



4th meeting of the CIOMS Working Group on Recommended Standards of Education and Training for Health Professionals Participating in Medicines Development

30 January 2023

Meeting Minutes

Participants:

Enrica Alteri (University of Geneva), Priya Bahri (EMA), Barbara Bierer (Harvard University), Malcolm Brown (Astellas), Domenico Criscuolo (Italian Society of Pharmaceutical Medicine), Andrzej Czarnecki (Eli Lilly), Luther Gwaza (WHO), Rieke van der Graaf (University of Utrecht), Tim Higenbottam (Faculty of Pharmaceutical Medicine, Royal Colleges of Medicine), Stuart Jones (King's College, London), Kenneth Kaitin (Tufts University), Sandor Kerpel-Fronius (Sемmelweis University), Gustavo Kesselring (IFAPP Academy), Ingrid Klingmann (President, PharmaTrain), Nilima Kshirsagar (ICMR, India), Raffael Kurek (Astra Zeneca), Michelle Limoli (FDA), Simon Maxwell (University of Edinburgh), Honorio Silva (IFAPP Academy), Stephen Sonstein (Committee on Accreditation of Academic Programs in Clinical Research), Peter Stonier (Faculty of Pharmaceutical Medicine, Royal Colleges of Medicine), Ichiro Uchida (Osaka University), Haruko Yamamoto (PMDA)

Regrets: Pravin Chopra (IFAPP Academy), Roberto Verna (World Association of Societies of Pathology and Laboratory Medicine), Pol Vandenbroucke (Pfizer)

Secretariat: Lembit Rago, Catherine Bates

Action/decision items:

- An amended report structure to clarify the target audiences will be produced (Ingrid)
- Glossary: chapter leads should list the terms they wish to include.
- WG should think about other appendices as well, e.g. references and examples/case studies.
- WG will meet virtually in April to align on Chapters 3 & 4 which will inform Chapter 5 (Catherine to send doodle)
- A doodle poll will be sent to the WG with dates in early May (Catherine)
- Wikipedia is not an appropriate source.
- Subgroups will meet separately to continue work on the content.

Introduction

Lembit welcomed the group and spoke about the upcoming CIOMS webinars. He suggested the Education WG could also conduct a webinar when the report is completed.

Highlights from chapter discussions:

Chapter 1

- Honorio presented some [slides](#) to update the WG on the latest draft
- The WG should share comments on Chapter 1 with Honorio and the chapter team.
- The four audiences could be described more clearly, including the related challenges for each.
- Each group should be bulleted.
- The description of ICH should be amended.
- The references to medical devices should be revisited
- A subgroup of regulatory parties should be formed to think about input into Chapter 1 and share views with the WG in the 1st half of February.
- The WG should wait to see what comes out of the regulators' subgroup and then share the draft with chapter leads.

Chapter 2

- WG was asked to contribute further input or/and critical comment to Chapter 2
- Should the report include the general public as one of its audience groups?
- The distinction between competence and competencies should be made clearer.
- The global perspective requires further input.
- The writing style will also require harmonizing due to input from multiple authors.

The target groups are:

- 1) Biomedical professionals: medical product developers (industry). More details are needed on the level of knowledge required of each subgroup.
 - **Medical product regulators and health technology assessment experts**. Maybe these two groups should be separate and the report should take a global view, describing different levels of needs across different geographies.
 - **Non pharmaceutical industry, health professionals**, e.g. clinicians who are also principal investigators, investigators, clinical research coordinators, project and research managers on the operational side.
 - **Physicians, nurses, and allied health care** professionals who are not engaged directly in medical product development, but nevertheless, need education on the development process.
- 2) General public, patients, patient advocacy groups, clinical trial participants, ethics committees

The WG will review how the audiences are clustered once it agrees on the number of groups. The WG should make a decision about the structure of the hierarchy i.e. there should be at least four groups as follows:

- 1) People who work in development in the **pharmaceutical industry** (also includes people doing phase I trials, even if they are not in the industry).
- 2) **Regulatory or health technology assessment professionals** who need to understand the development process.
- 3) People in the **healthcare sector** who do not develop medicines, but require more knowledge than the general public in order to be more savvy users, or/and supervisors of medicines.
- 4) **General public who might engage with the industry as subjects in clinical trials or who might be on ethics committees**. They might be a stakeholder in the wider debate about the industry and its activities and need to know less than the other groups. There are probably one or two principles about medicines development that the WG agrees the general public should know about.

