

University of Groningen

Patient participation in pharmacovigilance

Rolfes, Leàn

IMPORTANT NOTE: You are advised to consult the publisher's version (publisher's PDF) if you wish to cite from it. Please check the document version below.

Document Version

Publisher's PDF, also known as Version of record

Publication date:
2018

[Link to publication in University of Groningen/UMCG research database](#)

Citation for published version (APA):

Rolfes, L. (2018). Patient participation in pharmacovigilance [Groningen]: Rijksuniversiteit Groningen

Copyright

Other than for strictly personal use, it is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), unless the work is under an open content license (like Creative Commons).

Take-down policy

If you believe that this document breaches copyright please contact us providing details, and we will remove access to the work immediately and investigate your claim.

Downloaded from the University of Groningen/UMCG research database (Pure): <http://www.rug.nl/research/portal>. For technical reasons the number of authors shown on this cover page is limited to 10 maximum.

Patient participation in pharmacovigilance

Leàn Rolfs

Patient participation in pharmacovigilance

ISBN: 978-94-034-0444-8 (Printed version)

ISBN: 978-94-034-0445-5 (Digital version)

© 2018, Leàn Rolfs

No parts of this thesis may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopying, recording or any information storage and retrieval system, without permission of the author.

The work presented in this thesis was performed at the Netherlands Pharmacovigilance Centre Lareb and the University of Groningen, Groningen Research Institute of Pharmacy, PharmacoTherapy, - Epidemiology & -Economics

Het drukken van dit proefschrift werd mede mogelijk gemaakt met financiële steun van het Nederlands Bijwerkingen Fonds, de Rijksuniversiteit Groningen en Research Institute SHARE.

Cover design: Lucien Aspelung

Lay-out design and printed by: Optima Grafische Communicatie, Rotterdam



rijksuniversiteit
groningen

Patient participation in pharmacovigilance

Proefschrift

ter verkrijging van de graad van doctor aan de
Rijksuniversiteit Groningen
op gezag van de
rector magnificus prof. dr. E. Sterken
en volgens besluit van het College voor Promoties.

De openbare verdediging zal plaatsvinden op

vrijdag 23 maart 2018 om 12.45 uur

door

Leàn Rolfes

geboren op 4 oktober 1985
te Emmen

Promotores

Prof. dr. E.P. van Puijenbroek

Prof. dr. K. Taxis

Copromotor

Dr. F.P.A.M. van Hunsel

Beoordelingscommissie

Prof. dr. B. Wilffert

Prof. dr. H.G.M. Leufkens

Prof. dr. P.M.L.A. van den Bemt

Paranimfen

Israa Jaafar

Louise Andrews

TABLE OF CONTENTS

| | |
|--|-----|
| Chapter 1. General Introduction | 7 |
| Chapter 2. Nature of information reported by patients | |
| 2.1 Important information regarding reporting of adverse drug reactions: a qualitative study | 27 |
| 2.2 Adverse drug reaction reports of patients and healthcare professionals - differences in reported information | 35 |
| 2.3 The impact of experiencing adverse drug reactions on the patient's quality of life: a retrospective cross-sectional study in the Netherlands | 49 |
| Chapter 3. Quality of clinical information in patient ADR reports | |
| 3.1 The quality of clinical information in adverse drug reaction reports by patients and healthcare professionals; a retrospective comparative analysis | 69 |
| Chapter 4. Contribution of patient reports to signal detection | |
| 4.1 Does patient reporting lead to earlier detection of drug safety signals? A retrospective observational comparative study between adverse drug reactions reports by patients and healthcare professionals | 87 |
| Chapter 5. Practice of pharmacovigilance | |
| 5.1 Feedback for patients reporting adverse drug reactions; satisfaction and expectations | 107 |
| Chapter 6. General Discussion | 125 |
| Summary & Samenvatting | 139 |
| Dankwoord | 153 |
| Publications | 155 |
| About the author | 159 |

