Vaccine Safety Communication – Increasing Trust in Vaccines

SEC Conference
Kiev, October 2019

Dr Lembit Rägo
Secretary-General
Council for International Organizations of Medical Sciences
ragol@cioms.ch

Council for International Organizations of Medical Sciences

- ***Founded in 1949 by WHO and UNESCO***
- ***In official relations with WHO and UNESCO associate partner***
- ***ICH Observer since 2016***

- ***Mission Statement***

CIOMS mission is to advance public health through guidance on health research including ethics, medical product development and safety

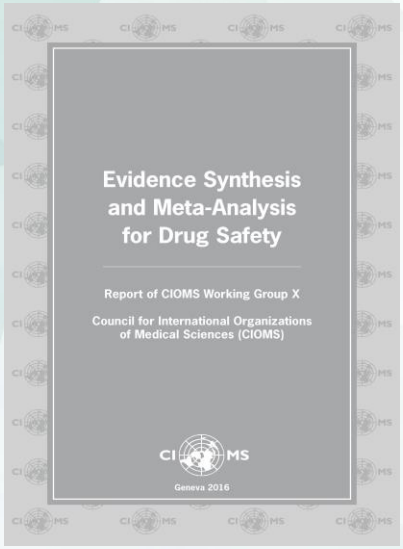
CIOMS and ICH Guidelines

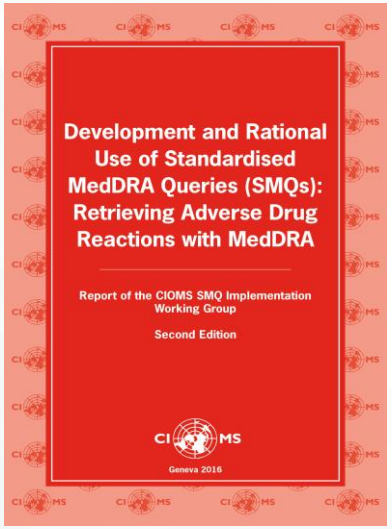
Earlier CIOMS pharmacovigilance guidelines served as a basis for several ICH guidelines. Some examples:

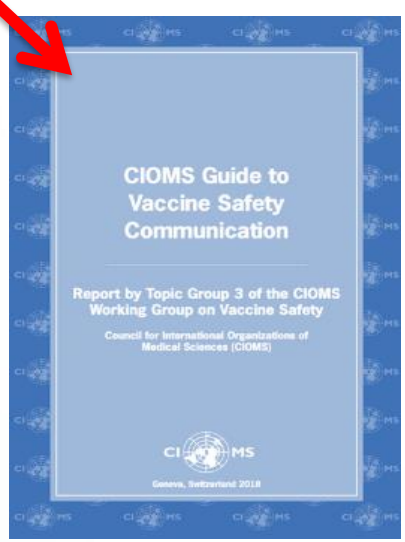
Working Group	ICH Guideline
CIOMS WG I und II Reports (1990, 1992)	ICH-E2A (1994): Clinical Safety Data Management – Definitions and Standards for Expedited Reporting
CIOMS IA Report (1992)	ICH E2B (1997): Clinical Safety Data Management – Data elements for transmission of individual case safety reports
CIOMS WGs II und III Reports (1992, 1995)	ICH-E2C (1996): Clinical Safety Data Management – Periodic Benefit-Risk Evaluation Reports (PBRER)
CIOMS WG V Report (2001)	ICH-E2D (2003): Post-Approval Safety Management – Definitions and Standards for Expedited
CIOMS WG VIII Report (2006)	ICH-E2F (2010): Development Safety Update Reports

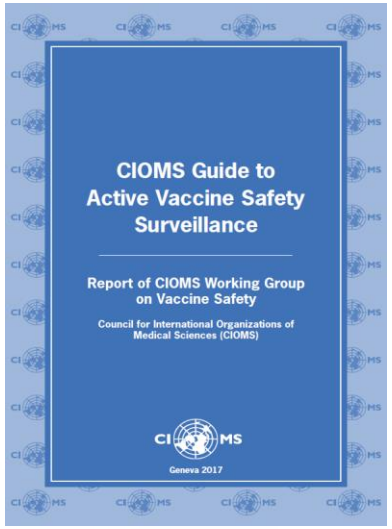
Pharmacovigilance: Recent Publications from 2010

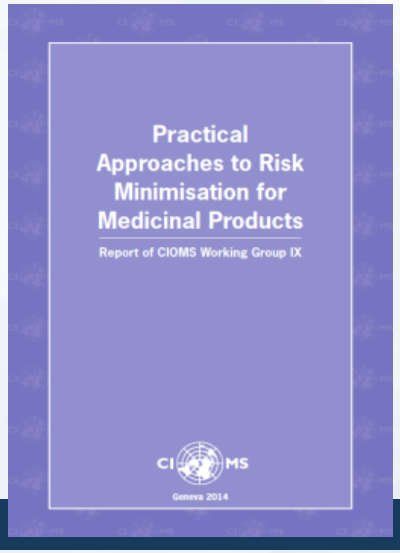
https://cioms.ch/shop/product-category/recently-published/

