Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

ANNEX C

MLX 391: MHRA public consultation on the Post implementation review of the Human Medicines Regulations 2012

Regulation 346 of The Human Medicines Regulations 2012 is outlined below, and defines the scope of the Post-Implementation Review of the 2012 Regulations.

Review

346.—(1) The Secretary of State must from time to time carry out a review of the provisions listed in paragraph (2).

(2) Those provisions are—

(a) Part 11;

(b) regulations—

(i) 59,

(ii) 60(3)(b), (9) and (10),

(iii) 61,

(iv) 63,

(v) 64(4)(b), (d) and (e), (5)(a) and (6)(c),

(vi) 65(2),

(vii) 66(5) and (6),

(viii) 68(2)(a) and (b) and (5),

(ix) 69(2)(a) and (b), (5) and (10),

(x) 75(2)(b) and (c),

(xi) 76,

(xii) 79,

(xiii) 85,

(xiv) 86,

(xv) 97,

(xvi) 105(3)(b),

(xvii) 107(2),

(xviii) 108(5),

(xix) 115(2)(b) and (c),

(xx) 132(2),

(xxi) 133(5) and (6),

(xxii) 266(4) and (5),

(xxiii)327(2)(g),

(xxiv)331, and

(xxv) regulation 349 insofar as it repeals section 10(7) of the Medicines Act 1968; and

(c) Schedules —

(i) 8 paragraphs 12, 13, 19, and 23,

(ii) 12 paragraph 21, and

(iii) 27 paragraphs 14 and 15.

(3) The Secretary of State must

(a) set out the conclusions of a review carried out in accordance with paragraph (1) in a report; and

(b) publish the report.

(4) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how the 2001 Directive and Directive 2010/84/EU of the European Parliament and of the Council amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community Code relating to medicinal products for human use(1) are implemented in other member States in relation to the subject matter of the provisions mentioned in paragraph (2).

(5) The report must in particular—

(a) set out the objectives intended to be achieved by the regulatory system established by the provisions of these Regulations that implement those Directives in relation to the subject matter of the provisions mentioned in paragraph (2)(a), (b)(i) to (xxiv) and (c);

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

(6) The first report under this regulation must be published before the end of the period of five years beginning with the day on which these Regulations come into force.

(7) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

(**1**)

OJ No L 348, 31.12.2010, p.74.