SUBMISSION TO THE HOUSE OF COMMONS STANDING COMMITTEE ON HEALTH

RE: BILL C-17 - PROTECTING CANADIANS AGAINST UNSAFE DRUGS ACT

June 6, 2014

SUBMISSION TO THE HOC HESA

BILL C-17 - PROTECTING CANADIANS AGAINST UNSAFE DRUGS ACT

Bad Science Watch

Bad Science Watch is an independent Canadian consumer protection organization dedicated to promoting good science in public policy. We are funded by donations from the public and we do not represent any corporate interests.

The following was prepared by volunteers and represents what we believe to be an honest, fair, and science-based evaluation.

We can be contacted as follows:

Bad Science Watch
180 Danforth Ave. P.O. Box 35024
Toronto, ON, M4K 3P5
www.badsciencewatch.ca
info@badsciencewatch.ca
888.742.3299 voice
888.813.3569 fax

SUBMISSION TO THE HOC HESA

BILL C-17 - PROTECTING CANADIANS AGAINST UNSAFE DRUGS ACT

Executive Summary

Bill C-17 is a welcome update to the Food and Drug Act, but it has been severely weakened by its exclusion of natural health products (NHPs).

NHPs are not inherently safe, or even 'low-risk'. Many are poorly studied, and there is little known about their interactions with each other or pharmaceutical products. They have poor quality control, and adverse reactions to them are more likely to go unreported than those of pharmaceuticals.

NHPs also present a danger of interaction with each other, and with prescription drugs. Such interactions pose a particular risk because NHPs are available without prescription, and pharmacists and medical practitioners may not be aware of their use by a patient when checking for potential interactions when prescribing drugs.

All adverse reactions should be reported, regardless of their source. The perceived level of risk of a product has no bearing on its manufacturer's susceptibility to failures in quality control, or deficits in our knowledge of ingredient safety.

As written, Bill C-17 would establish two different standards for health product manufacturers. Popular over-the-counter NHPs are found side-by-side on pharmacy shelves with products classified as drugs made by the same companies. There is no reason to make a distinction.

We therefore recommend the following amendments to Bill C-17, the Protecting Canadians Against Unsafe Drugs Act, and detail the reasons for each below.

1. ***Removal of the exclusion of natural health products (NHPs) from the bill's patient safety measures so that all health care products are protected.***

2. ***Addition of an amendment to the Food and Drug Act to establish a clinical trial database that would include all trial information on therapeutic products approved for sale in Canada.***

SUBMISSION TO THE HOC HESA

BILL C-17 - PROTECTING CANADIANS AGAINST UNSAFE DRUGS ACT

Contents

SUBMISSION TO THE HOC HESA

BILL C-17 - PROTECTING CANADIANS AGAINST UNSAFE DRUGS ACT

Introduction

Bill C-17 is a welcome update to the Food and Drug Act, but it has been severely weakened by its exclusion of natural health products (NHPs). It is our position that no consumer's safety should be ignored, and no product or company should be exempt from accountability.

Arguments

1. NHPs Pose Risks

NHPs are not inherently safe, or even 'low-risk'. Many are poorly studied, and there is little known about their interactions with each other or pharmaceutical products. They have poor quality control, and adverse reactions to them are more likely to go unreported than those of pharmaceuticals (Walji et al, 2011).

Evidence Of Harm

In 2013 alone, Health Canada was forced to issue advisory notices for at least 66 NHPs due to various safety concerns:

- Five products from two manufacturers were found to contain hidden ingredients such as hydroxyhomosildenafil thione and other sildenafil (Viagra) analogs. These pharmaceuticals are normally found in prescription drugs used to treat erectile dysfunction, and pose a particular risk to consumers with heart problems (Government of Canada, 2013a; Government of Canada, 2013b).
- A dietary supplement was found to be contaminated with two strains of bacteria, putting consumers at risk of infection, and undeclared caffeine (Government of Canada, 2013c).
- Sixty-one products from 13 manufacturers were recalled over concerns of contamination with chloramphenicol, an antibiotic associated with a risk of aplastic anemia, a potentially fatal blood disorder (Government of Canada, 2013d).

Poor Quality Control

A recent study conducted at the University of Guelph investigated the standards and quality control of 44 NHPs sold in Canada and the United States from 12 manufacturers (Newmaster et al., 2013). The results showed a shockingly high prevalence of contamination and inaccurate ingredient labelling in these products. 59% of the products were contaminated with active ingredients and fillers not listed on the labels. 32% of the samples did not contain the main labelled ingredient. Only 2 of the 12 manufacturers had accurate labeling on their examined products.