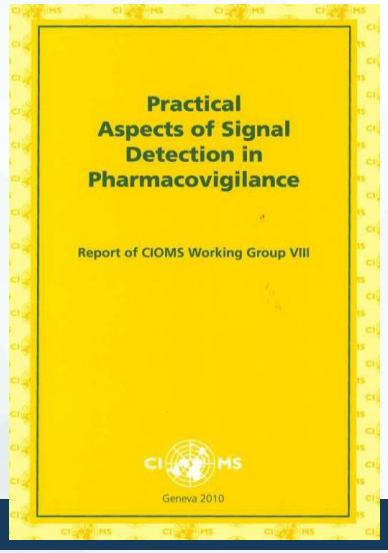


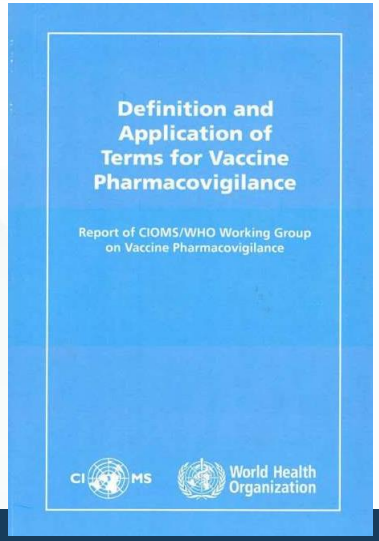












Context

- In 2013, CIOMS created the Working Group on Vaccine Safety to address unmet needs related to vaccine pharmacovigilance identified by WHO's Global Vaccine Safety initiative (GVSI), taking into account the need of resource-limited countries in particular.

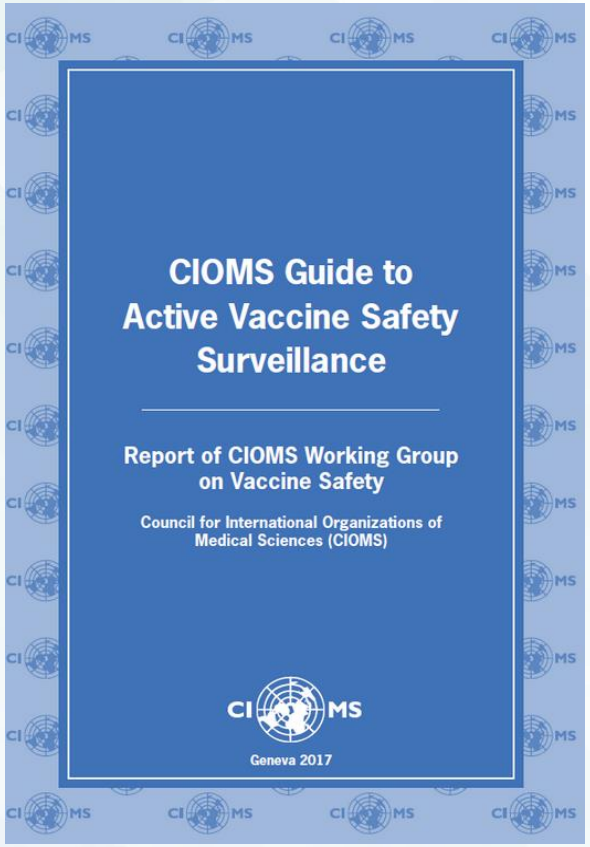
- CIOMS was asked to support the strategic objective 8 of the GVSI Blueprint, which is "to put in place systems for appropriate interaction between national governments, multilateral agencies and manufacturers at national, regional and international levels" *

- The Working Group divided itself into three areas of importance when a newly-developed or new-to-the-country vaccine is introduced into a population: **Topic Group (TG)1** on safety data needed by regulatory authorities and immunization programmes; **TG 2** on active vaccine safety surveillance; and **TG 3** on vaccine safety communication.

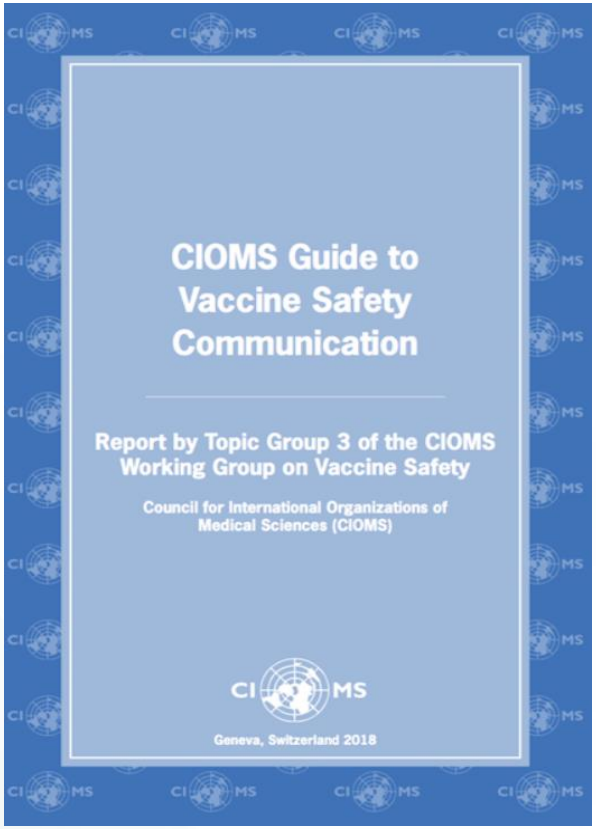
* World Health Organization (WHO). The Global Vaccine Safety Initiative (GVSI), Geneva: WHO; 2019. Accessible **https://www.who.int/vaccine_safety/initiative/en/**

