TABLES AND BOXES (if needed)

ABBREVIATIONS AND ACRONYMS

GLOSSARY

EXECUTIVE SUMMARY

INTRODUCTION

Background, The CIOMS Working Group, Structure and content of this report etc.

CHAPTER 1. Medicines development landscape

CHAPTER 2. Needs and benefits for education about medicines development

CHAPTER 3. Education strategies and tools

CHAPTER 4. Proposed principles of educating health professionals (more detailed)

CHAPTER 5. Proposed principles of educating other interested parties (high level, with some examples referred to)

CHAPTER 6. Conclusions and recommendations

REFERENCES

ANNEX 1.

ANNEX 2.

….

ANNEX X. CIOMS Working Group membership and meetings

ANNEX Y. Commenters

Other action/decision items

Day 1

- The title of the report will be reworded as “Education and Training in Medicines Development for Health Professionals”

- Proposed new structure of Chapter 2:

  Group 1. Health professionals working within the pharma industry

  1A. Medical product developers

  1B. Clinical operations teams within the pharmaceutical industry and external Contract Research Organizations (CROs)

  Group 2. Medical product regulators and health technology assessment experts

  Group 3. Health professionals collaborating on pre- and post-authorization development: clinical trial investigators and their teams (Group 1C was turned into Group 3)

  Group 4. Health professionals in research ethics committees

  Group 5. Health professionals involved in patient care are indirectly involved in medical product development

  Group 6. Other stakeholders/interested parties who need education in medicinal product development (General public, patients, patient experts, patient advocacy groups, clinical trial participants)

  6A. General public
  6B. Patient experts
  6C. Patient advocacy groups
  6D. Clinical trial participants

Proposed competencies

Proposed competencies in Chapter 4 for each group (re Chapter 2) need to be revised one by one from each sub-group of the WG working on that, advising also the level of knowledge they need to achieve

Group 1

1A → 7 domains of PharmaTrain

1B → → combination of clinical developments of Pharma train (not maximum knowledge) + entire JTF in high level (it has 3 levels)

Group 2. → relevant sector from PharmaTrain, + competencies in assessment of BR and HTA examples from TOPRA, WHO, CIOMS Benefit risk + Priya and Enrica to review

Group 3 → JTF competencies, level depending on the role of each person

Group 4 → Pharma train topics on ethics, ICH guidelines, CIOMS 2016 Guidelines, declaration of Taipei, DoH + results from the EC subgroup

Group 5 → develop the content

Group 6 → postponed to review EUPATI (but it is very EU focused, it is expanding but still very EU based, we can use it for the concepts)

- Ingrid to work on Chapter 5 based on experiences from Europe.
- Insert a footnote at a later stage on what a pragmatic trial is and maybe add it to the glossary
- Change phrasing in group 4
- Health professionals involved in patient care play an increasing role in collecting and generating health related data that can be used for product development
- Change Real World Evidence (RWE) to Real World Data (RWD)
- The whole last sentence of the first paragraph to be changed
- Remove “new” in the second paragraph
- Change …“and the principles of GCP” to …“and the principles of good clinical research practice”
- These HPs should also learn about safety monitoring requirements for all medicines → HPs should be aware of the importance of their duty for safety reporting requirements in addition to principles of benefit-risk assessment for all medicines

Day 2

The way forward

- The WG should move forward with a small Editorial Committee (EC) who will be designated by the Secretariat and will be responsible for completing the first draft of the report with input from the WG.
- Ingrid to lead the EC
- The WG will discuss after first draft is ready further whether to put the report out for public consultation. As an alternative, it can also be sent to specific parties – targeted consultation. In any case it will finally be a consensus report of the WG.

Action/decision items

- Proposed Group 5 “Health professionals involved in patient care indirectly involved in medicinal product development”
- Develop the concept of the new chapter (minimum they should know)
- Use lay language and a reader-friendly style to describe the following:
  a) Regulatory concepts for marketing authorisation
  b) Framework of med dev (GCP, ICH, methodology of CTs, academic research)
  c) Benefit risk concepts
  d) Post approval safety reporting
  e) Importance of collecting data from RWD/RWE
  f) Ethical principles of clinical research
  g) Building trust in drug development
  h) Supporting dialogue with patients and caregivers on their treatment
  i) Definition of drug therapies in different legal concepts (single patient, compassionate use. clinical trial/pragmatic trial with authorised medical products within or outside the label, use of medication without authorisation)

- Add Chapter 6 conclusions and recommendations
- Scientific societies linked to medicines development and therapy optimization should engage in raising awareness about the benefit of increased knowledge of medicines development.
- Scientific progress… (add something regarding this)
- All health professionals would benefit from knowledge and understanding of medicines development
- Better understanding of medicines development and improved scientific literacy will help engender trust in the process
- Education in medicines development should be based on quality assured, recognised or accredited resources
- Medical specialist training should include a module on principles of medicines development and regulation.
- PhD training in life sciences should include a module on principles of medicines development and regulation
- Principles of medicines development and regulation should be incorporated in the training of other health professionals such as nurses and other support staff (in the basic program, as part of continuous professional development, or post graduate courses)
- Funding organisations are encouraged to invest in high level quality courses and make them freely available to all stakeholders in medicines development
- Raising awareness in a systematic way of the benefit of the topic.