EXPLANATORY MEMORANDUM

1. Title of instrument

The Medicines (Standard Provisions for Licences and Certificates) Amendment Regulations 2004. No.1678

2. Laying Authority and Purpose

This explanatory memorandum is laid before Parliament by Command of Her Majesty.

Regulation making powers are provided to the Ministers, acting jointly, in accordance with sections 47(1), 129(5) and section 1(1) of the Medicines Act 1968.

3. Department Responsible

Department of Health

4. Description

The Statutory Instrument substitutes a new definition of “good manufacturing practice” into Regulation 2 of the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 [S.I. 1971/972] (“the Standard Provisions Regulations”).

5. Legislative Background

To manufacture medicinal products, manufacturers must hold a manufacturer's licence in accordance with Article 40 of Directive 2001/83/EC (implemented in the UK via section 8 of the Medicines Act 1968). Paragraph 3 of Schedule 2 to the Standard Provisions Regulations provides that holders of a manufacturer's licence must carry out their manufacturing operations in accordance with good manufacturing practice (GMP) in respect of medicinal products for human use. The requirement to comply with GMP implemented Commission Directive 91/356/EEC. Commission Directive 91/356 has since been repealed and replaced by Commission Directive 2003/94/EC on the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use.

The Statutory Instrument therefore amends the Standard Provisions Regulations to substitute the revised definition of GMP contained in Article 2(6) of Commission Directive 2003/94/EC to ensure that the principles and guidelines of GMP as set out in Commission Directive 2003/94/EC are complied with in the UK.

A Transposition Note has been produced and is attached to this Memorandum.

6. Extent

The Instrument applies to all UK.

7. European Convention on Human Rights

In the Minister's view, the Instrument is compatible with Convention rights.

8. Policy Background

Under the Community code relating to medicinal products for human use (Directive 2001/83/EC), medicinal products must be manufactured in accordance with good manufacturing practice (GMP). From 1st May 2004, this applies not only to products manufactured for the purpose of marketing, but also medicinal products manufactured for use in clinical trials (investigational medicinal products). The principles and guidelines of GMP are adopted by the European Commission under powers conferred by Directive 2001/83/EC, and are now set out in Commission Directive 2003/94/EC

The objective of GMP is to ensure that products are consistently produced and controlled to particular quality standards. This instrument seeks to achieve that objective by ensuring that UK manufacturers have a legal obligation to comply the Community GMP requirements as set out in the

Commission Directive. Compliance with GMP for investigational medicinal products is required by the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2004/1031)

The amendment is necessary in order to ensure that the UK complies with its Community obligation to implement Commission Directive 2003/94/EC, in so far as it applies to medicinal products for human use other than investigational medicinal products. The amendments are of a minor, technical nature, but are required to reflect the Community position.
In keeping with the requirements of the Medicines Act 1968, the Agency conducted a consultation exercise on the proposal to amend the regulations. Just four responses were received – none of which raised any objections to the proposed amendments.

9. Impact

The Agency has properly considered the case for a statement of regulatory impact, but has concluded that this is not necessary.

While the definition of good manufacturing practice requires an amendment to the Standard Provisions, the enacting Statutory Instrument will not:

- Incur additional costs on either the Exchequer or those persons already obliged to comply with existing legislation; or

- Introduce any new requirements on businesses;

These are purely technical changes for which no additional costs or regulatory burdens can be identified.

10. Contact

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