This presents the very real possibility of Canadians endangering their health by unknowingly consuming unlisted active ingredients and allergens in NHPs. For instance, one product labelled as St. Johns Wort actually contained Senna Alexandrina instead, which is a powerful laxative that can cause adverse effects ranging from chronic diarrhoea to liver damage. A ginkgo product contained undeclared Black Walnut, which could trigger potentially fatal anaphylaxis in individuals with tree-nut allergies.

Drug Interactions Contribute to Risk

In addition to safety concerns due to hidden and undeclared ingredients, NHPs present a danger of interaction with each other, and prescription drugs that Canadians use concurrently. Such interactions pose a particular risk because NHPs are available without prescription, and pharmacists and medical practitioners may not be aware of their use by a patient when checking for potential interactions when prescribing drugs.

For example, St John's Wort and garlic, common ingredients in many NHPs, were found to exhibit potentially serious drug interactions in at least 18 clinical investigations (Mills et al., 2005). Certain interactions between antiretroviral drugs and these ingredients can reduce the effectiveness of the treatment (Lee et al., 2006), putting patients' lives at risk.

Such findings are alarming, as a recent study conducted at ten community pharmacies in British Columbia and Alberta (Necyk et al., 2014) found 58.8% of the screened patients to use NHPs simultaneously with prescription drugs. Of those, 7.3% reported experiencing adverse events associated with the consumption of these products over a six month period. Crucially, these patients were also 6.4 times more likely to experience adverse reactions than those patients who took prescription drugs alone.

A 2007 paper by Dr. Mano Murty (then Manager of the clinical section of Marketed Biologicals, Biotechnology and Natural Health Products Bureau at Health Canada) stressed the need for close monitoring to address this issue.

2. No Adverse Reaction Should Be Ignored

Adverse reactions should be reported, regardless of their source. The perceived level of risk of a product has no bearing on its manufacturer's susceptibility to failures in quality control, or deficits in our knowledge of ingredient safety.

The purpose of surveillance is to determine unusual rates of health related events, such as serious adverse reactions associated with the use of a health care product, and to inform public health action, such as issuing a recall of an offending product. Just as with other therapeutic products, requiring adverse reaction monitoring for NHPs will enable rapid response to information about products that arises after they are licensed and brought to market.

Health Canada reports that 12% of Canadians who use NHPs experience adverse reactions, and yet only an estimated 41% of them report the reactions to Health Canada (Health Canada, 2012).

3. Companies Should Be Accountable For All Their Products

As written, the bill would establish two different standards for health product manufacturers. This introduces complexity and works against the Canadian government's own goals of less red tape and more consistency in regulation.

Popular over-the-counter NHPs are found side-by-side on pharmacy shelves with products classified as drugs made by the same companies. There are close to 1000 licensed NHPs made by some of the largest pharmaceutical companies in the world (Health Canada, 2014). For example:

- Pfizer: Preparation H® Cream, Centrum;
- Sanofi: Selsun Blue, Rolaids;
- GlaxoSmithKline: Sensodyne, Tums®;
- Novartis: Nicotinell, Desenex, Ex-Lax, Maalox;
- Bayer: Philips® Milk of Magnesia, children's multivitamins (Flintstones®, Bugs Bunny™);
- Johnson & Johnson: Fleet® Enema, Listerine, Benylin, Polysporin

The NHPs made by these pharmaceutical companies are not without risk, either. In 2009, laxative products from Johnson & Johnson, Pharmascience, and Odan Laboratories were recalled after 53 adverse reaction reports, including 27 cases of serious kidney injury (Health Canada, 2009a, 2009b).

Bill C-17 is meant to hold pharmaceutical companies accountable, but if their products are excluded from scrutiny, and they can still get away with mere $5,000 fines for causing injury to consumers, the spirit and intention of the bill is undermined.

4. The Measures Add No Undue Administrative Burden

Enabling the bill to cover all health products equally does not affect the NHP licensing process, it won't put any undue administrative burden on NHP manufacturers, and it won't restrict health care choice.

The existing burden of ensuring a product is safe and of high quality already falls on the manufacturer. The new powers given to the Minister in the bill would further compel companies to ensure that their quality assurance programs are robust and their products safe.

5. All Clinical Trial Data Should Be Made Available In A Public Database

It has become apparent that much of the clinical trial data used to seek approval for pharmaceuticals remains inaccessible to prescribers, clinicians, and scientists. This data is often withheld by manufacturers under the excuse of "trade secrets" and while it may be seen by regulatory agencies like Health Canada, it is in the public interest to make this data available for researchers and clinicians to ensure the greatest degree of scientific scrutiny.

This would enable clinicians to make better decisions when deciding what therapeutic products to recommend to their patients, and better tailor their treatments to the individual. It would also ensure the availability of data for post-market research, allowing scientists to draw fully informed conclusions.

