Audit of the Biologics and Radiopharmaceutical Drugs Program at Health Canada

Management Response and Action Plan

June 2018

Presented to HC Departmental Audit Committee on June 20, 2018

Recommendations	Management Response and Planned Management Action	Deliverables	Completion Date *	Accountability / Responsibility
Recommendation 1 The Assistant Deputy Minister, Health Products and Food Branch, should re-assess the risks associated with the current monitoring strategy of only assessing the initial reports related to certain types of Adverse Reactions and amend the strategy and methodology accordingly.	Management agrees with this recommendation.			
	Management agrees with this recommendation, and notes that work on this area is already underway. In an effort to protect Canadians from the residual risk associated with drugs approved for use in Canada, Health Canada monitors adverse reaction (ARs) reports that are received via Market Authorization Holders (required) and by Canadians directly (voluntary). Mandatory reporting of such reactions by hospitals is being proposed under Vanessa's Law, and is scheduled to begin in late 2019. Furthermore, Health Canada receives information not only on	1.1 Assessment of current processes which outlines areas for improvement.	November 2018	Director General, Marketed Health Products Directorate
		1.2 Action Plan to address the areas for improvement identified in the Assessment.	January 2019	

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	domestic ARs, but also international data for products that are also on the Canadian market. Together, this data forms a rich source of information from which to identify potential safety concerns for health products used by Canadians. There is room to optimize both the analysis of the individual reports when they are received, and the analysis of the full dataset for signals. Given this, Health Canada is reviewing current processes, modifying and updating processes accordingly, and developing IT infrastructure to optimize our ability to identify ('data mining') and act on safety signals in a timely fashion.	1.3 Procurement plan for a data mining tool to optimize signal detection.	January 2019	
Recommendation 2 The Assistant Deputy Minister, Health Products and Food Branch, should develop a systematic risk-based approach and associated standard operating procedures for the activities to be	Management agrees with this recommendation.			
	Management agrees with the recommendation and will develop an approach and associated standard operating procedure to address Adverse Reactions reported during clinical trials.	2.1 Record of results of the consultation.	July 2018	Director General, Biologics and Genetic Therapies Directorate

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undertaken and documented by the Branch related to Adverse Reactions reported during clinical trials.	Consultations with program partners will inform the development and implementation of a harmonized, systematic, risk-based approach for the review of Adverse Reactions reported during clinical trials. Based on the results of the consultation, a standard operating procedure for this activity will be developed.	2.2 Develop and approve "Monitoring the safety and data during clinical trials" standard operating procedure.	November 2018	
Recommendation 3 The Assistant Deputy Minister, Health Products and Food Branch, should ensure a data tracking system be implemented to record, track and follow-up on all signals and potential signal files that are at various stages in the signal lifecycle (identification, prioritization, assessment, follow-up).	Management agrees with this recommendation.			
	When a potential safety or effectiveness signal for a health product on the Canadian market is identified, that potential signal goes through a rigorous process to determine if the signal requires review, and if yes, how to prioritize that review based on risk to Canadians.	3.1 Business requirements document for a tracking system.	October 2018	Director General, Marketed Health Products Directorate

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	In an effort to respect the Government's commitment to openness and transparency, Health Canada publishes, monthly, a list of the signals currently being routed through this signal detection life cycle. There is room to improve and simplify the current practice across the Directorate by developing a single, comprehensive approach to documenting and monitoring progress on signals and their review. In this way, Health Canada will be well positioned to address any questions related to the status of potential signals, and to share the progress against our reviews openly and transparently.	3.2 Tracking system implemented. *Note, this project can be accomplished using existing IT solutions in the Directorate. No new IP project will be needed.	March 2019	