Management Response and Action Plan

Audit of Cost Recovery of Health Products

June 2015

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Recommendations	Management Response and Planned Management Action	Deliverables	Expected Completion Date	Responsibility
Recommendation 1 *It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, develop a formal process to analyze and benchmark year-over-year costs at the fee category level, to support management in determining the timing of user-fee renewal.*	Management agrees with the recommendation and will formalize its analysis process to further inform the timing of user-fee renewal.			
	Costs and revenues are reported annually in the Departmental Performance Report. Analyses of variances are also conducted annually. Health Canada committed in the Regulatory Impact Analysis Statement of the fee regulations that a review of the fees and costs would occur every three years and may propose new or amended fees to reflect the results of these reviews. The first Cost Recovery Review was published in October 2014, with the next review expected to be completed and published in 2017-18, including unit costs at the fee category level. Revising fees requires extensive consultation and tabling in Parliament, and generally takes two to four years to implement.	Develop consultation document on revised fees for drugs and medical device regulatory activities that includes: • Unit costs at the fee category level	June 30, 2016	Resource Management and Operations Division (RMOD)

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Recommendation 2 *It is recommended that Assistant Deputy Minister, Health Products and Food Branch, develop a permanent risk register to strengthen the management of issues that require longer-term solutions.*	Management agrees with the recommendation and will build a risk register for cost-recovery issues.			
	HPFB will develop a risk register, which will inform longer-term planning.	Develop a risk register for cost recovery	March 31, 2016	RMOD
Recommendation 3 *It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, modify the Establishment Licence renewal date in the* Food and Drug Regulations *so that the services can be provided in the year during which the revenues are collected.*	Management agrees with the recommendation and expects that moving the date will improve the predictability and availability of revenues to fund establishment licensing activities in the year when revenues are collected.			
	The current April 1st date in the *Food and Drug Regulations* for Establishment Licence renewals results in cash management challenges, as significant revenue arrives at the end of the fiscal year. HPFB will propose a date and initiate informal discussions with stakeholders. The process to revise regulations is complex and is dependent on departmental priorities.	Develop consultation document on revised fees for drugs and medical device regulatory activities that includes: • A revised renewal date for establishment licences.	June 30, 2016	RMOD/ Health Products and Food Branch (HPFB) Inspectorate

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Recommendation 4 *It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, develop and implement a risk assessment process to determine when audited financial information should be requested from applicants requesting a fee remission.*	Management agrees with the recommendation and that a risk assessment process would be appropriate to determine when to request audited sales records.			
	A significant number of companies and products apply and qualify for fee remissions based on small revenue streams, resulting in a significant impact on revenues available to Health Canada. The Minister has the authority to request audited sales records to substantiate a fee remission request. A strategy will be developed and a pilot project will be conducted, involving a small sample. Assessment of the findings and the pilot will inform the final strategy and process.	Develop a risk assessment process that includes appropriate criteria for requesting audited financial statements.	March 31, 2016	RMOD
		Conduct pilot project	June 30, 2016	RMOD

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Recommendation 5 *It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, review the Drug Establishment Licence (DEL) user-fee structure, to improve its alignment with the associated costing model, so that DEL user fees can be clearly identified and explained.*	Management agrees with the recommendation and will review and address the complexity of the DEL fee structure, which has multiple components dependent on, for example, activity, drug category and dosage form.			
	The revenue from the DEL fees supports the delivery of the national compliance and enforcement program, including good manufacturing practices inspections; it is not a fee-for-service. The fee will be restructured to more accurately reflect the level of effort for the different licensable activities. Revising fees requires extensive consultation and tabling in Parliament, and generally takes two to four years to implement.	Develop consultation document on revised fees for drugs and medical device regulatory activities that includes: • Revised drug establishment licence fee structure.	June 30, 2016	RMOD

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Recommendation 6 *It is recommended that the Assistant Deputy Minister, Health Products and Food Branch, establish a process whereby the activities of screening and first review of Class III and IV medical device applications are clearly separated.*	Management agrees with the recommendation. To reduce any misperceptions, HPFB agrees that a clear separation of responsibilities for screening and review may strengthen the integrity of the process.			
	The screening of an application is intended to identify if the application is administratively and technically acceptable. A screening pilot is currently underway to determine the viability of completing initial screening completely within the Device Licencing Services Division, rather than having some of the technical screening completed within the review areas.	Assess the feasibility of revising screening process	March 31, 2016	Therapeutic Products Directorate