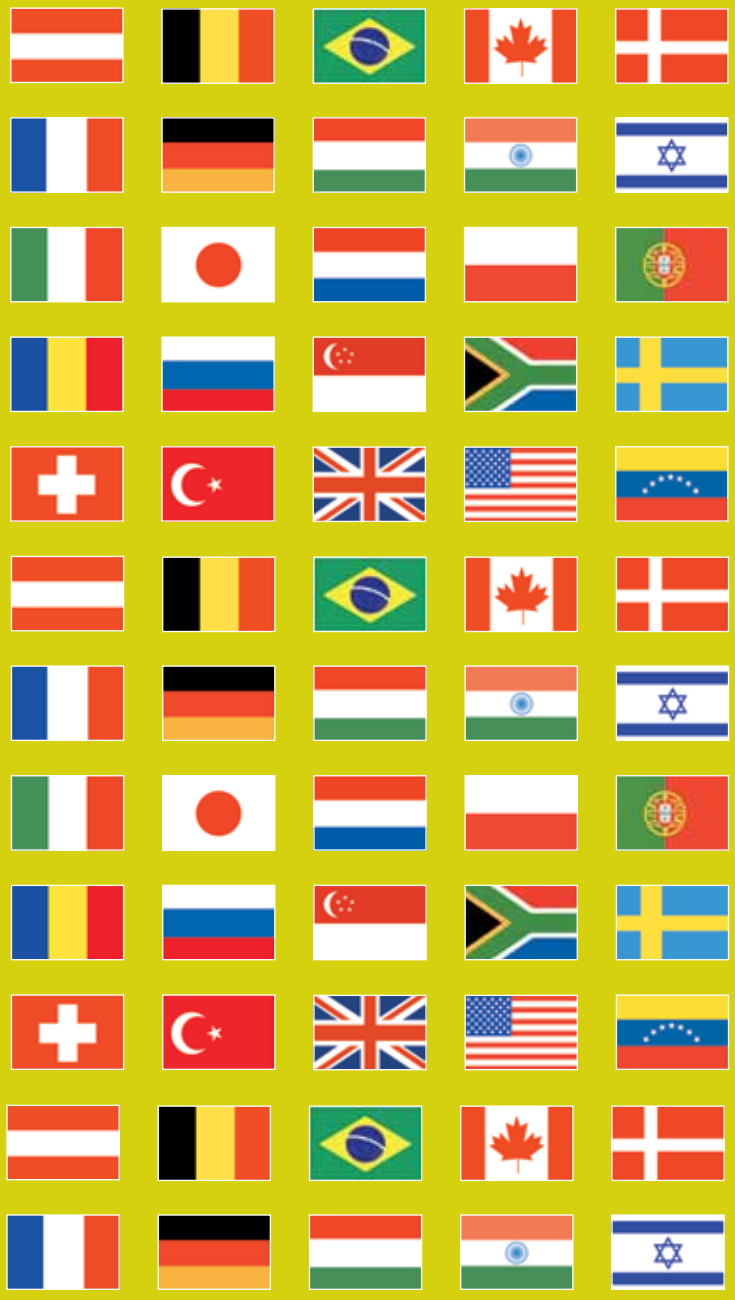
GETTING THE DEAL THROUGH

Life Sciences

in 25 jurisdictions worldwide

2012

Contributing editors: Alexander Ehlers and Cord Willhöft



Published by
Getting the Deal Through
in association with:

Adams & Adams

Anderson Mōri & Tomotsune

Beslay + Le Calvé

Bird & Bird

Brudkowski & Partners

Bruun & Hjejle

Dewallens & partners

Drew & Napier LLC

Ehlers, Ehlers & Partner

Fasken Martineau DuMoulin LLP

Gross, Kleinhendler, Hodak, Halevy, Greenberg & Co

Hoet Pelaez Castillo & Duque

Mattos Muriel Kestener Advogados

Mehmet Gün & Partners

PeliFilip SCA

Porzio, Bromberg & Newman PC

Preslmayr Rechtsanwälte OG

Rajinder Narain & Co

Salans

Setterwalls Advokatbyrå AB

SRS Advogados

Szecskay Attorneys at Law

Wenger & Vieli AG

GETTING THE DEAL THROUGH®

Life Sciences 2012

Contributing editors
Alexander Ehlers and Cord Willhöft
Ehlers, Ehlers & Partner

Business development managers
Alan Lee
George Ingledew
Robyn Hetherington
Dan White

Marketing managers
Ellie Notley
Alice Hazard

Marketing assistants
William Bentley
Zosia Demkowicz

Admin assistant
Megan Friedman

Marketing manager (subscriptions)
Rachel Nurse
Subscriptions@GettingTheDealThrough.com

Assistant editor
Adam Myers

Editorial assistant
Lydia Gerges

Senior production editor
Jonathan Cowie

Chief subeditor
Jonathan Allen

Subeditors
Sarah Morgan
Caroline Rawson
Charlotte Stretch

Editor-in-chief
Callum Campbell

Publisher
Richard Davey

Life Sciences 2012
Published by
Law Business Research Ltd
87 Lancaster Road
London, W11 1QQ, UK
Tel: +44 20 7908 1188
Fax: +44 20 7229 6910

ISSN 2042-4329

Printed and distributed by
Encompass Print Solutions
Tel: 0844 2480 112

Law Business Research

FSC www.fsc.org MIX Paper from responsible sources FSC®

CONTENTS

Introduction

Alexander Ehlers and Cord Willhöft
Ehlers, Ehlers & Partner

Life sciences law, the entire range of legal practice for the life sciences industry, has become more and more important in recent years. This can be said because the number of additional legal provisions and regulations regarding drug safety, pharmacovigilance, quality management, distribution, reimbursement and collaboration with health-care professionals or patient organisations has significantly increased, but this is not the only reason. In accordance with Warren Buffett's famous quotation: 'It takes 20 years to build a reputation and five minutes to ruin it.' The willingness of pharmaceutical manufacturers and manufacturers of medical devices to comply with these additional legal requirements and rules has increased, in particular in respect to collaboration with health-care professionals and patient organisations. Pharmaceutical and medical device companies are presently, more than ever, under public pressure to observe the respective requirements set out by legal provisions, directives and industry guidelines. Against this background, there is a high need for companies in the life science sector to be familiar with the legal environment in order to avoid any potential damages to their reputation.

Further, the market for medicines and medicinal devices is highly competitive and infringements of legal requirements are often also highlighted and pursued by competitors. These conditions are complicated even further because the activities of manufacturers of medicines and medical devices are rarely limited to one country and, therefore, compliance with several rules and pieces of legislation must be ensured. Nevertheless, it is not only the broad range of applicable rules and the competitive environment for manufacturers that has made life sciences law one of the most important legal areas in the recent past. Recently, due to tightening public finance constraints, the reimbursement of medicines and medical devices has become subject to strict requirements in several countries. Consequently, a great demand for legal advice with respect to reimbursement has arisen.

Considering this, the following legal outline is supposed to serve as a guide for the manufacturers of medicines and medical devices. It gives a helpful overview with respect to the applicable rules for a variety of activities. Furthermore, as numerous countries with differing jurisdictions are concerned, this edition of *Getting The Deal Through* is also a comparative legal guide for cross-border activities or activities in several countries. We are honoured by the great success of the previous editions of *Life Sciences* in 2010 and 2011 and we are very pleased to again be contributing editors of the third edition.

Of course, this legal outline is not a substitute for case-related legal advice. We, and the other lawyers who have written chapters, would be very pleased to provide you with further insights based on our experience in this important and challenging legal area.

LIFE SCIENCES 2012 ISSN 1750-9947