Health Canada / Santé Canada

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Cost Recovery

Why is the Therapeutic Products Programme implementing cost recovery?

Treasury Board policy stipulates that companies which benefit directly from or cause government activity should bear some or all of the cost of those activities, rather than the taxpayer in general. Cost recovery is also intended to promote more business-like and equitable management of government programs. Most drug regulatory activities are caused by drug companies, wanting to place a product on the Canadian market and therefore, the activities of the Therapeutic Products Programme (TPP) are considered an appropriate candidate for cost recovery.

How are the fees determined?

The development of cost recovery fees is governed by Treasury Board policy. This policy requires that the full cost of services (direct and indirect) be recovered. Fees for services may be set lower than full cost only if the charging of full costs would interfere with achievement of program objectives or would result in undue adverse effect on the stakeholders. In contrast, fees for rights or privileges may be based either on the cost or the value of the right.

Phase I of the Therapeutic Products Programme Cost Recovery Initiative – the Authority to Sell Drugs Fee Regulations – introduced annual fees for the right or privilege to sell drugs, represented by the holding of a General Product (GP) or Drug Identification Number (DIN). The activities supported by these fees include all types of investigative activities conducted across the country, including those intended to ensure equitable enforcement of the Food and Drug Regulations; the Adverse Drug Reaction Programme; and all tracking and notification activities of TPP. The fee levels were set to recover somewhat less than the full cost of the activities involved. Consultation on this first phase of cost recovery was abbreviated relative to normal Therapeutic Products Programme practice, but met all requirements of the regulatory process.

Phase II of the Initiative saw the introduction of fees for the evaluation of human drug submissions on September 1, 1995.

What was the consultation process for Phase II?

Consultation on these fees was extensive despite the short time frame. In March 1995, TPP managers met with representatives of ten industry associations to explain why fees were necessary and the proposed approach. In April 1995, at a meeting with three associations, it was decided to follow three additional processes over the May-July period. The first was a workshop held in May 1995, to explain how activities had been costed and fees derived. The second focused on the application of Treasury Board's Business Impact Test (BIT) to the proposed drug evaluation fees proposal. The BIT was eventually completed by 47 firms covering all segments of the industry, plus seven industry associations. A report prepared from BIT responses was written and distributed to all participants. Secondly, the

issues identified through the BIT process, from responses to Canada Gazette, Part I, and from letters received throughout the consultation period were summarized into eight broad groupings. These issues and the BIT report then served as the focus for discussion at a workshop held in July 1995, attended by senior managers of TPP representatives of eight industry associations, and senior managers of firms belonging to them. The outcome from this workshop was specific recommendations to the TPP on how to address the issues, either in the final fee regulations published in Canada Gazette, Part II or soon thereafter.

Which recommendations from the consultation process have been incorporated into the revised regulations?

To the degree possible and subject to constraints within which the Programme must operate (including the time frame available and the revenue targets which the Programme must respect), the recommendations from the workshop were followed. The final fee regulations include:

- lower fees than those published in Canada Gazette, Part I;

- single fees for the complete review of each submission component (separate fees for the review of responses to Notice of Non-compliances (NONs) were eliminated);

- a provision to allow a firm to apply for a reduced fee based on anticipated sales (with later verification through the provision of authenticated sales records); and

- a provision for split payment of fees where total fees exceed $10,000, with 75% of the fee billed at the completion of review, moving to 25% one year after first implementation of evaluation fees. Fees under $10,000, or 25% (later 75%) of fees for submissions costing more than this amount, will be billed after the submission content has been assessed. Under the original proposal, the fee would have been required to accompany the submission.

How has the Therapeutic Products Programme addressed the linkage of fees to performance targets?

Internationally competitive drug submission review targets have been developed in consultation with stakeholders. A formal link between fees and review performance, recommended at the July 1995 workshop, was not included in the approved fee regulations. The practice of linking performance standards to user fees could have implications for other government activities. It was not possible to complete the necessary consultation with other government departments in the time available. However, it was agreed that the fee regulations would be amended to make this link as soon as possible after the government determines the best way to proceed. The result of the linkage would be lower fees if performance targets are not met.

What impact will this initiative have on the natural health products and complementary medicine industry?

A decision on whether a product is or is not a drug is largely based on the presence of therapeutic claims. Regulatory controls on drugs vary according to the health risks they pose. It should be noted that the health risks posed by substances falling within the categories of natural health products and complementary medicines are not necessarily low. For example, Vitamin A, at levels not much higher than recommended for dietary supplements, has now been associated with fetal abnormalities, and there are numerous examples of traditional herbal therapies which are inappropriate for uncontrolled use.

The basic regulatory requirements for all drugs, including natural health products and complementary medicines, where claims made bring them within the definition of a therapeutic product, now include the payment of fees to recover the costs of the activities of the TPP. The fee structures are designed to reflect the level of activity required for different classes of drug, and therefore lower risk products attract the lowest fees.

During consultation with industry representatives (including the Canadian Homeopathic Pharmaceutical Association and the Canadian Health Food Association) on fees for therapeutic product evaluation it was agreed that, in the interest of equality of treatment, cost recovery fees should apply to all products, with no exemptions because of the class of therapeutic product. However, as noted earlier in this document this consultation also resulted in the introduction of allowance for a reduction in fees where the anticipated sales of the product would be low.

Health Canada has for some time been engaged in regulatory reform. In addition to the Regulatory Review of several years ago, the Therapeutic Products Programme is currently developing a regulatory strategy for complementary medicines which will ensure that activities are focused on those areas of greatest risk to health and safety. Should the controls on natural health products and complementary medicines be found inappropriate, changes, including to cost recovery fees, will be made to reflect these decisions.