

Orphan Drugs: Understanding the Rare Disease Market and its Dynamics (Woodhead Publishing Series in Biomedicine)

By Elizabeth Hernberg-Ståhl, Miroslav Reljanovi?

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This authoritative and comprehensive book makes the reader familiar with the processes of bringing orphan drugs to the global market. There are between 5,000 and 7,000 rare diseases and the number of patients suffering from them is estimated to be more than 50 million in the US and Europe. Before the orphan drug legislation enacted in the US in 1983, there was a limited interest from industry to develop treatment for very small patient groups. One of the difficulties is, of course, that similar levels of investment are needed from a pharmaceutical company to bring a drug to the market for both small and large patient groups.

The journey from application of an orphan drug designation to a reimbursed market- approved drug is long and many obstacles occur during the journey.

After reading the book, readers will: Understand who the players/stakeholders are in the rare orphan disease field and their specific needs and concerns: patients and patient organizations, researchers and treating physicians within the field, industry, regulatory and reimbursement bodies* Understand the strong partnership between the different players and the various initiatives to improve and increase access to treatment for patients; minimizing the gap between numbers of known diseases, orphan designations, approved drugs and paid drugs.

The book also provides short practical case stories from patients and researchers, as well as representatives from industry and authorities on the challenges they came across in developing orphan drugs or getting access to orphan drugs.

- A comprehensive overview of strategy, key activities and considerations of how to bring an orphan drug from concept to the market and make it available to patients
- A source of updated information, news and trends for those who are already active in this fast-evolving field
- Covers the global definitions and the criteria for getting an orphan drug

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Editorial Review

About the Author
Elizabeth Hernberg-Stahl, M.Sc, is founder of Late Phase Solutions Europe AB, based in Sweden; it is an independent consultancy focusing on providing strategic and operational guidance on late phase drug development as well as guidance on processes and activities related to orphan drug development and market access. The author has more than thirty years experience from the international biotech and pharmaceutical industry (20 of which were in the orphan drugs area). During her 10 years at TKT/Shire HGT Elizabeth was responsible for developing and establishing the Global Outcome Survey Department, which manages global patient registries. Elizabeth was also member of the Shire HGT European Management Team and the Global Medical Affairs Leadership Team. Before joining Shire HGT/TKT Europe-5S, Elizabeth held a similar position for 8 years at Pharmacia/Pfizer where she established and managed a global patient registry KIMS on the rare condition adult GHD and the outcome of growth hormone treatment. Elizabeth has published numerous papers and is a frequent speaker at several congresses on topics related to orphan rare diseases.

Miroslav Reljanovic, MD, MSc, is a board-certified neurologist. Whilst practising as a physician in a large WHO Collaborating Centre in Zagreb, he was the clinical investigator in numerous Phase II and III studies in the field of neurology and a consultant to various pharmaceutical companies. In 1997, Miro founded Ergomed contract research organization (CRO) and he introduced the novel Study Site Coordination model as an intrinsic part of the conduct of clinical studies. This model became a landmark of the Ergomed approach to clinical research which is paramount to provide high quality trial data in very demanding areas like oncology, neurology, and orphan diseases including rare cancers. Miro has also successfully introduced the first European innovative co-development business model and he has completed several transactions with European and North American listed biopharmaceutical companies. Together with co-founder Elliot Brown, MB, MRCGP, FFPM, a well known international expert in drug safety, Miro started PrimeVigilance in 2008, which soon became a leading specialist vendor of contracted pharmacovigilance services to the pharmaceutical industry. Through a strategic partnership with Elizabeth Hernberg-Ståhl, Miro established a specific division at Ergomed, focusing on providing assistance and support to biotechnology and drug industries, clinicians, and researchers, to facilitate the development of candidate drugs for rare diseases in this challenging field.

Users Review

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