EXPLANATORY MEMORANDUM TO

THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL AND LOCAL PHARMACEUTICAL SERVICES) (AMENDMENT) REGULATIONS 2017

2017 No. 709

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 These Regulations make an amendment to the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 ("the 2013 Regulations"). The 2013 Regulations govern the arrangements in England for the provision of NHS community pharmaceutical services, such as the dispensing of NHS prescriptions. Regulation 121 of the 2013 Regulations provides for reviews of the 2013 Regulations to be undertaken and for the conclusions of the reviews to be set out in reports (within five years of the preceding report). The first such report was due to be published before the end of 31st August 2017 but this deadline is being put back to 31st March 2018.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Other matters of interest to the House of Commons

3.2 As this instrument is subject to the negative procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

4. Legislative Context

- 4.1 The 2013 Regulations carried forward changes to the legal framework and the terms of service introduced by the National Health Service (Pharmaceutical Services) Regulations 2012 (S.I. 2012/1909, as amended) ("the 2012 Regulations"), in force from 1st September 2012, and amalgamated these with the National Health Service (Local Pharmaceutical Services) Regulations 2006 (S.I. 2006/552, as amended), to ensure both were fit for purpose in the new NHS architecture in place in England from 1st April 2013.
- 4.2 NHS community pharmaceutical services in England are provided on the basis of four sets of standard arrangements with the NHS. All of these sets of arrangements are governed by the 2013 Regulations. Arrangements with retail pharmacy businesses are made on the basis of either entry on approved lists (known as pharmaceutical lists) or much less often on the basis of a contract for "local pharmaceutical services". Arrangements with dispensing appliance contractors are made on the basis of entry on approved lists (also known as pharmaceutical lists) and with dispensing doctors for patients in some rural areas via entry on dispensing doctor lists.

- 4.3 These arrangements are the responsibility of the National Health Service Commissioning Board (known as NHS England), although the local plans outlining the needs and availability of NHS pharmaceutical services in an area (which are known as pharmaceutical needs assessments), are developed, maintained and updated by local authority Health and Wellbeing Boards (HWBs). HWBs took over this responsibility following the abolition of NHS Primary Care Trusts from 1st April 2013.
- 4.4 Whilst the review deadline specified in the 2013 Regulations is currently 31st August 2017, this is a shorter deadline than the standard deadline of five years set out in section 30(5) of the Small Business, Enterprise and Employment Act 2015, given that the "commencement date" of the 2013 Regulations for the purposes of that standard timetable was 1st April 2013. This shorter timetable reflected the fact that the 2012 Regulations, which the 2013 Regulations replaced, came into force on 1st September 2012.

5. Extent and Territorial Application

- 5.1 This entire instrument extends only to England.
- 5.2 This entire instrument applies only to England.

6. European Convention on Human Rights

6.1 The Parliamentary Under-Secretary of State for Public Health and Primary Care has made the following statement regarding Human Rights:

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

7. Policy background

What is being done and why

- 7.1 As noted above, the 2013 Regulations came into force on 1st April 2013 and the current statutory requirement is to review the 2013 Regulations and publish a report by 31st August 2017. This would have required the Secretary of State to begin the review earlier in 2017, to enable engagement with stakeholders, as intended.
- 7.2 The review has not yet begun because the Department generally follows a "negotiating model" in relation to the discussion of changes to community pharmacy terms of service, and its negotiating partner, the Pharmaceutical Services Negotiating Committee (PSNC) sought to Judicially Review decisions of the Secretary of State with regard to community pharmacy funding for 2016-2017 and 2017-2018. Given that a key part of the review process was always going to be discussions with the Pharmaceutical Services Negotiating Committee (PSNC), we decided it was better to wait for their Judicial Review on community pharmacy funding cuts at least to come to trial before starting the process. The trial was at the end of March, so the review was re-timetabled to start in April 2017.
- 7.3 The revised timetable was then further delayed by the unexpected amount of time it took the judge to hand down his judgment. Starting the review was then prevented by the calling of the 8th June General Election, with an associated pre-election period which came into force from 21st April, prohibiting new consultations.

- 7.4 These unavoidable delays, combined with the summer holiday period, has meant that extensive stakeholder engagement would not be possible without extending the deadline.
- 7.5 The maximum the deadline could be extended is to 31st March 2018, due to constraints set out in the Small Business, Enterprise and Employment Act 2015.

Consolidation

7.6 There are no plans to consolidate the 2013 Regulations.

8. Consultation outcome

8.1 No consultation has occurred as there are no changes to the substantive provisions of the 2013 Regulations.

9. Guidance

9.1 There are no plans to produce guidance, beyond informing stakeholders of the change of deadline.

10. Impact

- 10.1 There is no impact on business, charities or voluntary bodies.
- 10.2 There is no impact on the public sector.
- 10.3 An Impact Assessment has not been prepared for this instrument.

11. Regulating small business

11.1 The change does not affect activities that are undertaken by small businesses.

12. Monitoring & review

12.1 The Department monitors the implementation and efficient operation of the 2013 Regulations and has regular discussions with interested parties. The required review, due now to report by 31st March 2018, will take place as part of and alongside those regular decisions.

13. Contact

13.1 Gideon Levitt at the Department of Health can answer any queries regarding the instrument. Email: <u>Gideon.levitt@dh.gsi.gov.uk</u>