EXPLANATORY MEMORANDUM TO

THE PRESCRIPTION ONLY MEDICINES (HUMAN USE) AMENDMENT ORDER 2010

2010 No. 2998

1. This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA), part of the Department of Health, and is laid before Parliament by Command of her Majesty.

2. Purpose of the Instrument

2.1 This Order amends the Prescription Only Medicines (Human Use) Order1997 ("the 1997 Order") to amend the list of prescription only medicines (POMs) which can be administered by injection by anyone for the purpose of saving life in an emergency. The Order also adds Adrenaline Hydrochloride to the list of Prescription Only Medicines (POMs) which can be administered by registered paramedics.

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

3.1 None.

4. Legislative Context

4.1 The Order amends the 1997 Order which specifies the description, classes and circumstances under which medicinal products may be sold, supplied or administered including, any exception that may apply to those provisions.

4.2 The existing exemptions in the 1997 Order include provision for certain parenteral medicines to be administered by anyone for the purpose of saving life in an emergency. The list of medicines includes Glucose at a concentration of 50%. The amending Order will remove the reference to the specific concentration level so that Glucose may be administered at other strengths.

4.3 Other exemptions in the 1997 Order allow registered paramedics to administer a specific list of medicines on their own initiative. The amending Order will add Adrenaline Hydrochloride to the list.

5. Extent

5.1 This instrument applies to all of the United Kingdom.

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

7.1 The amendment relating to Glucose is intended to reflect best medical practice which is to use Glucose in concentrations of 10% or 20%. In particular, the 10% concentration is recommended for use in children.

7.2 The paramedics list includes Adrenaline Acid Tartrate for use in anaphylaxis and cardiac arrest. The addition of Adrenaline Hydrochloride which is on the market for the same indications, offers an alternative if the other medicine is unavailable.

8. Consultation Outcome

8.1 The MHRA undertook a three month consultation. There were 19 responses and nine of these expressed broad support for the proposals. A further five specifically supported the removal of 50% Glucose. The remainder made no comment specifically.

9. Guidance

9.1 The Joint Royal Colleges Ambulance Liaison Committee (JRCALC) which acts as a national focal point for ambulance issues will include Adrenaline Hydrochloride in the guidance it issues to paramedics.

10. Impact

10.1 An Impact assessment has not been prepared for these proposals as they do not impose significant cost compliance on business, charities or the voluntary sector.

10.2 The impact on the public sector is principally to benefit patient care.

11. Regulating Small Business

11.1 There are no adverse implications for small business.

12. Monitoring and Review

12.1 The changes in this instrument are aimed at benefiting patient care. In line with the Better Regulation Agenda, the instrument will be reviewed in three years time to assess whether it is still fit for purpose.

13. Contact

Anne Ryan at the MHRA (tel 0203 080 6392, e-mail anne.ryan@mhra.gsi.gov.uk) can answer any queries regarding the instrument.