



**NHPD Monograph Submission**  
on  
**Homeopathic Nosodes**

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# NHPD Monograph Submission on Homeopathic Nosodes



## Bad Science Watch

Bad Science Watch is an independent Canadian consumer protection organization dedicated to promoting good science in public policy.

The following was prepared by volunteers over the last several months and represents what we believe to be an honest, fair, and science-based representation of the state of affairs of nosodes on Canada. We are an independent body that is funded by private donations and we do not represent any corporate interests.

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## Homeopathic Nosodes



### Preamble

On behalf of Canadian consumers and our supporters we would like to submit for your review our comments regarding the proposed monograph for nosodes and combination nosodes and homeopathic medicines. Our primary concerns involve the use of nosodes as effective substitutes for vaccinations.

While it is the case that homeopathic products are regulated by Natural Health Products Directorate for over-the-counter use, it is worth noting that they are regularly prescribed by alternative health professionals in the context of a patient-practitioner relationship. In addition, Canadian naturopaths, homeopaths and alternative medicine websites are actively recommending nosodes for the prevention and treatment of potentially serious illnesses such as malaria and pertussis. In some cases these recommendations are blatant, specifically listing certain nosodes as effective vaccine substitutes (McLeod, 2012, Thomas, 2013, RHS, 2013, Sherwin, 2012,). In others, the recommendations are vague but the implication that nosodes can be successfully used to prevent disease is clear. The use of nosodes for the prevention of influenza is especially popular, and often linked with false or exaggerated claims against vaccines and their components (Peet, 2013, Der-Ohnian, N.D.).

Further, there are homeopaths in British Columbia and in Ontario that have received training in the use of nosodes for vaccination purposes. American homeopath Kate Birch independently certifies these homeopaths as “homeoprophylaxis supervisors” and lists their contact information on her website (Birch, 2012). In short, there is evidence that NHPD approved nosodes are being used by Canadian alternative medicine practitioners, their patients and the general consumer in substitution for standard vaccines. Current scientific evidence does not support the use of nosodes for this purpose.

To date, there have been no published double-blind placebo-controlled trials examining the effectiveness of prophylactic homeopathic nosodes that are approved by Health Canada (Chatterjee and Biswas, 2012, Picollo, 1964, Wiesenauer, 2001, Liao et al., 2010, Jenaer et al., 2000, Midulla and Marzetti, 1964, Everitt, 1964, Chand et al., 2011, Mercaldo, 1999, Chalmers and Toth, 2009, Eisfelder, 1961, Taylor-Smith, 1951, Chatterjee and Biswas, 2012, Xue et al., 2009). While those promoting homeoprophylaxis offer studies as proof of efficacy, none, save one, were randomized controlled trials (RCT), and many were published prior to 1980, with a very heavy reliance on anecdotes (the one RCT for tuberculinum showed no statistical significance in treatment (Friese et al, 1997)).

While there are no systematic reviews available to summarize the current consensus on nosodes, Linde et al 1999, and Shang et al, 2005 summed up homeopathy in general by concluding that there is little evidence to support the idea that homeopathy is better than placebo. Therefore, Canadian practitioners

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that recommend the use of nosodes for the prevention of disease and Canadian consumers who choose nosodes for this purpose, do so in the absence of an appropriate evidence base.

While we do not have a national program to track current immunization rates, recent outbreaks of pertussis and measles (Alphonso, 2012, CBC News, 2011, French and Hamilton, 2012) and regional evidence of falling immunization rates (Suttorp, 2012, Lunau and Patriquin, 2012) show a growing distrust of vaccines and a decrease in herd immunity. The use of nosodes in place of vaccines contributes to the lowering of herd immunity and therefore represents a threat to health and safety of all Canadians. Accordingly, the continued licensure of nosodes by the Natural Health Products Directorate and the prescribing of these nosodes by homeopaths and naturopaths is therefore contributing to this public health problem. The proposed pre-cleared monographs for nosodes, combination nosodes and homeopathic medicines fail to provide a safeguard for the inappropriate use of these products.

Below are specific comments on the proposed monograph, provided on your website at <http://webprod.hc-sc.gc.ca/nhp-id-bdipsn/atReq.do?atid=nosodes&lang=eng> and at [http://webprod.hc-sc.gc.ca/nhp-id-bdipsn/atReq.do?atid=nosodes\\_homeo&lang=eng](http://webprod.hc-sc.gc.ca/nhp-id-bdipsn/atReq.do?atid=nosodes_homeo&lang=eng).

## Main Conclusions

### **Proposed proper names and common names for nosodes and combination nosode and homeopathic medicines imply that the products are effective vaccines.**

In the proposed monographs 3 nosodes are permitted to imply that they are vaccines. These are listed as “BCG vaccine”, “Influenza virus vaccine” and “Smallpox vaccine”. It is not reasonable to expect that a consumer would be able to properly determine that the product is not a vaccine in the absence of specific language indicating such. Given no such language it is likely that the average consumer would indeed think that the Health Canada approved natural health product in their hand is a vaccine that is “safe, effective and of high quality”. Other nosodes included in both monographs, such as “Diphtherinum”, “Meningococcinum”, “Pertussinum” and “Tetanotoxinum” are also at risk of being confused with effective vaccines. This is especially the case if the consumer is considering these products in consultation with an alternative health provider or after consulting the readily available online literature that promotes nosode use for this purpose.

