

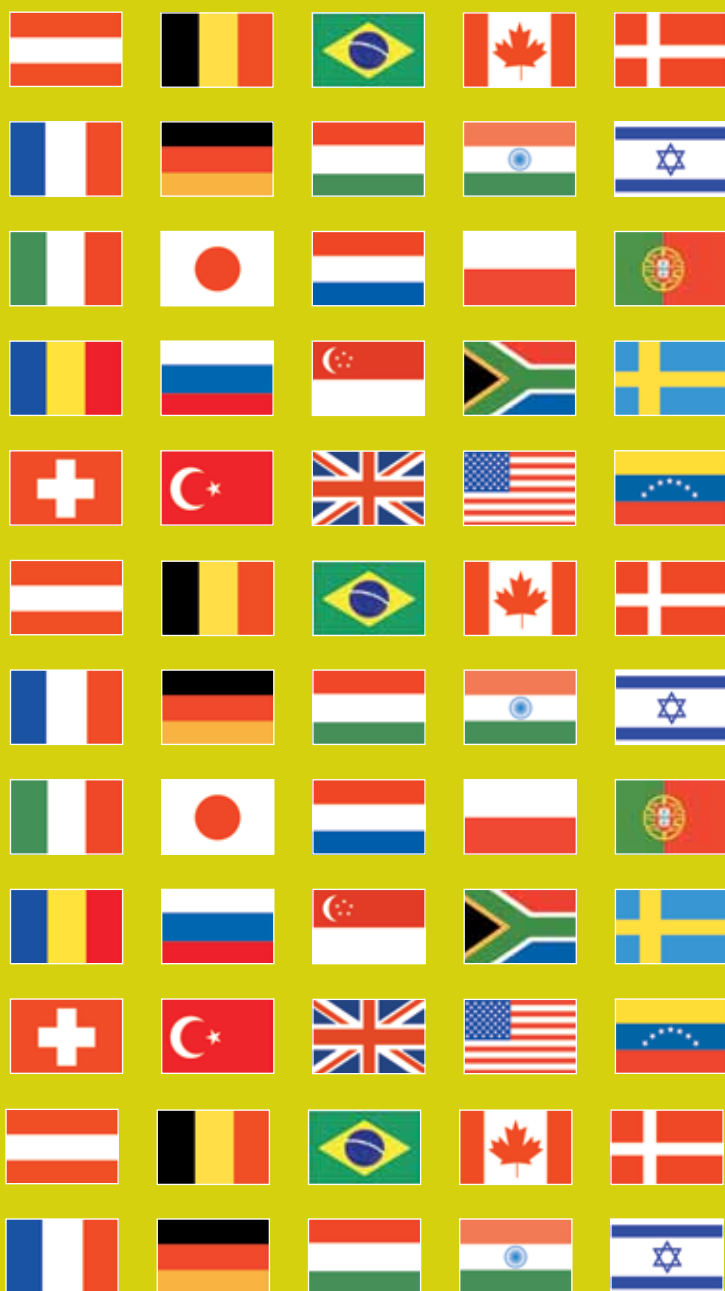


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Introduction

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.

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