



**CIOMS REPORT ON PATIENT INVOLVEMENT IN THE
DEVELOPMENT,REGULATION AND SAFE USE OF
MEDICINES**

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Contents of presentation

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- Organization, links with other international organizations
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About CIOMS

- Council for International Organizations of Medical Sciences (CIOMS) Founded in 1949 by WHO and UNESCO.
- Located in Geneva: CIOMS is an International Non governmental Not-for-Profit Organisation.
- An umbrella organization of medical science organizations

About CIOMS Cont'd

- **Mission Statement:** Is to advance public health through guidance on health research including ethics, medical product development and safety
- Forum for discussion and neutral platform to elaborate new ideas in medical product development, pharmacovigilance and research ethics (bioethics)

Mandate



Publication of detailed reports, guides and guidelines = Common result of working group stakeholders

Platform for debates: Existing / emerging issues in medicines safety, product development and research ethics, health policy

Forum for biomedical stakeholders (regulatory authorities, biopharmaceutical industry, academia, health professionals, patients, others)

United Nations
(WHO and UNESCO) ↔
cooperative relation, essential link

CIOMS Working Groups are Core: Composition

- CIOMS Working Groups are international – they try to involve experts from different countries and regions.
- CIOMS Working Groups are usually composed of all important stakeholders such as:
 - Regulators
 - Academia
 - Industries
 - WHO (as member/observer of the group)
- They also involve representatives from member organizations interested in the topics

CIOMS Working Group XI on Patient Involvement in Development, Regulation and Safe Use of Medicines

➤ **Launched in April 2018**

- It includes participants from patient organizations, industry, regulators, academia and the World Medical Association.
- These experts have worked together to formulate pragmatic Points to Consider in patient involvement. The guidance provides a comprehensive overview of present knowledge and existing initiatives, and addresses a wide range of challenges and practice gaps.

CIOMS Working Group



The draft report for Public consultation

- The report has been posted for comment on 21st February 2022 .You can submit your comments using the form posted on the CIOMS website
- Timeline for submission is 4th April 2022
- The report describes and promotes the idea that patients should be involved throughout the life journey of medicines- from their development , through regulation to ongoing safe use in everyday healthcare.

Chapters of the CIOMS draft report

1. Introduction
2. Landscape
3. Guiding Principles
4. Advancing Treatments
5. Use of Real- World Data
6. Product Labelling
7. Rapid Safety Communication
8. Additional risk minimization
9. Clinical practice guidelines
10. Low and middle-income countries
11. Pandemic considerations, Appendix 2: Case studies

Conclusion

- Patient Involvement can not be overemphasized and increasingly they are being recognized as key partners therefore the CIOMS report is timely. As key stakeholders we should maximize the opportunity to make a contribution to this draft report which has been sent out for public consultation until 11th of April 2022 .
- For more information about CIOMS please visit website: <https://cioms.ch>

Contact us

Please visit our website to find out more

www.chainproject.co.ug

