Under-Over into Fashion

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Sheer blouses worn over dark bras and low-waist garments revealing pierced navels, boxers and thong underwear, tummies, and more: the "under-over" fashion is really catching on — even at Health Canada!

In the 2002 Speech from the Throne, the Canadian government committed to "speed up the regulatory process for therapeutic product approvals to ensure that Canadians have faster access to the safe drugs they need, creating a better climate for research in pharmaceuticals." Who could oppose that commitment? It takes on average 2.2 years to launch a new therapeutic product in Canada, from first filing of an application anywhere in the world, but only 1.5 years in the United States and 1.9 years in the European Union. Recognizing the need for stakeholder engagement, Health Canada has held 7 days of consultation on improving Canada's regulatory process for therapeutic products since May 2003. The proceedings of the first 5 days are available on the Public Policy Forum Web site (http://www.ppforum.ca).

Eight issue clusters were hotly debated at the June 2003 multistakeholder sessions: safety, informed choice (consent), transparency and openness, accessibility, timeliness, collaboration, patient-centred system, and postmarket surveillance. The following key messages on safety, accessibility, and timeliness indicate that the goal of accelerating the regulatory process is not to be achieved at the expense of safety:

- Safety should be assessed on a harm–benefit index: some patients may be prepared to accept greater risk of harm given the irrevocable nature of their disease.
- An efficient process, keeping to predictable performance targets, is vital for timely access to therapeutic products, but rigorous review of submissions remains paramount.
- Timeliness means employing the required expertise, using resources wisely, and eliminating "dead time" in the system; regulatory reorganization should encompass the prioritization of reviews.

Another recurring theme was a desire for transparency throughout the regulatory process, from premarket submission, screening, review, and decision to postmarket surveillance. At the most recent consultation (June 10 and 11, 2004), Health Canada sought feedback on its Summary Basis of Decision (SBD), a first attempt at enhancing transparency. This document outlines the regulatory, safety, efficacy, and quality considerations that factor into a decision to grant market authorization for a drug or medical device. Templates have been tested, and pilot exercises can be viewed at http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_drugs_projects_e.html#sbd. However, the SBD may not add very much to the information already available to pharmacists in product monographs. Of note, the disclosure of negative outcomes or withdrawals (i.e., rejection of market authorization or submissions withdrawn by manufacturers before a decision by Health Canada) is not planned until phase 3 of the SBD implementation strategy, at an unspecified date.

A timid attempt at transparency, some would argue, and certainly nothing like the situation that led to Louisiana's bill banning low-slung pants that intentionally expose underwear — or more! Let's wait and see how much Health Canada will reveal in the future.

If you are interested in additional information about any of the aforementioned issues, please contact the CSHP national office (see page 201 for contact information).

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