

Understand the workings of the EU regulatory system from an insider's perspective

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Evaluating Medicines

PERSPECTIVES FROM A EUROPEAN REGULATORY AUTHORITY

Edited by:

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Topics covered:

- How medicinal products get onto the market
- Transparency – healthcare's new watchword
- European market for medicinal products
- Centralised registration – Europe and the role of the national authorities
- Pharmacovigilance
- Patient and consumer organisations
- Paediatric medicines
- Rare diseases, orphan drugs – another world?
- Combination products – two worlds, one patient

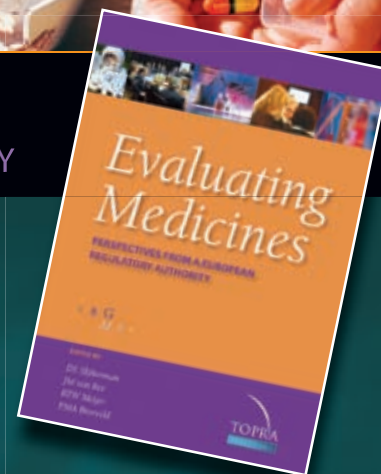
TOPRA Publishing's first book is a **collaboration with the Medicines Evaluation Board of The Netherlands (Dutch MEB).**

Evaluating Medicines was originally published in 2008 in Dutch under the title *Openheid van zaken – De werkzaamheden van het College ter Beoordeling van Geneesmiddelen*.

The pharmaceutical market is a global endeavour – **promoting health and treating illness crosses national borders**. Medicinal products are only allowed for sale or supply onto the market once they have been demonstrated to be efficacious and safe when used appropriately. This process doesn't stop once a medicine receives a marketing authorisation: from market launch onwards it is continuously monitored to identify unacceptable side-effects and for any drug safety issues.

In the European healthcare arena, the Dutch MEB plays an important and dynamic role in the regulation of medicines. The environment in which medicinal product evaluation takes place has been cloaked in mystery for a long time and the Dutch MEB is committed to changing this state of affairs. ***Evaluating Medicines* is proof positive of the Board's commitment to transparency in the regulatory process.** Its contributors are all from the Dutch MEB, so have first-hand knowledge of how products are assessed and registered, and how they are marketed and monitored thereafter.

The authors come from a wide variety of backgrounds and expertise and offer valuable insight into the world of medicines. In this concise publication **they explain in simple terms,**



the intricate nature of European regulatory affairs in order for this complex process to be understood and appreciated.

The book has been updated, translated into English and published by TOPRA Publishing so that it can reach a wider readership. **It is aimed at anyone who wants to understand what the work of a leading European regulatory authority is really about.**

Although written with the lay person in mind, this book has something to teach those who are starting a career in regulatory affairs, those who work outside of the European system and need to understand it more fully, and even experienced EU regulatory professionals who would like to have a view from inside one of our leading agencies.

The translated version has not altered the original esprit, but provides an updated text which retains the clarity of the original. **The authors express their own views candidly,** which are not necessarily those of the MEB or TOPRA, **in a way that will greatly add to an appreciation of the work of a busy EU agency.** Although written from the perspective of those who work in just one of the EU member states, the issues and challenges they discuss are relevant across the region.

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