

The Globalization of the Regulatory Affairs Profession

By Gordon S. Jepson, LLB

Regulatory affairs is increasingly a global profession. RRA professionals working in one country have to, as time goes on, be more and more cognizant of the regulatory environment in other countries.

You can be sure that, as you make decisions seeking approval for your product in one country, others in your company are planning on entering other markets. Can you be expected to advise them on what is needed? To some degree, the answer must be yes. A more troubling question is whether there is a risk that your submissions to and interactions with FDA will do something to jeopardize approvals and sales overseas. For that reason alone, it pays to have some familiarity with regulatory environment in your company's or client's existing or potential overseas markets.

In 2005, the US made up 48% of the world drug market in sales (and that number has since fallen). This sounds like a lot; but it means that more than half of potential sales may occur outside the US. Can any one person or department stay on top of the rules and regulations, not to mention the subtleties of interacting with local authorities, of the other large and potentially lucrative markets for your company's products?

In this issue, we've gathered together a fascinating sample of some of the recent regulatory issues arising in countries outside the US—perhaps just enough to whet your appetite on the subject.

While you read the details, a broader issue worth thinking about is not the specifics of regulation in, for example, the EU, India, or Canada, but some of the basic assumptions underlying approvals. It can be dangerous to assume that all countries will take the same approach to a product. For example, many products which are devices in the US are drugs in Europe, and vice-versa.

As a further example from my own perch here in Toronto, we often find that US companies assume, at the management and marketing level, that products that would fall under the rubric of DSHEA in the US will be sold similarly in Canada, i.e., as dietary supplements with no premarket approval. In fact, dietary supplements require premarket approvals by Health Canada after review of a drug-type submission. Although no one would expect a US regulatory affairs professional to know how to obtain such premarket approval in Canada, simply knowing that it

is necessary, and putting word in the right ear before trucks head north for the border, can provide tremendous value-added for your company or clients.

Another significant “philosophical” difference, if you can call it that, is in the attitude toward direct-to-consumer drug advertising. Many US practitioners are surprised to find that, in permitting DTC advertising of prescription drugs, the US is essentially alone. Sue Diaz has provided an update on the Canadian approach to DTC advertising in an article in this issue, but the same issue will arise worldwide.

Not just approvals, but clinical trials overseas provide both challenges and opportunities. About \$10 billion is expected to be spent worldwide on clinical trials this year alone. Can you save your company money by conducting trials overseas? Probably, but can you also control the quality of the trials and coordinate multinational sites, all operating under different national regulations? Can you ensure that appropriate ethical standards are upheld everywhere? Certainly some of the responsibility for these issues may be farmed out to Contract Research Organizations (CROs) with a multinational reach, but the final responsibility lies with those who engage the CRO. It pays to be as familiar as possible with the laws and regulations in the country concerned. Dr. Mahadev Murthy's article in this issue discusses the growing potential for clinical trials in India.

Finally, as time goes on, more and more hope is placed in Mutual Recognition Agreements, or MRAs, which permit transnational approvals. Progress in this area remains slow, however there is some hope in the medical device field. Jaap Laufer's article in this issue examines the US-EU device manufacturer's inspection program.

The other side of coin in all these matters is that you are not always dealing with other countries that have a well-developed drug and device regulatory regime, such as the EU or Canada. Your contacts in less-developed nations may look to you, and to the science-based approach to regulation used in the US, as a model. This gives all of us in RAPS—which has an increasingly global membership—an outreach opportunity, and an opportunity to help build a truly global healthcare system, which fulfills the ultimate goal of all our companies and clients: improved health that is cost effective, wherever a person buys or uses our products.

Gordon S. Jepson, LLB, is a partner with the Toronto regulatory and intellectual property law firm Deeth Williams Wall LLP and a member of the Board of Editors of Regulatory Affairs Focus.



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