



Department of
**Health, Social Services
and Public Safety**

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AN ROINN

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agus Sábháilteachta Poiblí**

MÁNNYSTRIE O

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Dear Colleagues

THE MEDICINES FOR HUMAN USE (PRESCRIBING) (MISCELLANEOUS AMENDMENTS) ORDER 2009 SI 2009 NO. 1165

THE MEDICINES FOR HUMAN USE (MISCELLANEOUS AMENDMENTS) REGULATIONS 2009 SI NO. 1164

Recent legislation has brought about changes in the way some medicines can be sold or supplied. The amendments affect emergency supplies of medicines to patients, certain aspects of the sale and supply of medicines relating to pandemic circumstances, and provide for arrangements for wholesale distribution, in certain circumstances, of medicines that are not authorised for use in UK.

Some of these changes are in operation from 8th May 2009 and are permanent – see bullet point 1. Other changes are contingent upon a Ministerial announcement that a pandemic disease is occurring, or announcing that it is anticipated to be imminently pandemic, and that it is a serious risk or potentially a serious risk to human health. This Ministerial announcement is different from any declaration that the World Health Organisation may make about the phase or progression of pandemic disease. The changes triggered by the Ministerial announcement will be temporary – see bullet point 2. A further change, although temporary, described in bullet point 3, is currently operating. This relates to unlicensed oseltamivir powder and solution.

Not all of the amendments described are relevant to community pharmacy, but are included for completeness. At the time of writing (with the exception of the matter relating to oseltamivir in bullet point 3), **no** Ministerial announcement has been made

that the circumstances exist for triggering the arrangements that will come into operation for pandemic disease or its anticipation.

1 Permanent changes

Emergency supplies of prescription only medicines at the request of a patient

From 8th May 2009, pharmacists may make an emergency supply of some prescription only medicines at the request of a patient for up to 30 days treatment. As before, the medicine requested must have been prescribed on a previous occasion by a specified type of practitioner. These practitioners now include dentists. Schedule 1, 2 and 3 controlled drugs (with the exception of phenobarbitone for the treatment of epilepsy) are excluded from the arrangements for emergency supply. For Schedule 4 and 5 controlled drugs, and phenobarbitone for treatment of epilepsy, as before, an emergency supply may be made for up to 5 days treatment.

Emergency supplies of prescription only medicines at the request of a practitioner

Pharmacists continue to be permitted to make an emergency supply at the request of specified types of practitioners who are unable to immediately provide a prescription. Dentists are now included among these practitioners. Schedule 1, 2 and 3 controlled drugs are still excluded from the arrangements, with the exception of phenobarbitone for the treatment of epilepsy. As before, there is no restriction placed on the quantity of medicine that can be requested by a practitioner.

2 Temporary changes to medicines legislation that will be triggered by a Ministerial announcement (Note: the provisions described below are not currently operating since, at the time of writing, no announcement has been made. You will be informed when these provisions become active.)

Emergency supplies of prescription only medicines at the request of a patient

In the event of a Ministerial announcement that a pandemic is occurring, or is imminent, rather than having to personally interview a patient requesting an emergency supply of a prescription only medicine, the pharmacist will only have to satisfy himself:

- i) that the medicine has on a previous occasion been prescribed for the patient by one of the specified types of practitioners and
- ii) as to the dose which in the circumstances it would be appropriate for the person to take.

Exemption, in pandemic circumstances, from certain requirements for the sale and supply of medicinal products

In the event of a Ministerial announcement that a pandemic is occurring, or is imminent, medicinal products will be able to be supplied in accordance with protocols, approved by specified bodies, which contain certain criteria about symptoms, treatment and records, as stated in the amended Prescription Only Medicines Order 1997. The arrangements also provide for supplies to be made from premises that are not registered as pharmacies.

Removal, in pandemic circumstances, of certain labelling requirements for antiviral solutions for treating children under one year old

In the event of a Ministerial announcement that a pandemic is occurring, or is imminent, normal labelling requirements will be suspended for antiviral solutions used for the treatment of children under one year of age. Instead of the disapplied requirements, the container of the medicine will need to be labelled to show only the name of the child to be treated, the date on which the medicine was dispensed and the necessary and usual instructions for proper use.

Clinical Trials

In the event of a Ministerial announcement that a pandemic is occurring, or is imminent an amendment has been made to allow for notice of urgent safety measures (taken in order to protect the subjects of a clinical trial) to be given as soon as possible to the licensing authority and an ethics committee established under the Regulations during a period in which a disease is pandemic and is a serious risk to human health or potentially a serious risk to human health.

3. Temporary change in operation

Wholesale distribution of unauthorised medicinal products

An amendment enables the wholesale distribution of unauthorised medicinal products in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation which could cause harm. Such distribution will be temporarily authorised by the Secretary of State.

On 8th May 2009 the MHRA announced that, in response to the confirmed spread of influenza virus, the Secretary of State for Health has temporarily authorised the distribution of unlicensed oseltamivir powder and an unlicensed oral liquid formulation of oseltamivir for administration to infants under 1 year of age in the prevention or treatment of influenza.

Further information may be obtained from the Department's web-site www.dhsspsni.gov.uk in the pandemic flu section.

Future letters from Pharmaceutical Advice and Services may only be published on the web-site.

Yours sincerely



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