One WG (2013-2016/18), two guidelines:

Topic Groups 1 & 2



Topic Groups 3



Resources for vaccines PV

HMA
Heads of Medicines Agencies

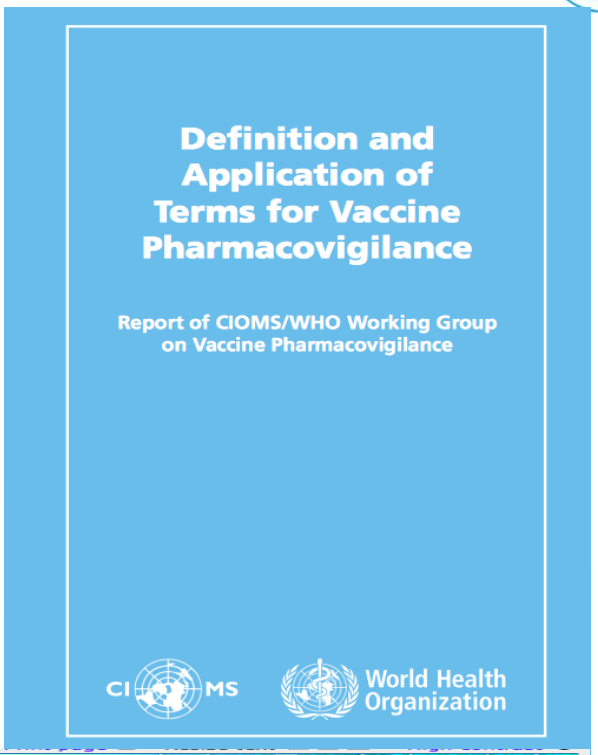
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

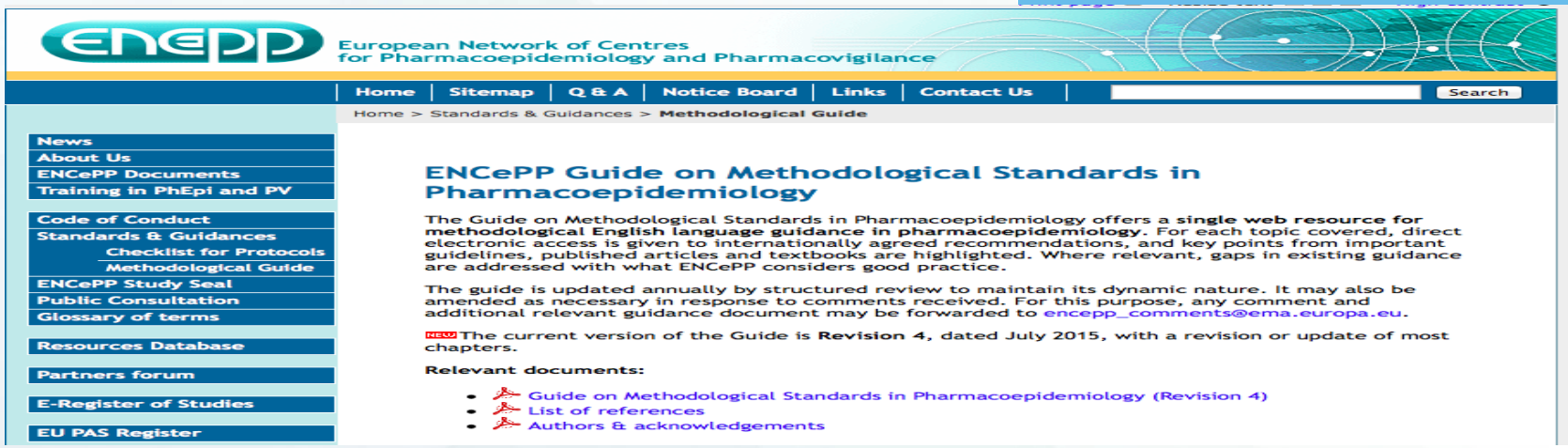
9 December 2013
EMA/488220/2012

Guideline on good pharmacovigilance practices (GVP)

Product- or Population-Specific Considerations I: Vaccines for prophylaxis against infectious diseases

Draft finalised by the Agency in collaboration with Member States	21 February 2013
Draft agreed by ERMS FG	8 March 2013
Draft adopted by Executive Director	9 April 2013
Start of public consultation	12 April 2013
End of consultation (deadline for comments)	12 June 2013
Revised draft finalised by the Agency in collaboration with Member States	23 October 2013
Revised draft agreed by ERMS FG	11 November 2013
Revised draft adopted by Executive Director as final	9 December 2013
Date for coming into effect after finalisation	13 December 2013





WHO Vaccine Safety Net (VSN)

- Global network of websites as trustworthy sources of evidence-based information on vaccine safety
  - 72 websites from 34 countries in 23 languages (June 2019)
- Established in 2003 to counterbalance groups using internet and websites to provide unbalanced, misleading and alarming information on vaccination and vaccine safety
- Criteria for good information practices defined by WHO Global Advisory Committee on Vaccine Safety (GACVS)

www.vaccinesafetynet.org

GOALS:

- ✓ To **facilitate** access to reliable, understandable, evidence-based internet information on the safety of vaccines, regardless of their geographic location and language
- ✓ To **collaborate** at an international level to increase awareness about vaccines, reduce vaccine hesitancy and strengthen confidence in vaccines