There is no such thing as a health care professional who doesn't have any relationship to drug development. Healthcare professionals have a critical role in pharmacovigilance and the assessment of value because value is something that only healthcare professionals and patients can determine.

The concept of bench to bedside to bench and what goes on in the clinic informs future activities at the bench for the development of new products. Instead of depicting healthcare professionals as outside the "sphere", the WG should look at HCPs as part of it. There's an overlap between their role and that of drug developers, particularly in the three following aspects:

- 1) Pharmacovigilance
- 2) Assessment of value
- 3) Bench to bedside to bench.

The group needs to be clear about the level of knowledge that each group needs to acquire e.g. nurses, junior doctors, etc.... If the report is too long or not sufficiently realistic, it will not be successful. The concern is that the WG cannot go into too much detail on the kind of knowledge the different audiences should gain.

Could the structure outlined in Chapter 2 be used as a model for an accredited search site such as that of WHO which includes a long list of medicines and information about them. A framework that highlights some of the steps by which a medicine is developed could be a very useful tool for people to find information. And it would be free of commercial aspects.

An educational activity should begin with a needs assessment which will determine the contents of the education. The WG can provide guidelines about what to teach, but the specific activity will be conducted locally, according to the results of the local needs assessment. And this will be part of the recommendations.

Chapter 3

This chapter is about educational objectives and should be written when there is agreement on how Chapters 1 and 2 will be structured, who the audience groups are, what the different levels of knowledge are and on the basis of which general principles.

Chapter 4

- The PharmaTrain syllabus should be included as an example because it covers the whole spectrum and is widely used as the basis for other syllabi.
- The CIOMS syllabus should not provide details on content for the general public or patients given that EUPATI focuses on these audiences.
- The chapter will address the needs of health professionals who are directly involved in product development as they are likely to benefit most from the CIOMS report. (please see model syllabus provided by Sandor)
- The chapter will also include a section with definitions and explanations of teaching concepts, e.g.
 - What is a syllabus?
 - How should it be structured and what are the elements that go into building it?
 - What is a curriculum?
 - What are learning outcomes?
 - What are teaching modalities?
 - What is meant by examination? Certification? Accreditation?
 - What is a training centre?
- A fourth section in Chapter 4 will describe teaching methodologies: e.g.
 - How to develop the required knowledge, skills and behaviours
 - How to develop a competency based learning programme
 - How to train for strategic versus operational roles
 - How to develop a training concept from intended level certification to syllabus etc.
- The fifth section in this chapter would be a list of syllabi that are currently available.
- Chapter 5 could put forward some recommendations about what the teaching standards should be for the different stakeholder groups.
- The WG should define who the target audience is and distinguish between investigators involved in product development and all other physicians rather than distinguish between those who are involved in clinical trials and have completed a GCP course and those who have nothing to do with clinical trials.

There seems to be an overlap between Chapters 3, 4 and 5. The competencies and how to achieve them as they are outlined in Chapter 4 could be covered in Chapter 3. One chapter could be about the competencies to be included in each group and another chapter could be about the educational theory and how it should be taught.

What's important is to address the needs of practitioners who might not deliver data from a clinical trial, but whose patients may ask them for information about participating in a trial or who might be involved in pharmacovigilance.

Drug development is more than clinical trials. One must not only focus on this narrow scope of healthcare professionals who are involved in clinical trials. Drug development means much more than that. Healthcare professionals need to know about the medicines that they prescribe.

Moreover, collecting data is not only useful for pharmacovigilance. The WG should be mindful of not reading the report with a too narrow view and to think beyond clinical trials to drug development in a broader sense which goes from cradle to bedside and back to bench.

Chapter 5

The chapter lead presented these [slides](#) on the outline.

- Some of the content would be better suited as appendices rather than in the body of the report.
- A list of learning objectives should be provided for each stakeholder as well as the competencies that must be achieved
- The WG should look at how the CIOMS principles will be taught, e.g. solely via the internet or a hybrid (part in-person and part internet)?
- The WG recommended waiting for more advanced versions of Chapters 3 and 4 before beginning work on Chapter 5. The Chapter 5 team should wait until April.

