Sixth meeting of the CIOMS Working Group XV:

Harnessing the Potential of Pharmacoepidemiology for Public Health

Geneva, 30 & 31 October 2025

Participants (in person)

CIOMS: Hervé le Louet (HL) (President); Lembit Rägo (LR) (Secretary-General).

Academia: Bernard Bégaud (BB) (University of Bordeaux, France); Yola Moride (YM) (Rutgers University, USA).

Industry: Ana Sofia Afonso (ASA) (Eli Lilly, The Netherlands); Alex Asiimwe (AA) (Gilead); Selin Cooper (SC) (AbbVie, UK); Alicia Gayle (AG) (Chiesi, UK); Karin de Haart (KH) (IQVIA, The Netherlands); Véronique Kugener (VK) (Takeda, USA); Marie-Laure Kurzinger (MLK) (Sanofi, France); Patricia Saddier (PS) (ex-MSD, USA); Montse Soriano-Gabarro (MSG) (ex-Bayer, Germany); Kiliana Suzart-Woischnik (KSW) (Bayer, Germany).

Intergovernmental organization: Noha Iessa (WHO, Switzerland) (day 2 only).

Regulatory: Craig Allen (MHRA, UK); Takashi Ando (Pharmaceuticals and Medical Devices Agency, Japan); Miguel Ángel Maciá (MAM) (Spanish Agency for Medicines and Medical Devices, Spain).

Participants (virtual)

Academia: Masao Iwagami (MI) (University of Tsukuba, Japan); Jennifer Lund (JL) (University of North Carolina, USA) (day 2 only).

Industry: Anne Deitz (AD) (MSD, USA).

Regulatory: Doris Oberle (DO) (Paul Ehrlich Institute, Germany).

DAY 1

Welcome and opening remarks

Hervé Le Louët (HL) opened the meeting and welcomed participants. He reminded participants that **the report is not intended to serve as a guidance document but as a set of recommendations for improving the application (i.e. the when, why, how) of pharmacoepidemiology (PE)**. Some text remains to be refined-

Lembit Rägo (LR) updated participants on recently published CIOMS working group (WG) reports (on the benefit-risk balance for medicinal products and severe cutaneous adverse reactions), CIOMS webinars which have started to be held as a means of introducing WG reports. He noted that the discussion sessions held at the end of the webinars have been much appreciated. He also indicated that the WGs each seek to publish at least one scientific article about their report and recommended that WGXV do the same. He mentioned that the topics of

some of the ongoing WGs might be of interest to this group (namely, WGXVI: Development Safety Update Report and WGXIV: Artificial Intelligence in Pharmacovigilance) and the launch of the new WGXVII (on the long-term safety issues of medicinal products).

Report overview

Bernard Bégaud (BB) gave an overview of the progress to date on drafting of the report. The editorial committee met three times virtually and a first full draft report circulated among the full group, which generated many comments, which remain to be reviewed and incorporated. The draft is available online on a Rutgers platform and can be accessed by all WG members. Titles and key terms to be used remain to be decided upon. The key concept of the report is the proper use of PE, but the question remains: for what purpose and by whom? The optimal order of the chapters also needs to be determined.

HL considers that **the report should be targeted at "the decider".**

YL suggested that the report title include a sub-title since the current title (*Harnessing the Potential of PE for Public Health*) is too broad. The report will be relevant not only to decision-makers in public health (PH) but also, for example, to regulators. **Finally, it was agreed that** *Realizing*[1] *the Potential of PE for PH Decision-making* would be an acceptable title.

Communication roundtable

The communication elements of the draft report– including where they should sit within the report – and whether communication should continue to have its own dedicated chapter (Chapter 6: How communication on pharmacoepidemiologic evidence can support decision-making in PH) were discussed at length. In particular, "interpretation" as an element, or most important element of communication (from the point of view of this report), was debated. Additional comments were as follows:

- **BB:** Some aspects of communication are included in chapter 4 since management of any crisis necessitates consideration of communication.
- **HL:** Today the profile of a crisis changes very quickly; communication is just one element of crisis management. What we may be talking about is, communication of the results.
- **MSG:** Communication is a very big topic which extends beyond the scope of this report. A chapter on communication is needed, as a reminder of its importance, but should be brief. Chapter 6 currently reads as a collection of general concepts, which are not within scope. Instead, interpretation, and how to transmit study results, should be its focus.
- **KH:** A PE study will not be useful if its results are not interpreted and communicated. She agreed with many other WG members that the emphasis should be on interpretation of results. HL commented that discussion of interpretation would necessitate a new book.

