



EUROPEAN MEDICINES AGENCY
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Health Canada and European Medicines Agency: update on activities in 2014

Beyond the interactions through topic-based expert 'clusters' and the 15 or so exchanges of information each month, the two agencies have deepened their relationship in a number of key strategic areas; in particular pharmacovigilance, development of medicines for children and patient involvement in orphan medicines.

As part of efforts to strengthen cooperation in the area of pharmacovigilance, Dr Chris Turner from Health Canada has spent two years as a visiting national expert at the Agency from January 2012 to December 2014. In addition to being an effective liaison between the two agencies, Dr Turner has increased awareness of the operations and the detailed pharmacovigilance activities of each agency, and strengthened the bilateral relationship. The Agency benefited from his presence for the preparation of the first year report to the European Commission on the Agency's implementation of the pharmacovigilance tasks following implementation of the new EU pharmacovigilance legislation, advice on continuous improvement for business operations, development of pharmacovigilance performance indicators and methods for reporting on the impact of pharmacovigilance.

A similar exchange of expertise was seen in the participation by Dr Agnès Saint Raymond from EMA in the Council of Canadian Academies' study on developing medicines for paediatric use. The report, entitled 'Improving Medicines for Children in Canada':

http://www.scienceadvice.ca/uploads/eng/assessments%20and%20publications%20and%20news%20releases/therapeutics/therapeutics_fullreporten.pdf, was commissioned by Health Canada and published in September 2014. It was compiled by a 14-member panel of national and international experts with backgrounds in academia, the pharmaceutical industry, regulatory science, and clinical and medical fields. Over a 14 month period, Dr Saint Raymond was able to contribute her experience in paediatric medicine from a clinical and regulatory perspective. While focusing on the Canadian situation, the report highlights some best practices and key findings that face regulators worldwide. The final report is intended for policy makers to better support the use of validated, age-appropriate therapies, as well as to stimulate further essential research for paediatric populations.

Other recent examples of the two agencies sharing their experience include the contribution by the EMA to the ongoing development of Health Canada's Orphan Drug Framework, in particular with regard to patient involvement in the product review process. In addition to ad hoc exchanges on labelling issues, the EMA has also participated as part of the expert advisory panel to the ISMP Canada/Health Canada Labelling and Packaging Project and contributed to the draft Good Label and Package Practices Guide.

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