The recent reviews of newly released data from the manufacturer-sponsored clinical trials on Tamiflu (olsetamavir) and Relenza (zanamavir) are good examples of the more complete picture of the efficacy

and risks of a new drug that can be formed using this process (Heneghan et al, 2014, Jefferson et al, 2014).

Conclusion

Given the obvious risks that NHPs pose to the Canadian public, and the lack of any reason for a double standard for manufacturers of these products, it is our recommendation that Bill C-17 be amended to remove the exclusion of NHPs as therapeutic products. Exclusion of NHPs achieves nothing and is a disservice to the health and safety of consumers.

As well, given the obvious benefits of mandating the release of all clinical trial results to researchers and clinicians, it would be a terrible waste not to use this opportunity to implement a clinical trials database.

References

Canadian Health Food Association. (2014). Snapshot of Canada's Natural Health Products and Organic Industry. Accessed online June 3, 2014 from https://www.chfa.ca/nhp/snapshot-of-canadas-natural-health-products-and-organic-industry/.

Government of Canada. (2013a). Authorized natural health product (Prema G) contains hidden dangerous ingredient. Accessed online June 4, 2014 from http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/35289a-eng.php

Government of Canada. (2013b). Natural health products contain hidden ingredients: May pose serious risk to health. Accessed online June 4, 2014 from http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/34719a-eng.php

Government of Canada. (2013c). Contaminated unauthorized natural health product (MaxHIMize). Accessed online June 4, 2014 from http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/37317a-eng.php

Government of Canada. (2013d). Important Recall Information: A number of natural health products potentially contaminated with chloramphenicol may pose serious health risks to consumers. Accessed online June 4, 2014 from http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2013/36355a-eng.php

Health Canada. (2009a). Fleet Phospho-soda oral laxative. Accessed online June 4, 2014 from http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2009/9807r-eng.php.

Health Canada. (2009b). Health Canada Warns That Use of Oral Sodium Phosphate Products For Bowel Cleansing May Lead to Kidney Injury. Accessed online June 4, 2014 from http://www.marketwired.com/press-release/health-canada-warns-that-use-oral-sodium-phosphate-products-for-bowel-cleansing-may-958043.htm.

Health Canada. (2012). About Natural Health Products. Accessed online June 4, 2014 from http://www.hc-sc.gc.ca/dhp-mps/prodnatur/about-apropos/cons-eng.php#a6.

Health Canada. (2013). The approach to natural health products. Accessed online June 4, 2014 from http://www.hc-sc.gc.ca/dhp-mps/prodnatur/nhp-new-nouvelle-psn-eng.php.

Health Canada. (2014). Drugs and Health Products: Search Licensed Natural Health Products. Accessed online June 3, 2014 from http://webprod5.hc-sc.gc.ca/lnhpd-bdpsnh/index-eng.jsp.

Heneghan, C. J., et al (2014). Zanamivir for influenza in adults and children: systematic review of clinical study reports and summary of regulatory comments. BMJ, 348(apr09 2), g2547–g2547.

Jefferson, T. et al (2014). Oseltamivir for influenza in adults and children: systematic review of clinical study reports and summary of regulatory comments. BMJ, 348(apr09 2), g2545–g2545.

Lee, L. S., Andrade, A. S. A., & Flexner, C. (2006). Interactions between natural health products and antiretroviral drugs: pharmacokinetic and pharmacodynamic effects. Clinical Infectious Diseases : An Official Publication of the Infectious Diseases Society of America, 43(8), 1052–1059.

Mills, E., Wu, P., Johnston, B. C., Gallicano, K., Clarke, M., & Guyatt, G. (2005). Natural health product-drug interactions: a systematic review of clinical trials. Therapeutic Drug Monitoring, 27(5), 549–557.

Murty, M. (2007). Postmarket surveillance of natural health products in Canada: clinical and federal regulatory perspectives. Canadian Journal of Physiology and Pharmacology, 85(9), 952–5.

Necyk, C., Tsuyuki, R. T., Boon, H., Foster, B. C., Legatt, D., Cembrowski, G., Murty, M., Barnes, J., Charrois, T. L., Arnason, J. T., Ware, M. A., Rosychuk, R. J., Vohra, S. (2014). Pharmacy study of natural health product adverse reactions (SONAR): a cross-sectional study using active surveillance in community pharmacies to detect adverse events associated with natural health products and assess causality. BMJ Open, 4(3), e003431.

Newmaster, S. G., Grguric, M., Shanmughanandhan, D., Ramalingam, S., & Ragupathy, S. (2013). DNA barcoding detects contamination and substitution in North American herbal products. BMC Medicine, 11(1), 222.

Walji, R., et al (2011). Reporting natural health product related adverse drug reactions: is it the pharmacist's responsibility? International Journal of Pharmacy Practice, 19(6), 383–391.

WHO. (2001). Sildenafil: Not for use with nitrates. WHO Drug Information, 15(2), 81.