

Explanatory Memorandum to The National Health Service (Pharmaceutical Services) (Wales) (Amendment) Regulations 2022

This Explanatory Memorandum has been prepared by the Primary Care and Mental Health Division within the Department for Health and Social Services and is laid before Senedd Cymru 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 (Pharmaceutical Services) (Wales) (Amendment) Regulations 2022.

Eluned Morgan MS
Minister for Health and Social Services
13 December 2022

1. Description

These regulations amend the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020 (“the 2020 Regulations”) which govern the provision of pharmaceutical services as part of the National Health Service in Wales.

The amendments require the Welsh Ministers to ensure that, where coronavirus vaccines and antiviral medicines, and influenza vaccines, are centrally purchased by Government (Welsh Ministers, Secretary of State) and provided to community pharmacies free of charge for use in NHS programmes, no remuneration (or only nominal remuneration) will be payable to them for those products, if certain conditions are met.

2. Matters of special interest to the Legislation, Justice and Constitution Committee

None.

3. Legislative background

The 2020 Regulations govern the provision of pharmaceutical services as part of the National Health Service in Wales under Part 7 of the National Health Service (Wales) Act 2006 (“2006 Act”).

The scheme for paying for pharmaceutical and local pharmaceutical services in Part 7 of the 2006 Act is predicated on the basis that the determining authorities for pharmaceutical remuneration will ordinarily include, in the payments for those services, an amount which is in respect of (but ordinarily slightly more than) the price paid by service providers when they purchased the prescription items that they supply or administer to NHS patients. However, there are powers in section 88 of the 2006 Act which enable alternatives to these ordinary remuneration arrangements in some circumstances. These regulations are made in the exercise of those powers in section 88 of the 2006 Act.

Section 88 of the 2006 Act was amended by section 2 of the Health Service Medical Supplies (Costs) Act 2017 which made statutory provision to expressly enable zero remuneration in relation to “special medicinal products” when supplied centrally and free of charge.

That amendment was commenced by the Health Service Medical Supplies (Costs) Act 2017 (Commencement No.1) (Wales) Order 2022 on 21 November 2022.

Section 88 was further amended by section 161(2)(a) of the Health and Care Act 2022 to extend the scope of that exemption to also expressly enable zero (or nominal) remuneration in respect of the following when supplied centrally and free of charge:

- a) vaccines and immunisations,
- b) other drugs or medicines used to prevent or treat pandemic diseases (or potential pandemic diseases), i.e. antiviral medicines, and
- c) associated products.

Those further amendments were commenced by the Health and Care Act 2022 (Commencement No. 1) (Wales) Regulations 2022 on 22 November 2022.

The Regulations are subject to the negative procedure.

4. Purpose and intended effect of the legislation

Coronavirus vaccines and antiviral medicines (used in the treatment of coronavirus) are currently procured centrally by Government and supplied to community pharmacies free of charge for use in NHS programmes. Community pharmacies are paid for the services they provide in administering those medicinal products but are not remunerated for purchasing them (because they were provided for free). No changes are currently proposed to those arrangements.

The purpose of the regulations, and the previous amendment to the 2006 Act made by the Health and Care Act 2022, is to remove any uncertainty and to put beyond doubt the basis of the remuneration arrangements for coronavirus vaccines [and antiviral medicines] that are purchased centrally and supplied free of charge to community pharmacies.

Influenza, like coronavirus, may be a pandemic disease. It is combatted by similar means through vaccination and antiviral medicines. Influenza vaccines may be centrally purchased by Government and supplied to community pharmacies free of charge. The regulations support a similar arrangement to that described above by expressly enabling zero (or nominal) remuneration for influenza vaccines that a pharmacy had received free of charge from centrally purchased stock.

5. Consultation

No formal consultation has taken place as these regulations make only technical amendments which do not alter existing policy arrangements.

6. Regulatory Impact Assessment

No Regulatory Impact Assessment has been produced to accompany these regulations as the amendments are technical and will have no major policy impact. This is in line with the policy set out in the Welsh Ministers' RIA Code for subordinate legislation.