NHP Reviews

by Brian Wagner, B.Sc.

Betrayed!

When the Standing Committee on Health convened in 1997 to propose a regulatory framework for nhps, their recommendations were based on a fundamental requirement: that the framework not impose unreasonable burdens on industry. So far, the process has been nothing but burdensome. The evidence requirements to substantiate safety and efficacy are definitely not reasonable, even though the Standing Committee required them to be.

NHPD Refusing Submissions

The NHPD was hoped by many to be an international leader in alternative medicine. After all, the NHPD's Director-General, Philip Waddington, is a naturopath by training, as is Michael Smith, their Director of Policy and Regulatory Affairs, along with many others.

But has the NHPD progressed in their mindset since they were inaugurated eight years ago? One of the greatest fears expressed by industry groups before the Standing Committee was that Health Canada would begin taking products off the shelves once again, albeit under a different name. This is what led to the effective lobbying efforts in the Spring of 1997.

At present, the NHPD is refusing over half the product licence submissions entered. And, they are refusing products not based on safety concerns, but because the products are apparently not "efficacious" according to their standards (which are, by and large, standards derived from the pharmaceutical realm).

The Standing Committee is discussing nhp regulation once again this year, and they have convened to discuss the performance of the NHPD, among other topics. In May of this year, Mr. Pierre Haddad of the University of Montreal (Professor, Department of Pharmacology) told the Standing Committee that, "the Natural Health Products Directorate is being somewhat alarmist about natural health products" in terms of evidence requirements. This is coming from someone with a pharmacology background.

"Banning" Products All Over Again

The NHPD has an immense backlog of product licence applications, around 13,000. It is steadily increasing. The NHPD would prefer not to call it a "backlog" as this sounds that the NHPD is not performing up to par. However, that is exactly what is happening.

In May of this year, Philip Waddington told the Standing Committee that their current operational changes, "have led us to a situation where we are confident that we'll be able to get through this backlog".

But in 2005, he also told the Standing Committee that, "as is human nature, people tend to leave things to the end, and we anticipate that we'll have an ever-increasing number of applications as we get closer to the deadline [of 2010]". In other words, the NHPD anticipates that the number of submissions they receive per day will increase as 2010 draws closer. Considering that about 94% of the applications in the backlog are based on original evidence submitted by the applicant, the single greatest challenge facing the NHPD is dealing with complex (i.e., combination) products trying to make claims which they have not pre-approved. And, that is what most companies are trying to do. But, the NHPD is refusing more than 75% of these Non-Traditional submissions *based on efficacy reasons, not for reasons related to safety or contamination*.

Appearing before the Standing Committee in May, Waddington noted that, "I'll be honest: the reason we refuse them is usually not because the product is found to be toxic", but rather, "the usual reason for refusing an application is because we have been unable to obtain the required data on the ingredients listed for the product". Waddington implies that it was simply a matter of not *having* the data, as though this data could be found *somehow*. This is simply is not true. Frankly, there isn't any "data" to support any claims whatsoever for the vast majority of products on the market, under the pharmaceutical-level evidence requirements the NHPD is imposing.

In 1997 when Mr. Grant Hill (Macleod, Ref.) confronted Mr. Dann Michols, then the Director-General of the pharmaceutical division of Health Canada, on why Health Canada was "banning" products and taking them off the shelves, Mr. Michols succinctly avoided the issue saying that, "we do not ban substances". According to Mr. Michols, "*It is not that we have banned it; it is that we have not approved it because we have not received a [data] package from a sponsor following the guidelines we have set".* Does this sound familiar?

The NHPD is definitely banning products. In fact, it is worse than the DIN system. At least, with the old DIN system, companies were not required to make health claims; now it's mandatory. The standards of evidence are virtually the same today, as they were with DIN's. *Sure, we can use "traditional medicine evidence", a fact the NHPD is quick to point this out, but the vast majority of products on the market would never qualify for using that kind of evidence.* Most of the nhp products are innovative and based on cutting edge concepts, not some folklore remedies our ancestors conjured up.

The Problem of Health Claims

The problem with this situation is twofold: (i) health claims are mandatory for products, and those claims must be specific (that is, virtually therapeutic); and (ii) the evidence requirements to substantiate such claims are too high – that kind of research just flat-out does not exist in the public domain. This means that the NHPD is refusing virtually every single one of their submissions for efficacy reasons, not safety or quality. It has nothing to do with safety. It has everything to do with health claims. It's comparable to being forced to play tennis with a basketball, and the winner takes all.

What happened? Was the industry not promised a "light regulatory touch" for these products, because of their high safety profile? The successful and powerful lobbying efforts of 1997 caused enough grief on Parliament Hill for the Minister of Health, David Dingwall, to lose his seat in that year's Federal election. The next Minister of Health, Alan Rock, referred the matter to the House Standing Committee on Health. Those were the days of Mr. Grant Hill, Ms. Judy Wasylycia-Leis and Ms. Carolyn Bennett, all Members of Parliament who fought for the industry's right to sell natural medicines. Rock's acceptance of all the Committee's 53 recommendations, eventually led to the creation of separate regulations for nhps in 2004.

However powerful, the majority of these recommendations have been abandoned by the NHPD. There is no light regulatory touch. We do not have a risk-based system. Products are not allowed to be on the market without claims. The Inspectorate still abuses their power with seizure and, with Bill C-51, they will gain even greater power. Products are "not being approved", not because they are dangerous or contaminated. *They are being banned because there are insufficient clinical trials published on their ingredients.*

Our industry must stop hoping beyond hope that the NHPD will somehow change their tune and start licensing more products, out of kindness or consideration. As a directorate, their business is to "process" submissions. And, the fastest way of doing this, is by refusing them, not licensing them. The NHPD's self-preservation depends on their banning most products on the market. So, the real question is, how will this industry respond? Will we roll over and play dead, or stand up and fight?

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