Are the new regulations good for our industry?

NHP regulations proving to be "unmitigated disaster"

by Shawn Buckey

The NHP regulations are an unmitigated disaster for the industry. In the 1990s, when the industry and consumers revolted against Health Canada enforcement actions, no one predicted that the industry would be manoeuvred into voluntarily removing far more products than Health Canada enforcement actions ever could. Yet that is what is happening. Indeed, it is the only logical consequence of the Regulations.

Following the successful industry and consumer revolt, we were supposed to get regulations designed to "increase" access to NHPs. This is important to note. The regulatory scheme is supposed to provide consumers with more NHPs, not what they had, not less. The only logical consequence of the regulations is, however, to restrict access. Instead of following the U.S. model where NHPs are deemed to be safe and the FDA can only remove them with evidence of harm, our regulations deem NHPs to be illegal, unsafe and ineffective. No NHP can remain on the market unless safety and efficacy can be proven. Deeming NHPs to be illegal and then placing barriers for entry onto the market cannot "increase" access. This can only decrease access. Tweaking barriers to entry – such as modifying evidence standards – will not solve the fundamental problem. Nor will this prevent abuses in the future. The fundamental problem is the deeming of all NHPs as dangerous and ineffective drugs.

Putting persons at risk

There is no reason why regulations could not be crafted to legitimize the industry, address fraud and safety and at the same time permit increased access to NHPs. Ironically, restricting access to NHPs in the name of safety, actually places consumers at risk. Persons who have tried pharmaceutical treatments without success are forced to forgo NHPs that provide relief. Persons managing conditions with NHPs are forced to access pharmaceutical treatments which carry significant risk.

In the name of "safety" we are putting persons at risk. We have dramatically increased the cost to the industry in efforts to comply with the regulations. We have lost tens of thousands of products. We have lost producers. Innovation has ground to a crawl on multi-ingredient products due to a belief they will not be licensed.

Most surprising of all, it is the industry – and not Health Canada's Inspectorate – that is removing most of the products from the market. Prior to the regulations, only products the Inspectorate targeted were removed. As diligent as the Inspectorate is, there are limits to how many NHPs a given inspector can remove in a day. Ironically, after fighting for regulations to increase the number of NHPs, the industry is voluntarily removing far more NHPs than Health Canada ever could. According to Health Canada's last Quarterly Report, 17,602 NHPs have failed the licensing process. Many have been voluntarily removed. We are left to guess how many NHPs have been voluntarily removed without license applications being filed. I know of entire lines that have been dropped without any applications being submitted.

The industry is in effect removing products in numbers that Health Canada could only have dreamed of. This cannot, by any measure, be considered "good" for an industry that fought for increased access. •

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Problem is the regulator, not the regulations

by Brian Wagner

When the House of Commons Health Committee submitted its report on natural health products to the Health Minister in 1998 (called *A New Vision*), they noted that, "The Committee takes the position that informed choice is fundamental. We believe that Canadian consumers are intelligent, independent, and capable of making responsible choices with respect to their health."

Since 1998, Health Canada created the Natural Health Products Directorate (NHPD) to take jurisdiction of NHPs away from the pharmaceutical division, and the new *NHP Regulations* (NHPR) were created in 2003 to regulate these kinds of products. But are these new regulations good for our industry?

The NHPR are indeed good for our industry, but the NHPD is not. Even though the Committee stated that informed choice was fundamental, it seems that the NHPD is limiting our choices to products. In fact, around 82 per cent of innovative products fail to meet the high standards for efficacy (health claims). This doesn't necessarily remove products from the shelves (i.e. you can always re-apply for a licence without penalty), however, we all know what repeated frustration leads to.

The Health Committee recommended general principles that should be followed, like not requiring double blind trials as evidence, or allowing traditional use claims instead of scientific evidence. The NHPD, in turn, was mandated with drafting the NHPR based on those general principles. But the NHPR themselves are not to blame — they are actually fairly innocuous on their own, and they couldn't really do any harm without an interpretive body like the NHPD. For example, the NHPR states that a licence application has to submit "information that supports safety and efficacy" of the product, but it does not define the word "support." The NHPD defines "support" and they have produced hundreds of pages vaguely outlining how much evidence is required. So then if an application fails because it is not "supported," surely the NHPR cannot be blamed; it is the fault of the NHPD. And without serious changes in that department, the future looks grim.