[1] In British English, both "realise" and "realize" are acceptable. "Realize" is the official spelling for the Oxford University Press and the Oxford University itself.

- **BB:** For this report, communications has two aspects: (i) how to communicate to prevent and/or manage a crisis and (ii) interpretation of PE (relative risk, etc.) to communicate to a decision-maker. Hormone replacement therapy (HRT) is a good example of the need for communication. Various lobby groups (including industry and practitioners) try to promote its widespread use. Old studies show that continued use of HRT over three years increases the risk of breast cancer by 20%. Decision-makers who have this information can calculate the likely population to be affected.
- **AG:** Are we focused on the decision as to whether to perform a study or on what we do or communicate following conclusion of the study? She favoured interpretation as the key issue for consideration. Current issues around use of paracetamol in pregnancy and perceived links between vaccines and autism demonstrate the centrality of interpretation to PE. **BB** commented that resolving controversy around paracetamol through conduct of a PE study would not be possible since exposure to it in Western countries is so extensive.
- **YM:** "Interpretation" could be used instead of "communication". For a decision-maker, the results of different studies with different results are not in themselves useful. The decision-maker needs to know how to interpret these results and what key message to communicate. You can ask PE experts how to interpret data, but the interpretation is never black and white. Yet a decision-maker is looking for a black-and-white answer. Which means that determining the key message from the available evidence or study results is even more important. **HL** responded that then the question is what level of confidence the decision-maker can have in the interpretation provided, or as **BB** expressed it, the problem is, how do we make the transition from the confusion of experts to the presentation of clear-cut information for the decision-maker.
- **KSW:** It will be important to include instructions as to how to evaluate risk at population level since policy-makers are unlikely to be epidemiologists.
- **VK:** Misinformation and miscommunication are a big problem in PH. Communication and interpretation need to be delineated.
- **ASA:** In Chapter 6 communication is treated as an interpretation issue. The topic of communication as interpretation could remain in Chapter 6, but perhaps the report should also include a chapter on communication proper.
- **LR:** The decision was taken previously that some pieces on communication could be included in the different chapters, but the communications chapter should be dropped.
- **MSG:** Sometimes, the reasons for initiation of a study or a decision not to undertake a study must be communicated.
- **MAM:** In normal everyday situations, a decision-maker would trust what experts told him or her with respect to use of a drug, since their advice would be scientifically based. **HL** responded that political decision-makers have many sources of information

- **PS:** It will be important to stress that expertise is essential to interpretation results and communication of study results.
- **MLK**: Interpretation is an important issue, but the relevant text should include reference to the relevant metrics for PH decision-making (such as absolute risk or the magnitude of the effect).
- **HL:** A decision-maker needs only to know whether PE would be useful for making a PH decision. He or she does not need to know how to carry out PE.
- **CA:** At a minimum, the report should contain a reminder about the importance of absolute and relative risk.
- **AA** and **SC:** Interpretation should be a focus for the discussion of communication.
- **PS:** A short, consolidated section on interpretation of results should be included, not from the point of view of how to interpret results, but the importance of using experts to help you to interpret results.

The conclusion of the foregoing discussion, as proposed by MSG, and accepted by the WG, was that:

- Chapter 3 should elaborate on interpretation and include some of the issues around communication currently covered as part of crisis management in Chapter 4.
- Crisis management is covered as originally drafted.
- Chapter 6 should be deleted.

Terminology

Some terms such as “global health”, “pharmacoepidemiology” and “public health”, must be clarified.

“Global health” is a difficult term to use given that many PH decisions are not made at the global level, but at a local or regional level. It can be used in the sense of being inclusive, although this may then mean it is taken to global populations and with an emphasis on low- and middle-income countries. Many European initiatives, and WHO, now refer to “One Health”. Both “global health” and “One Health” are used in the WG concept paper to demonstrate that new challenges have arisen and paradigms are shifting.

The International Society of Pharmacoepidemiology defines PE as: “...a scientific discipline that uses epidemiological methods to evaluate the use, benefits and risks of medical products and interventions in human populations.” This definition will be used in the report but with a note indicating that it has been modified to refer to “medicinal products”.[2] The term “public health” will be retained, but a clear definition should be included early in the report.