The concern about the overlap with Chapter 3 was reiterated. Much of what is proposed for Chapter 5 is based on educational theory. There's a real question mark about the content of Chapter 3 and 5. That would be the first thing one would want to know as an educator and then to cross-tabulate with the objectives already comprised in ones' current curricula. Maybe it is planned as an appendix. What are the learning objectives for each stakeholder group? Maybe creating separate chapters for three, four and five may not be required. The report could comprise two chapters instead with appendices, including educational outcomes. The outcomes would also have to be broken down into more detailed ones aimed at the industry group, a less detailed list for healthcare professionals and e.g. three key points that one would expect the general public to understand about drug development.

Another view was that the content of Chapter 5 describes what is mostly relevant for university teaching where one has a full semester to interact with the students. The WG could recommend how the education should be provided given that most of the courses will probably be internet-based or hybrids. Chapter 5 should be reworked, but kept as the closing chapter. It should not be merged with others in contrast to the previous comment. However, it should be much shorter and refer to how the principles will be taught.

The WG was reminded that the theory of education was meant to be covered in Chapter 3, how to organize an educational program, in Chapter 4. And then the tactical aspects (not the theory) on how to develop or implement an educational program and best practices were to be included in Chapter 5. An appendix would not be required as it could not include all relevant materials. In some WG's the structure that was originally agreed to was changed at a later stage. It's not that unusual. It is up to the group to decide what structure suits its needs best.

The WG should keep Chapter 5 as a series of conclusions and recommendations and an appendix would be welcome as well for reference materials as discussed earlier. It is key, however, to have some final statement for what the CIOMS recommendations are. In that case, however, maybe the WG doesn't need a whole other chapter, but a conclusion instead.

The WG felt it needed to see a draft of Chapter 3 so as to have a better idea of what to cover in Chapter 4 because there are several overlaps with Chapter 4. Chapters 3,4,5 need further discussion. Another option would be to merge Chapters 3 and 4. A solution could be to remove part I from Chapter 4 which explains the concepts. Maybe these could be covered in Chapter 3.

To recap,

- Chapter 1 is the introduction, the life cycle and the need for education.
- Chapter 2 is the description of the needs and benefits of teaching.
- Chapter 3 will explain the teaching theory and methodologies.
- Chapter 4 provides examples of the scope of learning and teaching and
- Chapter 5 will contain the conclusions on what are the best standards to meet the needs that have been described in previous chapters.

Therefore, the flow discussed at the WG meeting in Geneva is still relevant and achievable.

The WG agreed with this approach, but raised the point again about the competencies and where these will be included in the report? Also, credentialing or assessment: how will that be tested, particularly with those in the industry. How will CIOMS know whether the training has actually taken place? It is not yet clear where the competencies will be presented, e.g. Chapters 2 or 3. It fits in well with the definition of the needs and benefits of teaching i.e. Chapter 2. In any case, they should be at the beginning of the report.

The competencies are covered in Chapter 1 with references to PharmaTrain and IFAPP so it doesn't seem necessary to describe the competencies in the body of the text. If the WG decides it wants to include them as an appendix instead, this would be an acceptable alternative. Coming back on the previous comment, the competencies should be close to the syllabus and should be inserted later in the report, not at the beginning. Others concurred with this view.

A question was raised about the overall objective of the WG. Is it to develop a syllabus for better use of medicines or for better medicines development or both? The other point is that, one needs to think about who is going to certify that the person has received an adequate amount of training. Also, academic organizations often include industry and regulators in developing syllabi. So, the WG needs to consider these points too going forward.

The WG is not attempting to develop a curriculum for the better use of medicines as this is the purview of universities. The aim of CIOMS is to create a better understanding or preparedness about how medicines are developed because medicines are becoming increasingly complex.

The WG discussed the next in-person meeting and agreed it would make sense to hold it when a full first draft is available. It could be mid-May. There would still be time to work on individual chapters afterwards, to further align and perform a final review.

A point was raised about when a decision would be made about which/how many audience groups the report should be aimed at. In Geneva, the WG agreed on three and today, the WG talked about merging them into two.