Vaccine Safety Communications (VSC) e-Library

www.vsc-library.org

- Established in 2018
- **Open access, crowd sourced** repository of **pragmatic tools and resources** for health education and for health care providers, communication specialists and interested parties

- ✓ To assist in communicating about the risks and benefits of vaccines and on issues related to vaccine safety
- ✓ To increase public health knowledge
- ✓ To promote health-seeking behaviors
- ✓ To help prevent dangerous misconceptions about vaccine safety

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Before going to CIOMS Guide …

Table I. Development Stages in Risk Management (Ontogeny Recapitulates Phylogeny) *

- All we have to do is get the numbers right
- All we have to do is tell them the numbers
- All we have to do is explain what we mean by the numbers
- All we have to do is show them that they've accepted similar risks in the past
- All we have to do is show them that it's a good deal for them
- All we have to do is treat them nice
- All we have to do is make them partners
- All of the above

**Reference: Baruch Fischhoff, Risk Perception and Communication Unplugged: Twenty Years of Process. Risk Analysis, Vol. 15, No. 2, 1995*

CIOMS Guide to Vaccine Safety Communication: Added value

- Fills for the first time at global level the niche of the regulators role in vaccine safety communication
- Recommends a '*systems approach*' with defined functions and skilled persons who can efficiently and strategically run vaccine safety communication in collaboration with stakeholders
- Includes a template for Vaccine Safety Communication Plans (VacSCPs)
- Meant to support high- and low-income countries and WHO's Global Vaccine Safety Initiative (GVSI)

Working methodology

- Starting point – discussions in *CIOMS Working Group on Vaccines Safety*
- Based on more than 100 publications, either established guidance documents or peer-reviewed conceptual or empirical research findings, including from immunization programmes
- Added regulatory expertise
- Shares example-based learning from 13 challenging but successful *real-life cases*

Guide of VI chapters

The CIOMS Guide to Vaccine Safety Communication consists of six chapters, presenting:

- Underlying communication concepts (chapter 1);
- Considerations for vaccine safety communication as relevant to regulators (chapter 2);
- Vaccine safety communication as a pharmacovigilance task with a product-life cycle approach to the safety of vaccine products (chapter 3);
- An annotated template for vaccine safety communication plans (VacSCP) as a practical tool (chapter 4);
- Components and functions of vaccine safety communication systems (chapter 5); and
- Skill requirements and proposals for capacity-building of such systems (chapter 6).

Concepts

- Definition of vaccine safety communication as communication about potential risks, demonstrated safety and measures to minimize risks, and about programmes to support the safe and effective use of vaccines

- Focus on communication between regulatory authorities and multiple stakeholders

- Objective-setting of vaccine safety communication around:
  - providing accurate and complete information about risks and safe use;
  - understanding stakeholders;
  - demonstrating trustworthiness of the safety surveillance system; and
  - preventing crisis situations due to safety concerns

- Consideration of socio-ecological context to provide information for informed decision-making on immunization and safe use

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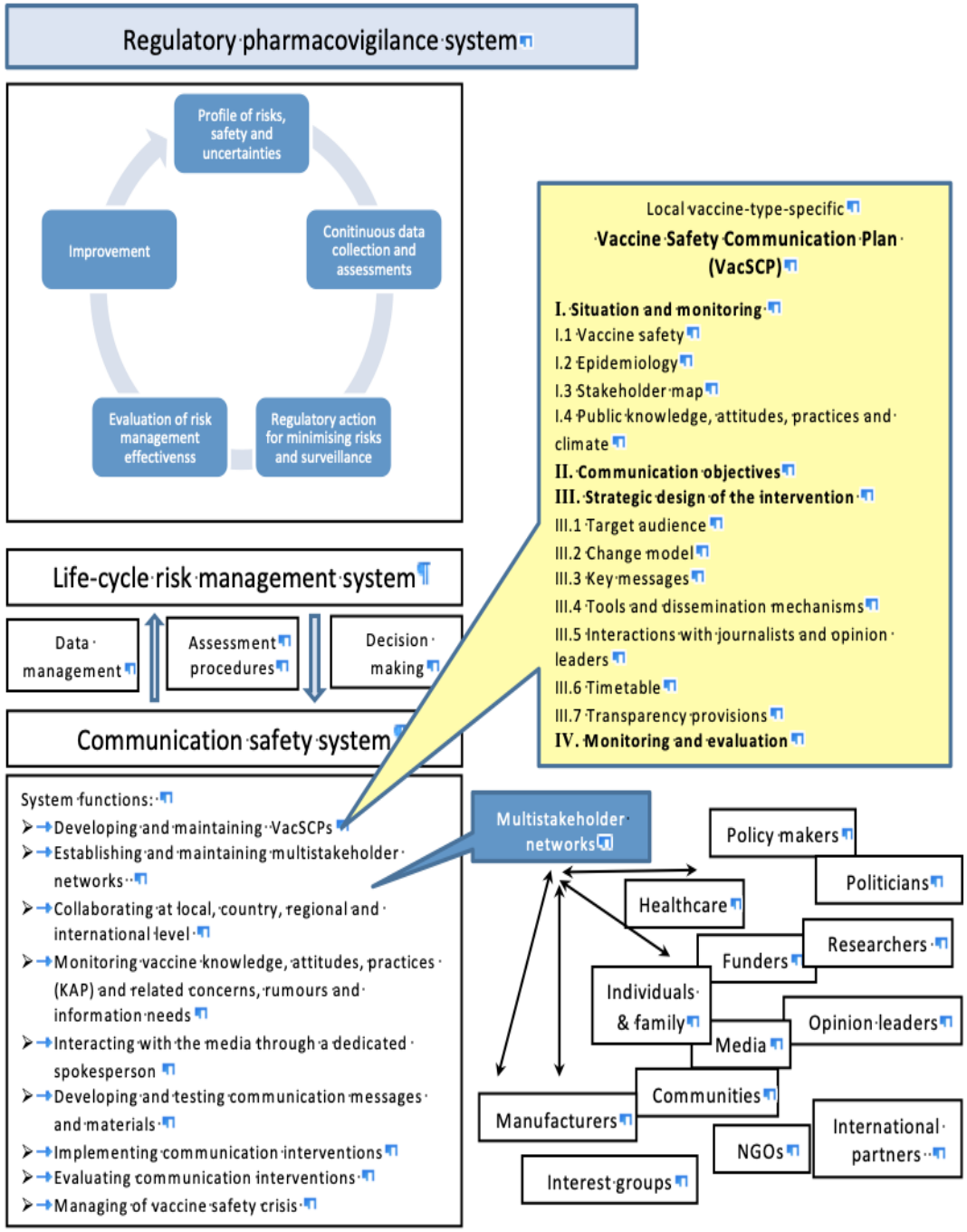
CIOMS Guide Executive summary – Visualisaton of the system approach



