

Explanatory Memorandum to the National Health Service (Charges) (Amendments Relating to Pandemic Influenza) (Wales) Regulations 2009

This Explanatory Memorandum has been prepared by the Department for Health and Social Services and is laid before the National Assembly for Wales in accordance with Standing Order 24.1.

Description

These Regulations make changes to the National Health Service (Free Prescriptions and Charges for Drugs and Appliances) (Wales) Regulations 2007 and the National Health Service (Charges to Overseas Visitors) Regulations 1989.

They apply to the supply of prescription only medicines where there is a pandemic, or anticipated pandemic disease, which poses a serious or potential serious threat to human health. They will ensure that the supply of anti-viral drugs to enable the provision of treatment in relation to pandemic influenza is to be without charge. They need to be made as a result of changes made by the Medicines for Human Use (Prescribing) (Miscellaneous Amendments) Order 2009 ("2009 Order") to the Prescription Only Medicine (Human Use) Order 1997 and the Medicines (Pharmacy and General Sale – Exemption) Order 1980 which will implement in Wales an exemption for the provision of flu anti-viral drugs from the requirements under section 58(2) of the Medicines Act 1968, and therefore enable them to be supplied without prescription. The power to prescribe exemptions to section 58 of the Medicines Act is not devolved to the Welsh Ministers and the 2009 Order is to be made on a UK wide basis by the Secretary of State.

Matters of special interest to the Subordinate Legislation Committee

The Regulations are required to come into force on 8 May 2009. In order to ensure that drugs provided other than by way of prescriptions are provided free of charge and to ensure that persons supplying or administering those drugs do not otherwise breach statutory requirements to recover charges for such drugs. Whilst charges must not be levied for drugs provided under prescription or at hospital as part of medical treatment, charges generally need to be levied when drugs are provided by other means. The Regulations will ensure parity with the charging regimes in England for the supply of drugs in the event of an influenza pandemic, it is considered necessary to breach the convention that they should be laid before the Assembly for 21 days before coming into force. Similar Regulations are also urgently being considered in Scotland. The Counsel General and Leader of the House has written to the Presiding Officer notifying him of the breach.

Legislative Background

Sections 121 (charges for drugs, medicines or appliances or pharmaceutical services), 124 (charges in respect of non-residents) and section 203(9) (orders, regulations and directions) of the National Health Service (Wales) Act 2006 enable the Welsh Ministers to make Regulations that deal with the

payment of and the remission of certain NHS Charges. This instrument follows the negative resolution procedure..

Purpose and intended effect of the legislation

These Regulations will disapply in Wales the requirement to recover charges from persons supplied with anti-viral drugs under any arrangements to distribute and supply antivirals without prescription.

The Regulations also ensure that overseas visitors will not be required to pay for treatment they receive for pandemic influenza. This reflects the position in England.

Implementation

The risk of not implementing the legislation at this time would be a less coordinated UK response and may disadvantage patients in Wales. It could also have the unintended effect of placing persons supplying and administering antivirals in Wales in breach of statutory requirements to recover charges from persons supplied with such drugs.

Consultation

There has been no consultation with stakeholders due to the tight timeframe and because these are technical changes to the Regulations.

Regulatory Impact Assessment

A Regulatory Impact Assessment has not been prepared for this instrument due to the tight timeframe and given the fact that no impact is foreseen on the voluntary or private sectors.