The term “PH decision-making” will be retained, meaning “decisions taken in the PH domain”. The target audience is not only high-level decision-makers (for whom only a two-page

[2] The CIOMS report on Patient involvement in the Development, Regulation and Safe Use of Medicines uses a plain-language version of the ISPE definition: “The study of the use and effects of drugs (including biologicals and vaccines) in large numbers of people using methods, analyses and reasoning based on general epidemiology.”

documents would be needed), but also those working in regulatory agencies, in industry, etc. However, a distinction should be made between "PH decision-maker" and "PH decision-making".

The term "medicinal products" (as opposed to "drugs" or "medicines") will be used wherever possible. When this is not possible – for example, when quoting from another text – a footnote can be referred to. Medicinal products will be defined as covering medicines (drugs), vaccines and medicinal devices.

Both benefit−risk ratio and benefit−risk balance are used in the draft. "Ratio" implies a metric. Therefore, "balance" is preferred.

It was agreed that the term "real-world evidence" is confusing. Rather, the report should refer to "PE in real-world settings".

The terms regarding use – "misuse", "overuse" and "overdose" − need to be clarified and harmonized. CIOMS definitions will be used, if available.

When appropriate, terms used in previous CIOMS reports will be used. CIOMS will forward a list and definitions of relevant terms for the consideration of the WG. Any additional terms defined by this WG will be included in the CIOMS Cumulative Glossary.

Tone of text

What will be the overall tone of the document? Positive? Encouraging? Critical? Neutral? Scientific? Informative? **KSW** mentioned that for her it is useful to have a reference document that can be used to counter some arguments used in opposition to a proposal to conduct a study.

The draft report includes some text that is highly critical in tone (e.g. "uninteresting articles"). This was considered inappropriate. It was agreed that the language used should be objective and neutral, and not judgemental. **BB** referred to the concept paper. Its starting point was the observation that many studies are redundant – and waste funding – since they focus on a very narrow issue and fail to present a global view of the risk−balance of a product. It is unacceptable that a large percentage of the female population is treated for menopausal symptoms even though understanding is lacking regarding risks associated with its use. "Proper" use of PE is important.

Content roundtable

Participants were requested for their opinion of the overall content of the draft report. Their principal comments are given below.

PS: The draft lacks uniformity and flow. Would it be possible for a medical writer to assist with improving the draft? **LR** responded that first the report content must be clear.

CA: Chapter 3 reads like a standard operating procedure.

MLK: An overview of the subsections of each chapter would be useful.

MSG: Once the final structure of the report has been agreed, the appropriateness of the examples used should be checked. The report needs to stress that the report is relevant to you the reader since you are part of an organization involved in PH decision-making. Also, the report mentions different sectors (academia, industry, etc.), but the report should stress that it is

decision-makers for PH within the different types of organization who are the report's target audience.

KSW: Framing of the report – in its introduction – is important.

MAM: The current Chapter 5 (When PE may not be the best option) is the most innovative and potentially controversial chapter of the report, but care needs to be taken to ensure that it is well grounded throughout. The opportunity cost of PE research could also be discussed in this chapter. He will propose some ideas to BB.

VK: Given the preponderance of examples referring to COVID-19 vaccines, could the use of vaccines examples be improved? Only parts of the world are represented adequately, yet the report is intended to be useful for PH decision-makers anywhere in the world.

ASA: Some text could be included on PE in 20 years' time, as a means of opening the report to considerations of the future of PE and its application.

AD: The draft would benefit from some streamlining. Who is the report trying to influence and what new information will it contain?

DO: The language of the report should be neutral, neither too positive nor too negative,

Summary

This will be rewritten. (It was later proposed that an executive summary be prepared.)

Text review

The overall report structure, title, content and consistency of each chapter were reviewed.

Overall structure

The overall report structure was agreed as follows:

Chapter 1: PE: a major tool for PH

Chapter 2: PH issues that could be informed by PE

Chapter 3: Appraisal of available pharmacoepidemiologic evidence to support PH decision-making

Chapter 4: Benefits of PE in anticipating and managing PH crises

Chapter 5: When a pharmacoepidemiologic study may not be a good approach.

It was noted that the text contains no visuals and that many of the sub-titles are too long.

