SCHEDULES

SCHEDULE 33

Regulation 212

Transitional arrangements: pharmacovigilance

Pharmacovigilance system master file

1. Regulation 182(2)(b) (obligation to maintain and make available pharmacovigilance system master file) does not apply in respect of a medicinal product granted an authorisation or registration before 21st July 2012 until whichever is the earlier of—

(a) the day on which the authorisation or registration is renewed under regulation 66 (application for renewal of UK marketing authorisation) or 133 (application for renewal of traditional herbal registration) for the first time after Part 11 has come into force; or

(b) 21st July 2015.

2. Regulation 210(3)(b) (offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004) does not apply in respect of a medicinal product granted an EU marketing authorisation before 21st July 2012 until whichever is the earlier of—

(a) the day on which the EU marketing authorisation is renewed under article 14 of Regulation (EC) No 726/2004 for the first time after Part 11 has come into force; or

(b) 21st July 2015

Post-authorisation safety studies

3. Regulations 198, 199, 200, 201 and 202 (provisions relating to post authorisation safety studies) do not apply to post authorisation safety studies commenced before 21st July 2012.

4. Regulation 210(3)(g) (offences relating to pharmacovigilance obligations under Regulation (EC) No 726/2004) does not apply to post authorisation safety studies commenced before 21st July 2012.

Reporting obligations

5. Paragraphs 6 to 8 apply for the period—

(a) that begins on the day that Part 11 comes into force; and

(b) concludes at the end of the period of six months beginning on the day following the day on which the EMA announces that the functionalities of the Eudravigilance database for the purposes of Title IX of the 2001 Directive have been established.

6. The references to "the Eudravigilance database" in regulation 188(1)(a) and (d) (reporting obligations on holders) shall be read as follows—

(a) in regulation 188(1)(a) and (d) in relation to serious adverse reactions that occur within the EEA, as a reference to the competent authority of each EEA State in whose territory the reaction occurred; and

(b) in regulation 188(1)(a) and (d) in relation to serious adverse reactions that occur within a third country, as a reference to—

(i) the EMA, and

(ii) the relevant competent authorities insofar as each of those competent authorities has requested that serious adverse reaction reports for third countries are submitted to it.

7. The licensing authority must ensure that all reports and updated reports it receives under regulation 188(1)(a) and (d) that relate to serious adverse reactions in the United Kingdom are made available to the Eudravigilance database promptly and in any event before the end of the period of fifteen days beginning on the day following the day on which the report or updated report is received by the licensing authority.

8. Regulations 186(1)(e) (reporting obligations on licensing authority in relation to non-serious suspected adverse reactions) and 188(1)(b) (reporting obligations on holders in relation to non-serious suspected adverse reactions) do not apply.

Periodic safety update reports

9. Paragraph 10 applies for the period—

(a) that begins on the day that Part 11 comes into force; and

(b) concludes at the end of the period of twelve months beginning on the day following the day on which the EMA announces it is ready to receive reports pursuant to Article 107b(1) of the 2001 Directive.

10. The reference to "the EMA" in regulations 191(1) (obligation on holder to submit periodic safety update reports: general requirements) and 192(3) (obligation on holder to submit periodic safety update reports: derogation from general requirements) should be read on both occasions as a reference to "the relevant competent authorities".