Canadian Regulatory Perspective on Subsequent-Entry Biologics (Biosimilars)

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Health Canada has maintained an approach that regulatory decisions regarding the quality, safety and efficacy of medicinal products should be based on scientific evidence and accepts that copies of biologics originally licensed by innovator companies will have a role in health care. Such products should not be considered as generics; however, information in the public domain regarding safety and efficacy of an innovator product over many years of use can be considered relevant if suitable data is provided demonstrating comparability/similarity to that specific reference product. Health Canada is in the process of developing a formal regulatory process for subsequent-entry biologics (biosimilars, follow-on protein products). Various challenges to the industry and to regulators will be discussed.