System functions:

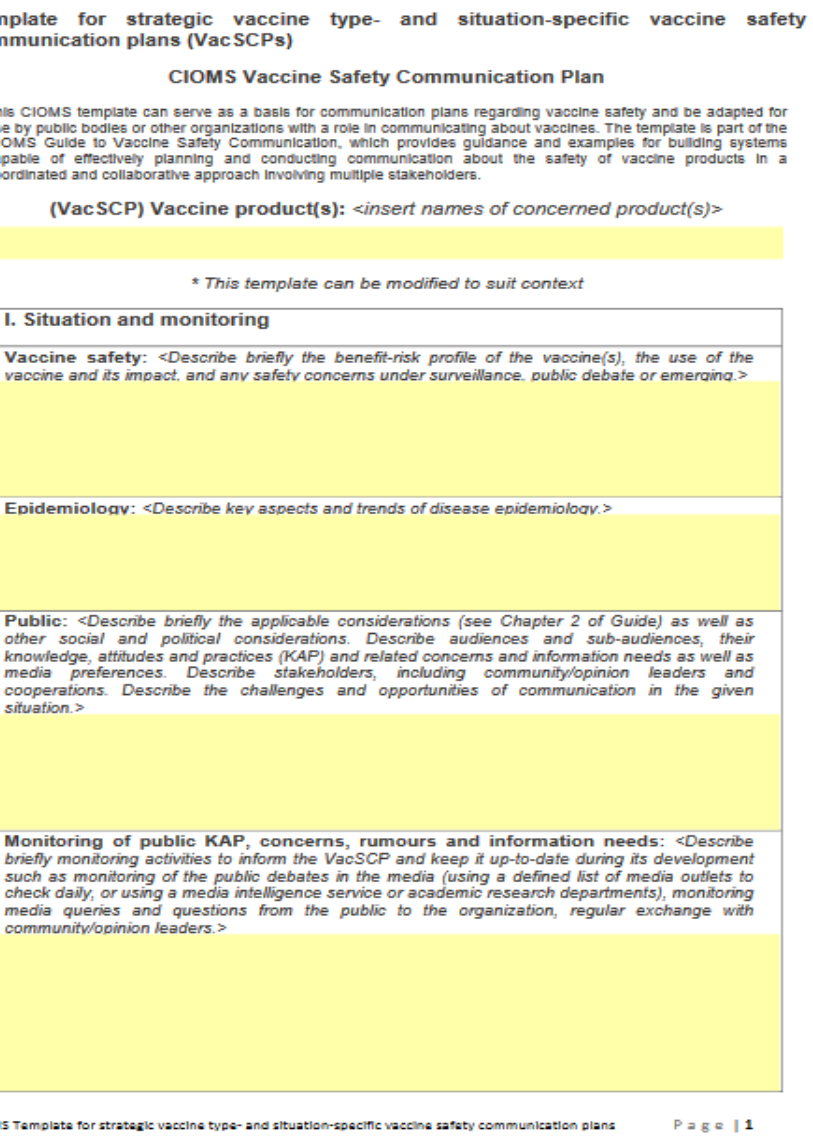
- ❑ Developing and maintaining VacSCPs
- ❑ Establishing and maintaining multistakeholder networks
- ❑ Collaborating at local, country, regional and international level
- ❑ Monitoring vaccine knowledge, attitudes, practices (KAP) and related concerns, rumours and information needs
- ❑ Interacting with the media through a dedicated spokesperson
- ❑ Developing and testing communication messages and materials
- ❑ Implementing communication interventions
- ❑ Evaluating communication interventions
- ❑ Managing of vaccine safety crisis

Local vaccine-type-specific
Vaccine Safety Communication Plan (VacSCP) TEMPLATE

downloadable at https://cioms.ch/wp-content/uploads/2017/06/Template-for-strategic-vaccine-type-form-web.pdf (3 pages, 1st display right)

Content:

I. Situation and monitoring
I.1 Vaccine safety
I.2 Epidemiology
I.3 Stakeholder map
I.4 Public knowledge, attitudes, practices and climate
II. Communication objectives
III. Strategic design of the intervention
III.1 Target audience
III.2 Change model
III.3 Key messages
III.4 Tools and dissemination mechanisms
III.5 Interactions with journalists and opinion leaders
III.6 Timetable
III.7 Transparency provisions
IV. Monitoring and evaluation



Template for strategic vaccine type- and situation-specific vaccine safety communication plans (VacSCPs)

CIOMS Vaccine Safety Communication Plan

This CIOMS template can serve as a basis for communication plans regarding vaccine safety and be adapted for use by public bodies or other organizations with a role in communicating about vaccines. The template is part of the CIOMS Guide to Vaccine Safety Communication, which provides guidance and examples for building systems capable of effectively planning and conducting communication about the safety of vaccine products in a coordinated and collaborative approach involving multiple stakeholders.

