

Global vaccine safety blueprint

The landscape analysis

Immunization, Vaccines and Biologicals



**World Health
Organization**

Global vaccine safety blueprint

The landscape analysis

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/12.04

Printed: March 2012

This publication is available on the Internet at:

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 •

© 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). 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).

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>Acknowledgements</i>	<i>v</i>
<i>Abbreviations & acronyms</i>	<i>vii</i>
<i>Preface</i>	<i>ix</i>
The capacity and needs of post-marketing vaccine safety monitoring in Low- and Middle-Income Countries (LMIC)	1
<i>Executive summary</i>	<i>1</i>
1. <i>Background</i>	<i>2</i>
2. <i>Objectives</i>	<i>2</i>
3. <i>Methods</i>	<i>2</i>
4. <i>Results</i>	<i>3</i>
5. <i>Discussion</i>	<i>8</i>
Enhanced Strength-Weakness-Opportunity-Threat (SWOT+) Analysis Of International Vaccine Safety Activities (IVSA)	13
<i>Executive summary</i>	<i>13</i>
1. <i>Rationale</i>	<i>14</i>
2. <i>Goals</i>	<i>14</i>
3. <i>SWOT analysis design</i>	<i>14</i>
4. <i>Results</i>	<i>15</i>
5. <i>Discussion</i>	<i>26</i>
6. <i>Conclusions</i>	<i>28</i>
Survey of regulators	31
1. <i>Introduction</i>	<i>31</i>
2. <i>Description of methods</i>	<i>31</i>
3. <i>Main Findings</i>	<i>32</i>
4. <i>Discussion and conclusions</i>	<i>36</i>
5. <i>Limitations</i>	<i>38</i>
Survey of vaccine manufacturers	44
<i>Executive summary</i>	<i>44</i>
1. <i>Introduction</i>	<i>44</i>
2. <i>Results</i>	<i>45</i>

Baseline assessment of the vaccine safety systems in the WHO global post-marketing surveillance network countries	50
<i>Executive summary.....</i>	<i>50</i>
1. <i>Introduction.....</i>	<i>50</i>
2. <i>Objectives</i>	<i>51</i>
3. <i>Methodology and analysis.....</i>	<i>51</i>
4. <i>Summary of the key findings.....</i>	<i>53</i>
Analysis of NRA assessment data	75
1. <i>Background and context.....</i>	<i>75</i>
2. <i>Results.....</i>	<i>77</i>
3. <i>General conclusions.....</i>	<i>82</i>
4. <i>Recommendations for country capacity and further analysis</i>	<i>83</i>
Financial assessment.....	85
<i>Executive summary.....</i>	<i>85</i>
1. <i>Introduction.....</i>	<i>86</i>
2. <i>Methodology.....</i>	<i>87</i>
3. <i>Costs and funding of national vaccine safety systems</i>	<i>88</i>
4. <i>Costs and funding of international vaccine safety initiatives.....</i>	<i>91</i>
5. <i>Financing strategies for vaccine safety.....</i>	<i>93</i>
6. <i>Conclusions.....</i>	<i>94</i>

Acknowledgements

The development of the Blueprint landscape analysis was supported by a grant from the Bill and Melinda Gates Foundation.

Authors of the respective sections are listed below. They received guidance from Collaborative Group members and the WHO secretariat.

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

Activity 1.1 - The capacity and needs of post-marketing vaccine safety monitoring in low- and middle-income countries

Principal Investigator: Dr Jan Bonhoeffer
Co-investigators: Dr Yulin Li, Dr Daniel Weibel
Collaborative Group Liaison: Dr Juhani Eskola, Dr Heidi Larson
Brighton Collaboration

Activity 1.2 - Enhanced strength-weakness-opportunity-threat analysis of international vaccine safety activities

Principal Investigator: Dr Jan Bonhoeffer
Co-investigators: Dr Yulin Li, Dr Daniel Weibel
Collaborative Group Liaison: Dr Alex Doodoo, Dr Sunheang Shin
Brighton Collaboration

Activity 1.3 - Survey of regulators

Principal Investigator: Dr Janice Graham
Co-investigators: Dr Alexander Borda-Rodriguez, Dr Farah Huzair
Collaborative Group Liaison: Dr Murilo Freitas Dias
**Technoscience and Regulation Research Unit,
Faculty of Medicine, Dalhousie University**

Activity 1.4 - Survey of vaccine manufacturers

Principal Investigator: Dr Elena Achkasova

Co-investigators: Dr Trevor Gibbs, Dr Lars Schmiedeberg,
Dr Jan-Willem van der Velden

Collaborative Group Liaison: Dr Sunheang Shin, Dr Stanley Plotkin
**International Institute for the Safety of
Medicines Ltd.**

Activity 1.5 - Baseline assessment of the vaccine safety systems in the WHO global post-marketing surveillance network countries

Principal Investigator: Dr Radmila Mirzayeva

Collaborative Group Liaison: Dr Alexander Dodoo, Dr Heidi Larson,
Dr Sunheang Shin
Independent Consultant

Activity 1.6 - Analysis of NRA assessment data

Principal Investigator: Mr Lahouari Belgharbi

Collaborative Group Liaison: Dr Murilo Freitas Dias
World Health Organization (WHO)

Activity 1.7 - Financial assessment

Principal Investigator: Ms Anaïs Colombini

Co-investigators: Mr Jean-Bernard Le Gargasson

Collaborative Group Liaison: Dr Steve Black, Dr Heidi Larson
Agence de Médecine Préventive (AMP)

Abbreviations & acronyms

ABC	Automatic Brighton Classification
AEFI	adverse events following immunization
AFR	WHO African Region
AMP	Agence de Médecine Préventive
AMR	WHO Region of the Americas
BC	Brighton Collaboration
CDC	Centers for Disease Control and Prevention (USA)
CIOMS	Council for International Organization of Medical Science
COFEPRIS	Comisión Federal para la protección contra riesgos sanitario (Mexico)
CP	country profile
DCVRN	Developing Countries' Vaccines Regulators Network
DPT	diphtheria-tetanus-pertussis vaccine
EMA	European Medicines Agency
EMR	WHO Eastern Mediterranean Region
EPI	Expanded Programme on Immunization
EUR	WHO European Region
FDA	United States Food and Drug Administration
FTE	full time equivalent
GACVS	Global Advisory Committee on Vaccine Safety
GMP	good manufacturing practice

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_28528

