

NAPRA Policy for Natural Health Products

Updated February 2012

Intent

The intent of this policy is to clarify the status of natural health products (NHPs) with regard to NAPRA's National Drug Schedules (NDS).

Background

In May 1995, NAPRA endorsed a national drug scheduling (NDS) model to align the provincial drug schedules so that the conditions for the sale of drugs in pharmacies would be more consistent across Canada.

The model consists of three schedules or four categories for drugs: Schedule I, Schedule II, Schedule III and Unscheduled, with specific conditions for sale expected and corresponding to the level of professional intervention and advice necessary for the safe and effective use of these drugs by consumers. Standards of practice for pharmacists corresponding to the level of pharmacist intervention and advice necessary for the safe and effective use of these scheduled drugs were developed to support the NDS.

The NDS model was developed at the time when all drugs that received market authorization from Health Canada were regulated under the *Food and Drug Regulations*. When the *Natural Health Products Regulations* (NHPR) came into force in 2004, many products that were included in the NDS became reclassified as NHPs.

At the April 2006 NAPRA Board of Directors meeting, a decision was made that NHPs would not be considered for scheduling within the NDS. The principle rationale was that the requirements for obtaining market authorization for NHPs were based on a different paradigm than for traditional pharmaceuticals, and that the monitoring and enforcement of conditions for sale of NHPs were beyond the scope of pharmacy regulatory authorities.

At the April 2009 meeting, the Board decided to reexamine the 2006 policy for NHPs. In the interim, the Board agreed that NHPs currently listed in the NDS be maintained in the drug schedules. To facilitate the reexamination of the policy, an ad-hoc committee called the NHP Policy Working Group was struck within NAPRA.

The NHP policy was reexamined by the NAPRA Working Group at the request of the NAPRA Board of Directors. Following a fulsome review and deliberation of the Working Group's findings, the Board expressed their intention in 2011 to maintain the decision previously made which means that NHPs are outside the scope of the NDS.

Furthermore and following consultation with external stakeholders, NAPRA's Board of Directors decided to maintain, on an interim basis, NHPs currently listed in the NDS while discussions continue regarding a possible framework for determining the place and conditions of sale for NHPs.

NAPRA Policy for Natural Health Products

Updated February 2012

Policy

Natural health products (NHPs)¹ approved for sale under the *Natural Health Product Regulations*, are not considered products for scheduling within the National Drug Schedules (NDS). However, as an interim measure, NHPs currently listed on the NDS² will be maintained.

Updated policy approved by the NAPRA Board of Directors
November 5, 2011
Revised February 6, 2012

¹ NHPs are denoted with the following designations by Health Canada: Natural Product Number (NPN), Drug Identification Number-Homeopathic Medicine (DIN-HM) or an Exemption Number (EN).

² Exceptions will be made in situations where Health Canada removes naturally sourced medicinal ingredients from Schedule F of the *Food and Drug Regulations*.