(VacSCP) Vaccine product(s): *<insert names of concerned product(s)>*

** This template can be modified to suit context*

I. Situation and monitoring

Vaccine safety: *<Describe briefly the benefit-risk profile of the vaccine(s), the use of the vaccine and its impact, and any safety concerns under surveillance, public debate or emerging.>*

Epidemiology: *<Describe key aspects and trends of disease epidemiology.>*

Public: *<Describe briefly the applicable considerations (see Chapter 2 of Guide) as well as other social and political considerations. Describe audiences and sub-audiences, their knowledge, attitudes and practices (KAP) and related concerns and information needs as well as media preferences. Describe stakeholders, including community/opinion leaders and cooperations. Describe the challenges and opportunities of communication in the given situation.>*

Monitoring of public KAP, concerns, rumours and information needs: *<Describe briefly monitoring activities to inform the VacSCP and keep it up-to-date during its development such as monitoring of the public debates in the media (using a defined list of media outlets to check daily, or using a media intelligence service or academic research departments), monitoring media queries and questions from the public to the organization, regular exchange with community/opinion leaders.>*

Synergies created with:

Accelerated **D**evelopment of **VA**ccine be**N**efit-risk **C**ollaboration in **E**urope

→ **BR monitoring methods**

ADVANCE Guidance on Developing Communication Strategies on Vaccine Benefits and Risks

→ **Development of communication strategies for BR monitoring results from public-private partnerships**

ADVANCE document – more **process** focused

CIOMS document – more **system** focused

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Examples from CIOMS Guide – It can be done!

Overcoming vaccine hesitancy related in anthroposophic and Somali communities fulfilling expectations for complete and neutrally framed information and arranging for individualised and peer-supported dialogue between community members and healthcare professionals – MMR vaccines in Sweden with the help of the WHO (TIP) method (identifies barriers and motivations and recommends evidence-based responding)

Managing a case of death after HPV immunisation through collaboration across public institutions, adherence to an honest and strict media policy and building on existing media collaboration – UK

Involving local health workers and communication experts for setting up clinical trials in communities with limited literacy and initial mistrust – Ebola vaccines in West African countries

Conducting media monitoring and strong engagement with local HPs (re-assessment), journalists and folk art communicators for introducing the Pentavalent vaccine in Kerala

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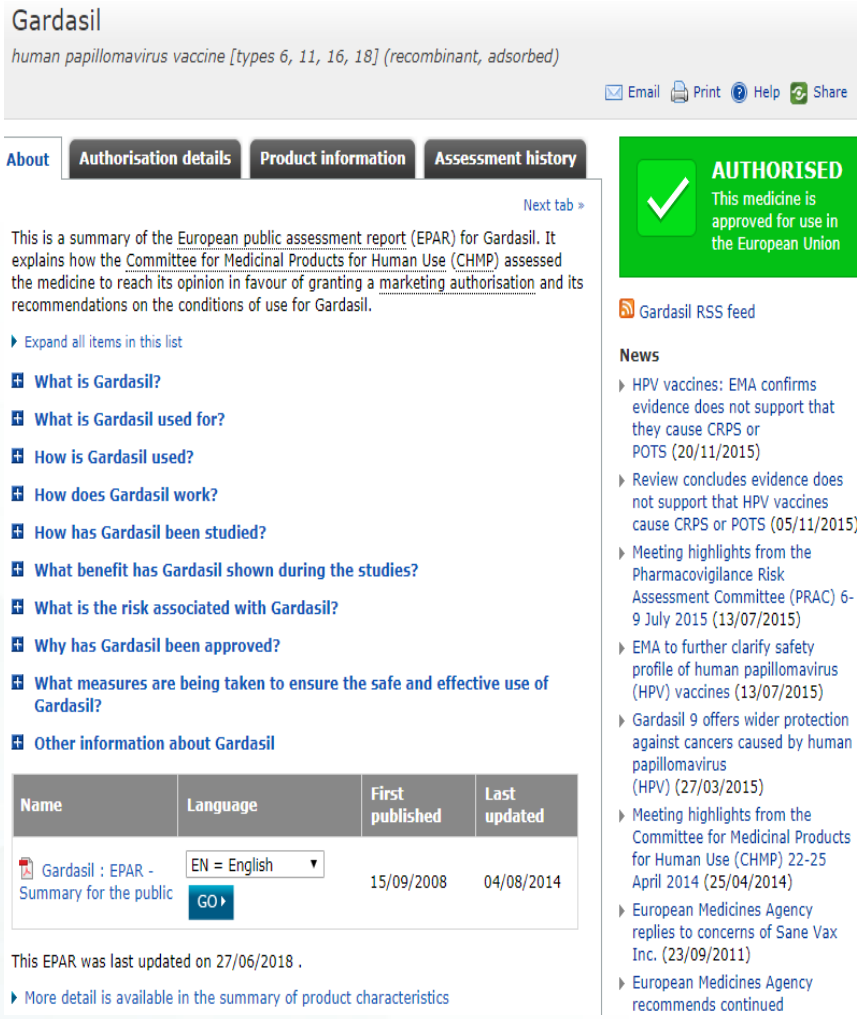
Transparency: EPAR example

