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UK/Canada Deal Lets Drug Agencies Avoid Brexit-Related Trade Disruption

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An interim trade deal between the UK and Canada means that the regulators in these countries will carry on accepting each other's batch testing and GMP certificates.

UK and Canadian medicines regulators have agreed to continue recognizing each other's certificates on batch testing and good manufacturing practice (GMP) on a temporary basis now that the Canada-EU Comprehensive Economic and Trade Agreement (CETA) no longer includes the UK.

The <u>move</u>, designed to avoid any disruption in trade following the UK's departure from the EU on 1 January, is part of an interim Canada-United Kingdom Trade Continuity Agreement (Canada-UK TCA) that the governments of both countries signed last December. Domestic ratification procedures are underway in the UK and Canada to put a comprehensive free trade agreement in place.

The UK regulator, the MHRA, this week said it had jointly agreed with Health Canada's Regulatory Operations and Enforcement Branch on an interim arrangement for continued cooperation on the application of the CETA protocol on pharmaceuticals.

"Specifically, for stakeholders this means that Canada and the UK will continue to recognize certificates of GMP compliance issued by each country's regulatory agencies and to accept batch testing certificates held by a manufacturer without re-control of that batch at import."

No UK-EU Deal On Batch Testing

The life sciences industry in the UK had been pressing for the mutual recognition of batch testing between the UK and the EU, and was disappointed when no such agreement was included in the trade and cooperation deal agreed by the two parties and implemented on 1 January. The UK BioIndustry Association says it will continue to press for some sort of agreement on batch

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testing. (Also see "*UK BIA To Push For Post-Brexit Regulatory Agreement With EU*" - Pink Sheet, 7 Jan, 2021.)