

# Global vaccine safety blueprint

**Immunization, Vaccines and Biologicals**



World Health  
Organization

# **Global vaccine safety blueprint**

**Immunization, Vaccines and Biologicals**



**World Health  
Organization**

---

**The Department of Immunization, Vaccines and Biologicals  
thanks the Bill and Melinda Gates Foundation  
whose financial support has made the production  
of this document possible.**

This document was published by the  
*Quality, Safety and Standards unit*  
of the Department of Immunization, Vaccines and Biologicals

*Ordering code: WHO/IVB/12.07*

*Printed: February 2012*

**This publication is available on the Internet at:**

[www.who.int/vaccines-documents/](http://www.who.int/vaccines-documents/)

**Copies of this document as well as additional materials on  
immunization, vaccines and biologicals may be requested from:**

World Health Organization  
Department of Immunization, Vaccines and Biologicals  
CH-1211 Geneva 27, Switzerland

• *Fax:* + 41 22 791 4227 • *Email:* [vaccines@who.int](mailto:vaccines@who.int) •

© World Health Organization 2012

All rights reserved. Publications of the World Health Organization can be obtained from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel: +41 22 791 3264; fax: +41 22 791 4857; email: [bookorders@who.int](mailto:bookorders@who.int)). Requests for permission to reproduce or translate WHO publications – whether for sale or for noncommercial distribution – should be addressed to WHO Press, at the above address (fax: +41 22 791 4806; email: [permissions@who.int](mailto:permissions@who.int)).

The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall the World Health Organization be liable for damages arising from its use.

The named authors alone are responsible for the views expressed in this publication.

**Printed by the WHO Document Production Services, Geneva, Switzerland**

---

# Contents

<i>Glossary</i> .....	<i>v</i>
<i>Acknowledgements</i> .....	<i>vii</i>
<i>Abbreviations &amp; acronyms</i> .....	<i>ix</i>
 <b>Part 1: The Global Vaccine Safety Blueprint</b> .....	<b>1</b>
<b>Mission, vision and goals</b> .....	<b>1</b>
<i>Mission</i> .....	<i>1</i>
<i>Vision</i> .....	<i>1</i>
<i>Strategic Goals</i> .....	<i>1</i>
<b>Background</b> .....	<b>5</b>
<i>Purpose and scope of this document</i> .....	<i>5</i>
<i>A changing landscape of vaccine use</i> .....	<i>6</i>
<i>A changing landscape for vaccine safety</i> .....	<i>7</i>
<i>Communicating about vaccine safety</i> .....	<i>7</i>
<i>Medicines and vaccines</i> .....	<i>8</i>
<i>Taking advantage of global resources</i> .....	<i>9</i>
<i>Situation analysis</i> .....	<i>9</i>
 <b>Part 2: Objectives</b> .....	<b>11</b>
<b>Objective 1: To strengthen vaccine safety monitoring in all countries</b> .....	<b>11</b>
1.1 <i>Rationale for action</i> .....	<i>11</i>
1.2 <i>Targets and outputs</i> .....	<i>12</i>
<b>Objective 2: To strengthen the ability of countries to evaluate vaccine safety signals</b> .....	<b>16</b>
2.1 <i>Rationale for action</i> .....	<i>16</i>
2.2 <i>Targets and outputs</i> .....	<i>17</i>
<b>Objective 3: To develop vaccine safety communication plans at country level, to promote awareness of vaccine risks and benefits, understand perceptions of risk and prepare for managing any adverse events and concerns about vaccine safety promptly</b> .....	<b>19</b>
3.1 <i>Rationale for action</i> .....	<i>19</i>
3.2 <i>Targets and outputs</i> .....	<i>20</i>