During the discussion focusing on individual chapters, many comments and suggestions for their improvement were made. These are given in the appendix and were also noted in the online version of the draft report that is available on the platform and accessible to all WG members.

DAY 2

Discussion continued to focus on review of the content of each chapter content. See the appendix.

A decision remains to be taken as to whether this report should include its own glossary. If not, readers could be referred to the CIOMS Cumulative Glossary and the CIOMS Glossary of ICH Terms & Definitions, both of which are available online. Or reference could be made to the two

CIOMS glossaries and a short glossary included that covers terms already defined by the WG but not included in either CIOMS glossary.

An executive summary should be included to help readers quickly understand what the report covers.

Each chapter should have its own conclusion.

Next steps

- **CIOMS will forward definitions of relevant terms** that have been used in previous CIOMS reports for the consideration of this WG.
- Based on the meeting's discussions, the **Editorial Committee will fine-tune the text (other than that to be rewritten SC).** It will meet virtually on 18 November 2025. **The revised draft will be circulated to the whole WG before being made available for public consultation.**
- **An executive summary must be written and the introduction rewritten.**
- **Once final comments have been received from the WG and incorporated, the draft report will made available for public consultation.** The public consultation is provisionally scheduled for a period of six weeks, from mid-January 2026. It is anticipated that many comments will be received. CIOMS will compile the comments in a single document. Up to six months may be needed to review them.
- **Comments must be submitted in a prescribed format, otherwise they will be discarded.** Organizations should be requested to submit a single set of comments. It will not be necessary to respond to each individual or organization regarding the comments they have submitted. If any query is received regarding a comment(s) that were rejected, CIOMS will respond that all comments were reviewed by the editorial board and accepted or rejected as it considered appropriate, and that the report is a consensus report of the WG experts. If the editorial board is unable to reach agreement on a comment, it will consult the relevant section lead.
- **During the public consultation period, WG members can also submit comments using the CIOMS form.**
- **CIOMS will raise awareness among its contacts that the report is out for public consultation. MSG will collect contact details from WG members of organizations who could also be informed about release of the report for public consultation.**
- **CIOMS will organize the final editing and layout of the report.**
- **LR encouraged the group to write at least one scientific paper for submission to a peer-reviewed journal.** Ahead of submission WG members should consult journal editorial boards among whom they have contacts, to increase the likelihood that the planned article(s) will be accepted for publication. He also suggested that WG members assist CIOMS in organizing a webinar on the report following its publication.

Appendix: Comments from the discussion focusing on individual chapters

The chapter titles and numbering are given below are as they appear in the draft of 21 October 2025.

Chapter 1: PE: a major tool for PH

This chapter aim to describe how PE can be useful for PH decision-making.

The chapter text is derived from the concept paper, with parts added to it from some of the other chapters. **It is text-heavy; VK's group will reduce it.**

Some of the early parts of Chapter 1 could be moved to the introduction.

Section 1.2 (PE framework) does not actually incorporate a framework. It simply provides a definition of the term. There needs to be more of a link between this section and what follows.

Sections 1.2.1 (Academia), 1.2.3 (Patient engagement) and 1.2.4 (Regulatory) could each be shortened to two paragraphs, and Section 1.2.2 (Industry) could be lengthened.

Section 1.2.4 does not need to list the regulatory initiatives that different regulatory agencies have created with respect to the generation and integration of real-world evidence, especially since this would be to risk exclusion of an important framework.

The title of Section 1.2.5 will be changed from "Examples and projects within the PE framework" to "Examples of a PE framework". The reference to GPP to will be moved elsewhere. The IMI-PROTECT example will be retained.

Section 1.3 (An urgent need for a new era) overlaps with Section 1.5 (The CIOMS XV guidance). Section 1.5 can be shifted into the report introduction. The rearranged text should be checked for duplication. The first paragraph of Section 1.3 should be eliminated.

Chapter 2: Types of PH issues that can be addressed with PE

Some good examples of the use of PE to address gender and health inequities could be included in this chapter.

Many problems linked to medical products relate to off-label use, misuse or over-long use. The estimations of the benefit−risk balance or benefit−ratio of these products will not have considered these types of use since they will have been based on the use of the products in certain circumstances or ideal conditions. Therefore, ahead of Section 2.1 (Utilization of medicinal products and polypharmacy), a statement should be included to the effect that an understanding of medical product use is key to answering many PE questions. Additionally, a sentence could be added to effect that the knowledge acquired through a PE study can complement that generated by a clinical trial.