To be fair, the NHPD staff have great intentions and are doing good work despite the challenges at the directorate level. But this isn't the problem. The NHPD, as a collection of operations and procedures, is set dead against the ambitions and dreams of this industry. •

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Are the new regulations good for our industry?

Implementation of the new regulations a positive progression

by Carl Carter

In order to discuss the merits of the revised regulations, it is important to understand the underlying reasons that led to its development in the first place.

On January 1, 2004, NHPD issued the original regulations for the NHP industry. NHPD outlined a six year phase-in period which staggered the level of compliance for all manufacturers, packagers, labellers and importers. The original expectation was that when the six years ended on January 1, 2010, the regulations would come into full force. However, as January 1 came and went, there was still a backlog of approximately 10,000 products pending review.

While Health Canada was content with the status quo, the National Association of Pharmacy Regulatory Authorities (NAPRA) had concerns with unlicenced NHPs being sold in pharmacies. In January 2010, NAPRA released a statement indicating that pharmacists should not sell a marketed NHP without a NPN or DIN-HM. As expected, there was much concern industry-wide regarding the potential effects of this statement. Such direction on products that are generally viewed as safe and are in demand across the country would be detrimental to manufacturers, retailers and consumers alike.

This position would not improve consumer safety, but would likely lead to consumer confusion and reduced confidence in the NHP sector.

UPLAR a "temporary tool"

CHFA wrote to Health Canada requesting that action be taken to legalize the backlogged products in order to decrease the potential effect of NAPRA's position. Health Canada then released the draft Unprocessed Product Licence Application Regulations. CHFA and its members expressed their support for UPLAR with the understanding that it would be a temporary tool to allow these products to be sold even though a decision to issue or refuse a licence based on the PLA had not been made. In other words, this regulation would make the sale of the backlogged 10,000 products legal. This would be of great benefit to many companies and would begin to reduce some of the dissatisfaction due to the NAPRA position and current Health Canada processes.

CHFA has been a strong promoter of the need for legal certainty because of the position taken by NAPRA and we appreciated that Health Canada recognized the impact that failure to act on this issue would cause.

CHFA is supportive of an appropriate regulatory environment for natural health products, coupled with fair standards of evidence, product testing requirements, and compliance and enforcement. Implementation of the new regulations is a positive progression for the natural health products industry.

Carl Carter is the director of regulatory affairs and policy development with the Canadian Health Food Association (CHFA). Carl leads his department to ensure a fair and appropriate regulatory environment in which CHFA members can operate their businesses. Contact Carl at 800/661-4510 or info@chfa.ca

To read more on the new regulations, please go to cnhr.ca

Product safety, restoring consumer confidence good reasons for the regs

by Bernie Desgagnés

We need the regulations for the following two major reasons; product safety and to help restore consumer confidence in NHPs.

I believe over the years, many consumers have been influenced by negative media about our products regarding safety and efficacy, so having regulations in place – which consumers can trust and believe in – will only benefit the industry over time. It's all about putting the consumer in a comfort level with what we as an industry are doing.

Prior to the NHP regulations, health claims were not permitted on most of our products. The regulations were outdated, inadequate and quite restrictive. This resulted in consumers making decisions on product use without having the proper information to make an informed decision. Consequently, people were often not getting the full benefit of the products. In addition, there were some safety concerns. Natural health products are relatively low risk compared with medicines, but they are not without risk to consumers' health.

Risk can occur from the following: poor quality in manufacturing, (e.g. contamination, incorrect ingredients, incorrect dosage); making unsubstantiated claims (which can lead to consumers taking inappropriate products for their health condition), inadequate information for consumers to make an informed choice (e.g. incorrect instructions or inadequate warnings that a product may not be suitable for certain groups such as pregnant women) and interaction with prescription drugs or with other natural health products.

The majority of our industry manufacturers are very responsible and get their raw materials and finished products tested before going to market. They see the "big picture," which is putting high-quality, safe and effective products to market, so consumers will have confidence in our products and our industry.

On the other hand, I have seen manufacturers who do not have the same high standards as the majority and have produced products which do not meet acceptable standards of either safety and efficacy. Without standard government regulations, these products could easily find their way to market. In the event customers purchased and used these ineffective and possibly unsafe products, the backlash to our industry could be extremely negative. It would be tragic to see our entire industry painted with the same brush, and all the honest, reputable manufacturers being punished because a few took short-cuts or used low dosages or non-quality ingredients. •

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