

SAFETY MONITORING *of* **MEDICINAL PRODUCTS**

Reporting system for the general public



**World Health
Organization**

SAFETY MONITORING *of* **MEDICINAL PRODUCTS**

Reporting system for the general public



**World Health
Organization**

WHO Library Cataloguing-in-Publication Data

Safety monitoring of medical products: reporting system for the general public.

1.Essential drugs – standards. 2.Drug monitoring. 3.Adverse drug reaction reporting systems. 4.Pharmacovigilance. 5.Drug utilization review – methods. 6.Consumer participation. I.World Health Organization.

ISBN 978 92 4 150319 8

(NLM classification: QV 771)

© World Health Organization 2012

All rights reserved. Publications of the World Health Organization are available on the WHO web site (www.who.int) or can be purchased from WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland (tel.: +41 22 791 3264; fax: +41 22 791 4857; e-mail: 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 through the WHO web site (http://www.who.int/about/licensing/copyright_form/en/index.html).

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.

Printed in Spain

CONTENTS

	Preface	v
	Introduction	1
1.	Why consumer reporting?	2
2.	Definitions	3
3.	How to start a consumer reporting system	4
3.1	Basic steps in setting up a consumer reporting system	4
4.	Reporting of adverse reactions to medicines	5
4.1	Reporting form	5
4.2	Means of reporting	6
4.3	What to report?	6
5.	Special issues in reporting	8
5.1	Central or decentralized reporting?	8
5.2	Stimulation of reporting	8
5.3	Medical confirmation of reports	9
5.4	Consumer reports received by the pharmaceutical industry	9
6.	Practicalities in the organization of consumer reporting	10
6.1	Staff	10
6.2	Equipment needs	10
6.3	Special training needs	10
6.4	Input from the public	10
6.5	Information service	11
6.6	Communication	11
7.	Assessment of case reports	12
7.1	Data processing	13
8.	Use of the data	14
8.1	Hypothesis generation and strengthening	14
8.2	Medicine regulation	14
8.3	Information	14
8.4	Education and feedback	14

9.	Relations with other parties	15
9.1	Consumer and patient organizations	15
9.2	Medicine regulatory authorities	15
9.3	Pharmaceutical companies	15
9.4	Professional medical and pharmaceutical organizations	15
9.5	World Health Organization	15
9.6	National pharmacovigilance centres	16
9.7	Media	16
	References	17
	Glossary	18
	Annex 1. Examples of consumer reporting forms	21
	A. Netherlands	21
	B. Sweden	23

PREFACE

A handbook for consumer reporting of ADRs was discussed and requested at the thirty-first meeting of the National Pharmacovigilance Centres held in Uppsala, Sweden from 20–23 October 2008, and the development of this publication has been incorporated into the aims of the Seventh Framework Programme of the Research Directorate of the European Commission and its project Monitoring Medicines (<http://www.monitoringmedicines.org/>).

This document aims to provide practical guidelines on how to set up national systems for consumers to report adverse reactions to medicines. Throughout this document, the phrase “consumer reporting” is used to refer to reporting of adverse drug reactions (ADRs) by the general public.

Acknowledgements

Anne Kiuru, Medical Products Agency, Uppsala, Sweden and Linda Härmark, Netherlands Pharmacovigilance Centre Lareb, the Netherlands developed the manuscript. Members of the WHO Advisory Committee on Safety of Medicinal Products, Gunilla Sjölin-Forsberg, Council for International Organizations of Medical Sciences (CIOMS), Geneva, Cecilia Biriell, Uppsala Monitoring Centre, Sweden and Kees van Grootheest, Netherlands Pharmacovigilance Centre Lareb, the Netherlands reviewed the draft. Staff from the national pharmacovigilance centres in Italy, Norway, Serbia, Suriname and the United Kingdom provided valuable comments. Shanthi Pal, WHO, provided technical editing.

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_28578