In Section 2.1, the text on prescribing patterns should precede that on polypharmacy. "Polypharmacy" should be removed from the section title since it is already incorporated under "utilization". The statement, "PE provides the data needed to evaluate these practices critically", included in the text on prescribing patterns, may be too strong. In this section the COVID-19 example should be retained and the others removed. Use of COVID-19 means that the background to the example does not have to be explained here since it was given earlier.

Use of different, new examples would necessitate more "story telling", lengthening the text.

The title of Section 2.2 will be revised to: "Effectiveness, safety and benefit−risk balance of medical interventions".

The title of Section 2.3 will be revised to: "PE to support medicinal product development". Section 2.3 should include mention of external comparators.

The title of Section 2.5 (Understanding the impact of healthcare systems, policies, and regulatory actions on PH) does not refer to PE but to PH. Moreover, it is not clear how this section links to Section 2.5.3 (The patient's perspective). The text will be clarified to state that PE could help facilitate, for example, patient-reported outcomes.

Section 7 (Other PH questions addressed by pharmacoepidemiology) will be deleted, but its final sentence regarding the use of PE to evaluate the effectiveness of risk mitigation measures and of policy changes that affect product use and PH outcomes, will be incorporated in Section 2.6 (Optimization of implementation of PH interventions).

Chapter 3: Evaluating existing PE evidence to support PH decision-making.

This is an important chapter asking how can we evaluate existing PE evidence in order to address a PH issue. Yet it is currently rather short and perhaps should be developed further. It should be emphasized that the topic of this chapter is evaluation of existing evidence.

Part of Chapter 6 (on interpretation of study results) will be incorporated into this chapter.

Section 3.1 needs to be more descriptive and not simply a listing of how-to steps.

For Step 4, a caveat should be added: "If time permits, establish…."

Section 3.2.1.1 (COVID vaccine: what is the optimal immunization strategy for the upcoming winter season?) will be removed since its subject matter is covered elsewhere in the report.

PS will review Section 3.2.1.2 (National implementation of a varicella vaccine programme in the context of its potential impact on zoster epidemiology.

Responding to antibiotic resistance could be an additional example. (Antibiotic resistance is mentioned in Section 4.3.4 (Medicinal product resistance). **ASA will review relevant papers and provide an example for inclusion in this chapter.**

MSG will also look for additional examples for inclusion in Section 3.2 (Examples of evaluation of existing PE evidence when addressing a PH issue.

Chapter 4: Using PE to anticipate and manage PH crises

MSG queried how the group wanted to position Chapter 4. The focus could be on when to use PE, in which case its content should be under Chapter 2, or it could become the final chapter if the focus is on use of PE in special situations.

PS suggested that the order of Chapters 4 and 5 (How communicating on pharmacoepidemiologic evidence can support decision-making in health) be reversed.

This chapter requires a statement that, as the examples to be presented demonstrate, PE can assist decision-makers and could be used more extensively for PH decision-making during crisis situations. The chapter should accordingly focus more on the use of PE during crises than it currently does.

The first sentence of paragraph 1 of Section 4.1 (PE in PH crises) should be made more positive. The final sentence of this first paragraph will be removed.

Section 4.2 (Importance of timely, evidence-based interventions) is very short but is an important section. It needs to developed further, including with some examples (possibly Mpox or anthrax), and including a non-vaccine example.

In Section 4.3.1 (Disease outbreaks, epidemics and pandemics), the example of meningitis epidemics in Virginia, USA, should be removed since epidemiologists would not consider describe them as epidemics. **MSG will find a replacement example of an epidemic.** However, any examples of outbreaks, epidemics or pandemics should be very brief. Additionally, the text describing the origins and spread of COVID-19 will be reduced.

The text of Section 4.3.2 (Medicinal product recalls and safety concerns) does not include anything about product recalls. An example of a regulatory recall could be added. (See, for example, the relevant FDA page: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts.) Neither does the text present any PE solution to the problems of the section title.

