

Health Canada Natural and Non-Prescription Health Product Directorate (NNHPD) Draft Guidance Labeling Update

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Highlights

- Implementation of a Product Facts Table (PFT) for all NHPs, with some exemptions I'll mention later, to help consumers find important information and compare similar products
- New general legibility requirements, including dark print on light backgrounds (max 5% colour tint) and minimum font sizes and specific allowable font types
- Some limited flexibility for items in small packages or "very small packages" (defined as 77.5 cm² or less – that may translate to a bottle size of about 125cc, but certainly no more)

Highlights (continued)

- Allowance for innovative labels accessible at the point of purchase such as a peel backs, but excluding QR codes or other online links
- A manufacturer may display either an email address, telephone number or website instead of a postal address, as currently required
- Annex B: Single entity mineral supplements would require clarity about the form of the mineral as it affects potency (absorption characteristics)

Exemptions for a PFT

- Lowest Risk Products defined as cosmetic style topical products (sunscreen, lip products, etc.) and minor health benefit products (cough drops, oral rinses, toothpastes, aromatherapy)
- Products with 3 or fewer doses
- Products in very small packages as Health Canada defined
- For the latter two, the required info can be moved from the label to a tag or leaflet attached to the product, an insert, or a webpage, but otherwise must meet the font and contrast requirements

Concerns

- The impracticality of a multilingual PFT on limited label space
- Consumers don't seem to be asking for changes
- Data is limited showing this change will result in improvements for consumers
- The changes cause unnecessary costs (design, inventory management, etc.), a hardship for SMEs
- Environmental concerns of increased packaging to accommodate label requirements
- There are numerous other higher priorities for the NNHPD

Higher Priorities

- The proposed NPN appeal process as it is neither independent nor transparent, the benchmark the NNHPD identifies. However the proposal remains, an obtuse, insider process that is even more challenging for NHPs than for OTC products.
- Cost recovery is coming, but it is unclear to what extent it is. For example, will there be standard moderate fees, such as for a personal passport (not a bad thing), or will there be exorbitant fees? Will the fees be for product licensing, site licensing, 'right to sell' fees, or all of the above? We don't know.
- Other phases of the self-care framework such the phase II or III (product categorization and standards of evidence) will impact product approvals, both future and likely retroactively.

Higher Priorities (continued)

- The updates to monographs that are mentioned in sections of the consultation documents. NNHPD is indicating that they are going to review/update all monographs. Theoretically, if your product attests to a monograph, you cannot change/update a label until this work is complete. This will take time and will 'eat into' the six-year transition that is currently being consulted on.
- Compliance issues: from products not meeting the requirements (i.e. not licenced) and are being sold into Canada (either through ecommerce or other methods) to licenced products marketing outside of their market authorization, there are practices that industry is undertaking that impact business competitiveness and under mine the strength of the Canadian regulatory system.
- We should also keep an eye on site compliance and the pilot inspection program that was launched this year and the results from the findings. Previous site 'programs' have found a varying degree of compliance issues that have resulted in more government attention to the Site License process. It is likely that the site inspection program will become permanent – maybe not a bad thing (but could be impactful if standards/requirements are heightened). This is just another financial/business impact.