European Public Assessment Report (EPAR):

- EPAR summary for the public
- Summary of Risk Management Plan (RMP)
- Approved Product Information
- Initial assessment report (at time of approval)
- Assessment report following a variation (after approval)
  - Extension of indication and line extensions
  - Change to contraindications
  - Outcome of a safety review
  - Paediatric application



Gardasil

human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed)

Email Print Help Share

About | Authorisation details | Product information | Assessment history

Next tab »

This is a summary of the European public assessment report (EPAR) for Gardasil. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Gardasil.

Expand all items in this list

- What is Gardasil?
- What is Gardasil used for?
- How is Gardasil used?
- How does Gardasil work?
- How has Gardasil been studied?
- What benefit has Gardasil shown during the studies?
- What is the risk associated with Gardasil?
- Why has Gardasil been approved?
- What measures are being taken to ensure the safe and effective use of Gardasil?
- Other information about Gardasil

Name	Language	First published	Last updated
Gardasil : EPAR - Summary for the public	EN = English GO	15/09/2008	04/08/2014

This EPAR was last updated on 27/06/2018 .

More detail is available in the summary of product characteristics

AUTHORISED
This medicine is approved for use in the European Union

Gardasil RSS feed

News

- HPV vaccines: EMA confirms evidence does not support that they cause CRPS or POTS (20/11/2015)
- Review concludes evidence does not support that HPV vaccines cause CRPS or POTS (05/11/2015)
- Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 6-9 July 2015 (13/07/2015)
- EMA to further clarify safety profile of human papillomavirus (HPV) vaccines (13/07/2015)
- Gardasil 9 offers wider protection against cancers caused by human papillomavirus (HPV) (27/03/2015)
- Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 22-25 April 2014 (25/04/2014)
- European Medicines Agency replies to concerns of Sane Vax Inc. (23/09/2011)
- European Medicines Agency recommends continued

EMA communication re HPV vaccine

https://www.ema.europa.eu/en/medicines/human/referrals/human-papillomavirus-vaccines-cervarix-gardasil-gardasil-9-silgard (Press release 20.11.2015)

Overview

HPV vaccines: EMA confirms evidence does not support that they cause CRPS or POTS

Reports after HPV vaccination consistent with what would be expected in this age group

EMA has now completed its review of the evidence surrounding reports of two syndromes, complex regional pain syndrome (CRPS) and postural orthostatic tachycardia syndrome (POTS) in young women given human papillomavirus (HPV) vaccines. These vaccines are given to protect them from cervical cancer and other HPV-related cancers and pre-cancerous conditions. In line with its initial recommendations, EMA confirms that the evidence does not support a causal link between the vaccines (Cervarix, Gardasil/Silgard and Gardasil 9) and development of CRPS or POTS. Therefore there is no reason to change the way the vaccines are used or amend the current product information.

CRPS is a chronic pain syndrome affecting a limb, while POTS is a condition where the heart rate increases abnormally on sitting or standing up, together with symptoms such as dizziness, fainting and weakness, as well as headache, aches and pains, nausea and fatigue. In some patients they can severely affect the quality of life. The syndromes are recognised to occur in the general population, including adolescents, regardless of vaccination.

Symptoms of CRPS and POTS may overlap with other conditions, making diagnosis difficult in both the general population and vaccinated individuals. However, available estimates suggest that in the general population around 150 girls and young women per million aged 10 to 19 years may develop CRPS each year, and at least 150 girls and young women per million may develop POTS each year. The review found no evidence that the overall occurrence of these syndromes in vaccinated girls were different from expected occurrence in these age groups, even taking into account possible underreporting. The review noted that some symptoms of CRPS and POTS may overlap with chronic fatigue syndrome (CFS, also known as myalgic encephalomyelitis or ME). Many of the reports considered in the review have features of CFS and some patients had diagnoses of both POTS and CFS. Results of a large published study that showed no link between HPV vaccine and CFS were therefore particularly relevant.

Leverage – potential use

- Adaptable to other organisations
- Adaptable to other medicinal products
- Engaging patient/consumer organisations and healthcare professional organisations
- Raising awareness: WHO GVSI, WHO VSN, EU PRAC
- Building global regulatory capacity

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What is needed:

Communication systems and process that integrate with

1. Proactive and continuous evidence generation and assessment

** CIOMS Guide on Vaccine Active Safety Surveillance*

2. Clear vaccine pharmacovigilance concepts

** WHO-CIOMS Report on vaccine pharmacovigilance*

3. Stakeholder engagement

** CIOMS Working Group on Patients Involvement in Drug Development and Safe Use (Ongoing WG)*

** Designates relevant CIOMS publications and initiatives which, among others, are relevant*

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Vaccine 37 (2019) 401–408

Contents lists available at ScienceDirect

Vaccine

journal homepage: www.elsevier.com/locate/vaccine

Conference report

CIOMS Guide To Vaccine Safety Communication – Executive summary

Priya Bahri[a,*], Lembit Rägo[b], on behalf of the CIOMS Working Group on Vaccine Safety

