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Health Canada's exploration of the use of European Directorate for the Quality of Medicines (EDQM) Certificates of Suitability (CEP)

The Therapeutic Products Directorate (TPD) of Health Canada is undertaking a project to explore the official and systematic use of Certificates of Suitability (CEP) issued by the European Directorate for the Quality of Medicines (EDQM).

The monographs of the European Pharmacopoeia are a collection of standardized specifications that define the quality of pharmaceutical preparation, their constituents or their containers. The EDQM issues a CEP which confirms that the monograph of the European Pharmacopoeia, in some cases with the addition of specific tests, is suitable for control of materials from a given source. By demonstrating that they have been granted a CEP for their substance, suppliers of raw materials can provide evidence of this suitability to their pharmaceutical industry clients and/or the licensing authorities.

TPD is undertaking this initiative to examine options that will provide for a more efficient review process and more optimal use of resources. Further detail on the nature and scope of the project and proposed options for the use of the CEP in Canada will be communicated as the project progresses.

CONTACT:

Cathy McEnaney
International Programs Division
Therapeutic Products Directorate
HEALTH CANADA
Cathy_McEnaney@hc-sc.gc.ca