

**EXPLANATORY MEMORANDUM TO
THE HEALTH PROTECTION (VACCINATION) REGULATIONS 2009**

2009 No. 38

1. This explanatory memorandum has been prepared by the Department of Health (“the Department”) and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 These Regulations place an obligation on the Secretary of State to accept certain recommendations of the Joint Committee for Vaccination and Immunisation (JCVI) regarding national vaccination programmes, and make arrangements for such programmes to be implemented

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 This is the first use of powers inserted in the Public Health (Control of Diseases) Act 1984 by section 129 of the Health and Social Care Act 2008.

4.2 There have been no relevant undertakings or commitments made to the House.

5. Territorial Extent and Application

5.1 This instrument applies to England.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- What is being done and why

7.1 Previously, no legal right has existed by which individuals could ensure that they received the vaccinations recommended for them by the Joint

Committee on Vaccination and Immunisation (JCVI)¹ under a national vaccination programme. Up until now, it has been within the Secretary of State's discretion whether to accept or reject the JCVI's recommendations (although in practice he has always accepted them). This contrasted unfavourably with the position in relation to NICE approved drugs in respect of which there is a legally enforceable right².

7.2 These regulations address that disparity. They oblige the Secretary of State to make arrangements to ensure that JCVI recommendations for new national vaccination programmes, or for changes to existing programmes, are implemented where those recommendations meet certain qualifying conditions. The conditions include that the recommendation must be shown to be cost effective.

7.3 Placing such an obligation on the Secretary of State creates a legally enforceable right by which individuals can ensure that they get the vaccination recommended for them under a national programme by the JCVI. This will bring the status of vaccines closer to that of NICE recommended drugs.

7.4 The first "arrangement" that the Secretary of State will make under his new duty will be to direct Primary Care Trusts to ensure that all individuals in its area who meet the criteria under a JCVI recommendation are offered the opportunity to be vaccinated in accordance with the recommendation. A copy of the draft Directions can be found at Appendix AA.

8. Consultation outcome

8.1 These regulations have been made in response to comments made earlier this year during the consultation on the draft NHS Constitution.

The draft NHS constitution was published on 30 June 2008 and underwent an immediate twelve week public consultation. The draft constitution included a pledge that "*The NHS will strive always to provide vaccination and screening programmes as recommended by the appropriate national advisory bodies*". The draft NHS constitution also contained a commitment on drugs: "*You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you*". There were few responses that mentioned the vaccination pledge. However, of those that did respondents felt that the vaccine pledge should be upgraded to a right.

The Department has acted on the views of the respondents and the constitution, to be published on 13 January 2009, will contain a right to

¹ The JCVI is a statutory advisory committee. It advises the Secretary of State for Health on matters relating to communicable diseases, preventable and potentially preventable, through immunisation.

² The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. Individuals have an enforceable legal right to NICE approved drugs as primary care trusts (PCTs) are legally obliged by directions from the Secretary of State to fund NICE recommended drugs.

vaccination: “*You have the right to receive the vaccinations that the Joint Committee on Vaccination and Immunisation recommend that you should receive under an NHS provided national immunisation programme.*”

The regulations provide the legal underpinning of the right to vaccinations included in the NHS Constitution. . As the policy has already been consulted on as part of the NHS constitution consultation, and the regulations are being drafted in response to the views of respondents, no further consultation has been carried out.

9. Guidance

9.1 The NHS constitution handbook will provide additional information on the vaccination right and the source of this right – i.e. the regulations and accompanying directions. The JCVI Terms of Reference and Code of Conduct will be amended to reflect the new regulations. Information on the regulations, directions and amended terms of reference will be placed on the immunisation website³, and health professionals will be informed through the monthly newsletter “*Vaccine Update*”.

10. Impact

10.1 The impact on business, charities or voluntary bodies is zero.

10.2 The impact on the public sector is zero until a new JCVI recommendation is made. The implementation of any JCVI recommendation for a new national vaccination programme or amendment to an existing national vaccination programme will be accompanied by an Impact Assessment.

10.3 An Impact Assessment has not been prepared for this instrument.

11. Regulating small business

11.1 The legislation does not apply to small business.

12. Monitoring & review

12.1 The Secretary of State will need to ask the JCVI to consider issues relating to the introduction of national vaccination programmes or amendments to existing programmes. When new recommendations are made in response to these requests the Secretary of State will be obliged to implement them.

13. Contact

Ray Smith at the Department of Health Tel: 02079724460 or email: Ray.Smith@Dh.gsi.gov.uk can answer any queries regarding the instrument.