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### **The proposed recommended use/purpose is problematically vague.**

The proposed allowed statements “Nosodes preparation” and “Nosodes and homeopathic preparation” are ambiguous and can be interpreted as meaning that the product is effective for any purpose that a nosode happens to be recommended for. It does not alert the consumer to the fact that there is no purpose for which Health Canada and the Natural Health Products Directorate considers these products effective. Practically, a consumer or patient receiving advice to use a nosode to prevent disease would not, upon inspection of the label or the monograph indexed in the NHPD database, be alerted to the fact that nosodes cannot be used effectively for this purpose.

### **The proposed directions for use put Canadians at risk of following inappropriate medical advice.**

The statement “Take/use as directed by a healthcare practitioner” reassures a patient that has been urged to use nosodes as vaccine substitutes by a healthcare provider that the advice they are receiving is likely to be sound. Nothing on the product label or the product monograph would alert them to the fact that the use of nosodes for vaccination is unsupported by science and not condoned by Health Canada.

### **The proposed risk information fails to caution the consumer against inappropriate use.**

While the proposed monographs provide for minimum acceptable dilutions, it fails to consider the risk to the consumer from using a product that is biologically inactive as medicine. Since nosodes are broadly promoted as effective vaccine substitutes, without a specific warning against the use of nosodes for vaccination or the prevention of disease, Health Canada cannot be reasonably assured that they will not be used for this purpose. Further, the legitimacy that the NHPD license confers on these products only increases the chances that Canadians will trust these products to work in the way that promoters claim.

### **The proposed monographs do not list nosodes as being contraindicated for use in children.**

Anti-vaccine messaging is largely targeted at parents during the time when they would be vaccinating their children and naturopaths and homeopaths are more likely to send this message (Busse, 2008, 2011, Downey, 2010, 4. Lehrke, 2001, Schmidt et al, 2002). Often parents want their children to be protected from infectious disease, but fear the risks they erroneously believe are associated with conventional vaccines. Homeopathic vaccination by using nosodes is marketed to these parents who may misinterpret NHPD licensing as approval for this use.

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### **The proposed minimum acceptable potencies may be inappropriate.**

In 2009 the World Health Organization published a technical document discussing safety issues in the preparation of homeopathic medicines. In it, they note that homeopathic nosodes preparations constitute potential safety hazards, even at high dilutions, due to the nature of the source materials. They also note key differences between homeopathic pharmacopoeia preparation standards that practically result in homeopathic potencies not being interchangeable (WHO, 2009). It is unclear whether the minimum acceptable potencies for nosodes take this into account.

### **The label does not reflect actual ingredients**

Adherence to the European Union standard of homeopathic preparation, specifically H.A.B. regulation 43 and 44, and the sterilization standards in the European Pharmacopoeia (H.A.B., 2005, Council of Europe, 2004), would ensure that, with good manufacturing procedures in place and high quality control, any original biological substance would be destroyed in the manufacture of the dilution. The use of ethyl alcohol would denature any proteins that would act as antibodies in solution, and subsequent sterilization would destroy any other biological substance. This ensures that the final dilution not only contains no original substance, but even if it did, it would not be recognizable as the original nosode. What this standard insures, therefore, is that the homeopathic nosode contains nothing. The registration, therefore, of a homeopathic nosode, assures the Canadian public that what they are buying does not contain what it says on the label.

### **Conclusion**

The above are specific concerns regarding the proposed pre-cleared product monographs for nosodes and combination nosodes and homeopathic medicines. In closing we would like to emphasize that the nature of nosodes demands a higher standard of safety than Health Canada currently applies to them. Indeed on page 4 of the WHO document they note the following:

“...because many homeopathic medicines can be purchased as non-prescription medicines in community pharmacies and health stores, without consultation with a healthcare provider, it has become increasingly important to provide sufficient and accessible information on such medicines. Although homeopathic medicines are generally assumed to be benign, the level of authorization, appropriate labeling and quality assurance should take into consideration its extensive use, also within vulnerable populations such as the elderly, pregnant women and children”.

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The use of homeopathic nosodes for vaccination and the prevention of disease is not supported by scientific evidence. They are extensively promoted and used for this purpose in Canada, especially for children, in a time when vaccination rates are falling and outbreaks of vaccine preventable diseases are increasing. Health Canada has failed to provide appropriate information regarding the nature of these products and appropriate and specific warnings against the use of nosodes for vaccination purposes while simultaneously allowing these products, through registration with the NHPD, to market themselves as “safe, effective and of high quality”. With the current standard, the HP number insures that not only is the product indicated for nothing, it also contains nothing: a bizarre standard indeed.

In light of this, we submit that homeopathic nosodes represent a direct risk to the health and safety of Canadians and we urge Health Canada to de-register all currently licensed nosodes and to issue no more licenses until the balance of evidence from peer-reviewed scientific research supports their efficacy and safety.

We appreciate the opportunity for comment and we look forward to hearing your response.

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