Section 4.3.3 (Medicinal product overuse) includes reference to the opioid epidemic. What has been the role of PE during this crisis? Did any countries use PE to monitor it? If an example is needed for a crisis that PE has helped resolve, the opioid crisis is not appropriate. But the crisis did start following prescription use and PE did establish that chronic opioid use is a risk factor for overdose and other conditions/events. Follow-up interventions involved limiting the number of packets dispensed. PE can monitor where and in what quantity opioid medicines are being prescribed. The opioid example will be retained but including a clarification that it is prescribed opioid medicines that are being considered. The withdrawal, in Australia, of codeine from over-the-counter sale would be a good example of the application of PE to tackle overuse.

Sections 4.3.4 (Medical product resistance) and 4.3.5 (Medical product shortages) are very generic and need (referenced) examples.

The second paragraph of Section 4.3.6 (Environmental disasters and climate emergencies) will be deleted. (Actually, each section in this chapter should be reviewed to ensure that sufficient (referenced) examples of the contribution of PE to PH are included.)

Section 4.2 (Importance of timely, evidence-based interventions) and Section 4.5 (Practical and ethical considerations in pharmacoepidemiologic studies during PH crises) contain similar elements and need to be reviewed and merged. (Content from Section 4.5 will be moved into Section 4.2.) Moreover, during a crisis there may not be sufficient time in which to carry out a study. One of the key points of this report is that often a previous PE study can provide the information needed. That said, you may be able to conduct a study to prevent the crisis from becoming much more serious, and especially if existing study results do not provide the needed information. Or maybe the point is that a decision must be taken now based on existing evidence, but you must also invest in a new study to collect information.

Given that they address the same topic, Sections 4.2 (Importance of timely, evidence-based interventions), 4.3 (Examples of PH crises and PE applications) and 4.5. (Practical and ethical considerations in pharmacoepidemiologic studies during PH crises) should be reviewed and modified to eliminate repetition/reorder.

Section 4.6 (Uses of PE in PH crises and or emergencies) is incomplete.

The PMID references in Section 4.7 (Environmental disasters, climate crises, and healthcare access and outcomes) are meaningless as presented. Some of AA's text on these references will be reinstated.

"...and public health agencies" is to be added to the end of the first sentence of Section 4.8 (Defining the gaps of PE applied to PE).

Chapter 5: When PE may not be the best option

Some of the wording in this chapter should be softened. For example, point (i) in Section 5.1 (Introduction), could be revised to: "Many published studies do not provide the information that would be necessary to have an overall view of a problem. They may provide only minimal new insights, focus on only a narrow aspect of the problem (e.g. studies conducted in sub-populations or assessments limited to a specific effect or risk), or lack robustness in their results and conclusions."

The Wakefield study referred to under point (iii) is an example of fraud and can be dismissed from a scientific point of view. We should replace this example with an example of a study that is scientifically weak but not fraudulent. (In fact, the Wakefield study was not only fraudulent but also scientifically weak since it was based on only 12 children.) It should be underlined how important it is to carry out meaningful studies, the results of which can be trusted, and that researchers need support to be able to conduct such studies.

The first paragraph of Section 5.2 (Situations where a study could or should not be conducted) should be modified slightly, since otherwise the report recommendations could be perceived as aiming to limit the conduct of academic research. The word "primarily" will be deleted from the first sentence. The final sentence of this first paragraph ("This framework is more stringent and restrictive…") will be deleted. (However, the implications of a piece of academic research can be significant for PH if the results are released but not fully understood.)

In Section 5.2 it should be clarified that from a PH perspective, a PE study should aim to support PH decision-making and that funding and time should not be invested in pursuit of a PE study that will not produce meaningful results for PH. Resources for PE studies that support PH are limited and should be allocated wisely. A point about study feasibility will also be added. It can be cross referenced with the CIOMS report Real-world Data and Real-world Evidence in Regulatory Decision-making which discusses many aspects of feasibility.

Chapter 6: How communicating on pharmacoepidemiologic evidence can support decision-making in PH

Section 6.1 (A strategic communication process) will be deleted since it is not descriptive and merely presents a stepwise approach which is only appropriate for a how-to manual.

SC will rewrite the introduction to this chapter. She will also rework the text on interpretation that is currently under Section 6.2 (What type of information should be communicated) and move it to Chapter 3.

Meaningful elements of Section 6.3. (Tailoring communication to the audience) and Section 6.4 (Communicating complex findings effectively and without misleading) will go to Chapter 3.

Section 6.6 (Transparency and ethical disclosure) will be deleted.

Section 6.7 (Timing and framing) will be modified and moved into Chapter 4.