---

<b>Objective 4: To develop internationally harmonized tools and methods to support country vaccine safety activities .....</b>	<b>22</b>
4.1. <i>Rationale for action.....</i>	22
4.2. <i>Targets and outputs.....</i>	23
<b>Objective 5: To promote a legal, regulatory and administrative framework for the safety of vaccines at national, regional and international levels .....</b>	<b>25</b>
5.1 <i>Rationale for action.....</i>	25
5.2 <i>Targets and outputs .....</i>	26
<b>Objective 6: To strengthen regional and global technical support platforms that meet countries' expressed needs .....</b>	<b>28</b>
6.1 <i>Rationale for action.....</i>	28
6.2 <i>Targets and outputs .....</i>	29
<b>Objective 7: To provide expert advice on vaccine safety issues at national, regional and international levels .....</b>	<b>31</b>
7.1 <i>Rationale for action.....</i>	31
7.2 <i>Targets and outputs.....</i>	32
<b>Objective 8: To put in place systems for appropriate interaction between national governments, multilateral agencies and manufacturers at national, regional and international levels .....</b>	<b>33</b>
8.1 <i>Rationale for action.....</i>	33
8.2 <i>Targets and outputs.....</i>	34
<b>Part 3: Framework for implementation.....</b>	<b>35</b>
<b>Implementation of the Global Vaccine Safety Blueprint .....</b>	<b>35</b>
<i>Introduction.....</i>	35
<i>Function and institutional base .....</i>	35
<i>Global Vaccine Safety Initiative — a minimal structure .....</i>	36
<i>Workplan.....</i>	37
<i>Relationship with industry.....</i>	37
<i>New collaborators.....</i>	37
<b>Annex: What is an adverse event following immunization (AEFI)?.....</b>	<b>38</b>

---

# Glossary

## **Prequalification**

Prequalification is the procedure for assessing the acceptability of medicines, diagnostics and vaccines for purchase by the United Nations. Information on the prequalification of vaccines can be seen on the WHO web site at [http://www.who.int/immunization\\_standards/vaccine\\_quality/pq\\_system/en/index.html](http://www.who.int/immunization_standards/vaccine_quality/pq_system/en/index.html).

## **Signal (safety signal)**

The Council for International Organizations of Medical Sciences (CIOMS) has defined a signal as “information (from one or multiple sources) which suggests a new potentially causal association, or a new aspect of a known association, between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verifactory action.” A signal is therefore a hypothesis, together with data and arguments.

## **Surveillance**

Systematic ongoing collection, collation and analysis of data and the timely dissemination to those who need to know the information so that action can be taken. The data-collection method determines the type of surveillance, so that:

- passive surveillance is based on passive reporting;
- stimulated surveillance is based on stimulated reporting;
- active surveillance is based on systematic search for cases.

Active surveillance, in contrast to passive surveillance, seeks to ascertain completely the number of adverse events via a continuous pre-organised process. Examples of active surveillance are, cohort studies that have been conducted in the United States of America, the United Kingdom, Denmark and others, to evaluate the safety of vaccines, in which all outcomes for specified events are identified in a predefined cohort using clinical information databases. Using such systems it is possible to ascertain events in a population completely, and in an unbiased manner, which facilitates accurate assessment of any potential safety issues.

---

## Vaccine pharmacovigilance

The science and activities relating to the detection, assessment, understanding, prevention and communication of adverse events following immunization, or of any other vaccine- or immunization-related issues. Explanatory notes on this definition can be found at [http://www.cioms.ch/activities/frame\\_vaccpharmadef.htm](http://www.cioms.ch/activities/frame_vaccpharmadef.htm).

The term “enhanced capacity” for vaccine pharmacovigilance is used in the Blueprint in contrast to minimal pharmacovigilance capacity. Enhanced vaccine pharmacovigilance, at a minimum level, includes improved data collection, in passive surveillance, towards higher data quality and more complete data sets, but also improved collation, verification, analysis and communication by building capacity for stimulated and active surveillance. It also includes the ability to perform population-based studies and appropriate epidemiologic studies testing hypotheses by assessing relative and absolute risk ratios, when appropriate.



---

# Acknowledgements

The development of the Blueprint, including its landscape analysis (WHO/IVB/12.04), was supported by a grant from the Bill and Melinda Gates Foundation.

David Bramley wrote this document with guidance from a Collaborative Group composed of Steve Black, Jan Bonhoeffer, Alex Dodoo, Juhani Eskola, Heidi Larson, Stanley Plotkin, Sunheang Shin and the WHO secretariat.

The Blueprint and its strategies benefitted from multiple inputs, including but limited to all participants in the surveys of vaccine safety experts, regulators and vaccine manufacturers, all participants in the Global Vaccine Safety Meeting that took place at WHO headquarters on 26 and 27 September 2011, colleagues responsible for quality and safety of vaccines in WHO regional offices and from the Departments of Immunization, Vaccines and Biologicals and Essential Medicines and Health Products.

Throughout the development process, members of the Global Advisory Committee on Vaccine Safety (GACVS) provided advice and support on the development of this plan.

WHO would like to express its sincere thanks to all contributors for their support and judicious advice.

预览已结束，完整报告链接和二维码如下：

[https://www.yunbaogao.cn/report/index/report?reportId=5\\_28544](https://www.yunbaogao.cn/report/index/report?reportId=5_28544)

