Medicines & Healthcare products Regulatory Agency

Department of Health
An Roinn Sláinte
Männystrie O Poustie
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23rd July 2021

Dear Colleague,

USE OF EUROPEAN MEDICINES AGENCY (EMA) AUTHORISED MEDICINES IN NORTHERN IRELAND

The Department of Health NI and Medicines and Healthcare products Regulatory Agency (MHRA) recently became aware that certain amendments to the Human Medicines Regulations 2012 (HMRs) are inadvertently ineffective in Northern Ireland due to a drafting error in the amending legislation.

The HMRs are the primary instruments which govern the sale, supply, possession, manufacture, distribution and licensing of medicines throughout the UK. The practical effect of this drafting anomaly is that certain provisions of the HMRs, including in particular elements of regulations 3, 3A and 4, do not currently have effect in Northern Ireland.

As a result of the drafting anomaly a healthcare professional in Northern Ireland who assembles or prepares a European Medicines Agency (EMA) authorised medicine for supply to a patient would theoretically, inadvertently be acting outside the legal framework, and such acts would give rise to a technical breach of the HMRs.

The COVID-19 vaccines are not within the scope of this error and would not give rise to a technical breach.

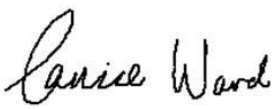
In Northern Ireland the Department of Health's Medicines Regulatory Group (MRG) is the enforcement authority responsible for ensuring compliance with the various provisions contained within the HMRs. The MRG has been in discussion with MHRA and it is jointly agreed that no regulatory action be taken against any healthcare professional in Northern Ireland in relation to any such technical breaches of the HMRs.

The public interest is best met by prompt access of Northern Ireland patients to safe, effective, high quality medicines that are authorised in accordance with the EU regulatory procedures. No healthcare professionals acting in accordance with their professional obligations to ensure that patients access these important medicines should be concerned that they are potentially at risk of regulatory action, whilst this anomaly is addressed. We are confident that there is no risk to patient health as a result of the anomaly.

Please be assured that prompt action has been taken to amend the legislation and the necessary corrections will come into force on 3 August 2021. In the meantime, any enquiries can be raised by contacting the MHRA at:

Email: info@mhra.gov.uk

Yours sincerely,



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