[a] European Medicines Agency (EMA), Pharmacovigilance Department, Surveillance & Epidemiology Service, 30 Churchill Place, London E14 5EU, United Kingdom
[b] Council for International Organizations of Medical Sciences (CIOMS), 20 Avenue Appia, 1211 Geneva 27, Switzerland

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CIOMS
WHO Global Vaccine Safety Initiative

ABSTRACT

Background: In 2018, the Council for International Organizations of Medical Sciences (CIOMS) issued their Guide to Vaccine Safety Communication. This has been built upon existing guidance and a new review of research and compilation of latest experiences, in order to fill, for the first time at global level, a specific niche for regulatory authorities in the contexts of vaccine hesitancy and informed choice. The Guide was developed by the international multi-stakeholder CIOMS Working Group on Vaccine Safety, formed to assist the Global Vaccine Safety Initiative (GVSI) of the World Health Organization (WHO).

Summary: Besides the public health authorities responsible for immunization programmes, regulators have their own role in communicating about vaccine safety. As they are responsible for licensing vaccine products, they need to be transparent about their assessments of data on quality, safety and efficacy. Furthermore, they are responsible for continuous safety surveillance and keeping safe use advice to the public up-to-date. The Guide stresses the fundamental importance of regulatory bodies to have a system in place with defined functions and skilled persons who can efficiently run vaccine safety communication in collaboration with stakeholders. This system should take a strategic approach to communication, be integral to safety surveillance and risk assessment, and support vaccine safety communication plans (VacSCPs) adapted to vaccine types in local situations. The Guide provides recommendations and examples for the system components as well as a practical VacSCP template.

Conclusions: While the Guide should help strengthening regulatory bodies worldwide with regard to vaccine safety communication, it is meant to help regulators in resource-limited countries in particular. It can also be of interest to other stakeholders and be leveraged to other medicinal products.

1. Background

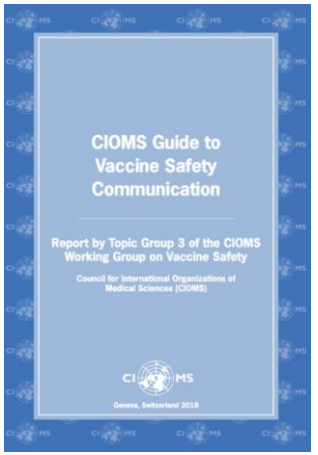
In January 2018, the Council for International Organizations of Medical Sciences (CIOMS) issued their Guide to Vaccine Safety Communication [1]. This discusses the relevance of communicating about vaccine safety in the contexts of vaccine-induced health gains, vaccine hesitancy and informed choice over immunization. The Guide has been developed to fill, for the first time at global level, a specific niche for regulatory authorities in low, middle and high-income countries. Among the many stakeholders and besides the public health authorities responsible for immunization programmes, regulators have their own role to play in communicating about vaccine safety. As they are responsible for licensing vaccine products, they need to be transparent about their assessments of the data on quality, safety and efficacy. Furthermore, they are responsible for continuous safety surveillance, or pharmacovigilance, and keeping safe use advice to the public up-to-date. While the Guide has been developed for strengthening regulatory systems, it may be of interest, and in many aspects transferrable, to other stakeholders.

With the objective of supporting the dissemination and raising interest in the Guide in wider communities of healthcare professionals, health policy makers and leaders in public bodies, this article summarises the recommendations. An overview of the

Abbreviations: ADVANCE, Accelerated Development of Vaccine Benefit-Risk Collaboration in Europe; AVSS, active vaccine safety surveillance; CDC, Centers for Disease Control and Prevention of the United States; CIOMS, Council for International Organizations of Medical Sciences; ECDC, European Centre for Disease Prevention and Control; EMA, European Medicines Agency; EPI, WHO Expanded Program of Immunization; EU, European Union; EVI, essential vaccine information; GACVS, Global Advisory Committee on Vaccine Safety; GVSI, Global Vaccine Safety Initiative; HPV, human papillomavirus; ICDRA, International Conference of Drug Regulatory Authorities; IMI, Innovative Medicines Initiative; MMR, measles-mumps-rubella; NESI, Network for Education and Support in Immunisation; SAGE, WHO Strategic Advisory Group of Experts; SEM, social-ecological model; TIP, WHO Tailoring Immunization Programmes method; UNESCO, United Nations Educational, Scientific and Cultural Organization; UMC, Uppsala Monitoring Centre; VacSCP, vaccine safety communication plan; VSN, Vaccine Safety Net; WHO, World Health Organization; WHO-EURO, WHO Regional Office for Europe.

* Corresponding author.
E-mail addresses: priya.bahri@ema.europa.eu (P. Bahri), ragol@cioms.ch (L. Rägo).

https://doi.org/10.1016/j.vaccine.2018.11.082



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- Since 6 May 2019 pdf copy freely downloadable at: https://cioms.ch/shop/product-category/recently-published/
- Increasing downloads – 30+ per week

Conclusions

- Addressing vaccines hesitancy and increasing trust in vaccines is a multi stakeholder challenge
- Regulators have an important role in it
- Regulators need to improve their communication strategies – including new strategies involving digital technologies and social media
- Regulators increasingly need to act more as a functional network rather than individual agencies (re recent ICMRA initiative)
- …