

Explanatory Memorandum to the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) (Amendment) Regulations 2014

This Explanatory Memorandum has been prepared by the Welsh Government's Department for Health, Social Services and Children and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) (Amendment) Regulations 2014, I am satisfied that the benefits outweigh any costs.

Mark Drakeford AM

Minister for Health and Social Services, one of the Welsh Ministers
20 January 2014

1. Description

These Regulations amend The *National Health Service (General Medical Services Contracts) (Prescription of Drugs Etc.) (Wales) Regulations 2004* (“the 2004 Regulations”) in respect of the circumstances in which a provider of general medical services may prescribe drugs for erectile dysfunction and for other conditions for which those drugs are also licensed.

2. Matters of special interest to the Constitutional and Legislative Affairs Committee

A shortened and specific consultation exercise with relevant representative interests was conducted from 16 October to 15 November 2013 because this instrument makes a technical change which clarifies the intention in the Regulations; it does not alter the policy. In addition, it is considered that the proposed changes need to be introduced as soon as possible in order to resolve the current legal uncertainty in the Regulations both for manufacturers and prescribers of the relevant ED treatments and to ensure continuity of patient care.

3. Legislative Background

The 2004 regulations and the amendments to these regulations are made using powers conferred by sections 46(2), 203 (9) and (10) of the *National Health Service (Wales) Act 2006*. These powers are exercisable by the Welsh Ministers.

4. Purpose and intended effect of the legislation

There is some legal uncertainty relating to the operation of the 2004 Regulations. The 2004 Regulations currently restrict NHS prescribing of drugs for the treatment of erectile dysfunction (ED) other than in specified circumstances. Since the 2004 Regulations were introduced, some drugs for the treatment of ED listed in Schedule 2 to the 2004 Regulations have received further marketing authorisations for the treatment of medical conditions other than those specified in Schedule 2. The 2004 Regulations prohibit those drugs from being prescribed for the treatment of these alternative medical conditions. This is not consistent with the original policy intention which had been only to restrict the prescribing of treatments for erectile dysfunction. At that time it had not been foreseen that these treatments would have alternative medical indications. The proposed changes to be made by the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) (Wales) (Amendment) Regulations 2014, clarify the position regarding the availability of the drugs for the treatment of ED specified in Schedule 2 to the 2004 Regulations when they are prescribed on the NHS for the treatment of other medical conditions.

These Regulations will ensure treatments for benign prostatic hyperplasia and pulmonary arterial hypertension can be prescribed by providers of general medical services for NHS patients. These Regulations will allow these drugs to be prescribed for other conditions provided that the manufacturer holds a UK or EU marketing authorisation for the drug for the treatment of those conditions. These Regulations will continue to restrict the prescribing of drugs for the treatment of ED for conditions other than those for which the manufacturer holds a UK or EU marketing authorisation.

5. Consultation

These Regulations have been subject to a four week consultation with the following representative interests:

- All Wales Prescribing Advisory Group
- Association of the British Pharmaceutical Industry (Wales)
- Board of Community Health Councils
- Community Pharmacy Wales
- General Practitioners Committee (Wales)
- Local Health Boards
- Royal College of General Practitioners
- Royal Pharmaceutical Society

Reponses were received from Hywel Dda, Betsi Cadwaladr University, Aneurin Bevan and Cardiff and Vale University Health Boards and the Royal College of General Practitioners, all of which agreed with the proposed changes. No other responses were received.

6. Regulatory Impact Assessment

The Welsh Ministers' Code of Practice on the carrying out of Regulatory Impact Assessments was considered in relation to these Regulations. As a result, it was not considered necessary to carry out a regulatory impact assessment as to the likely costs and benefits of complying with these Regulations.