STATUTORY INSTRUMENTS.

S.I. No. 151 of 2014

MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET) (AMENDMENT) REGULATIONS 2014
MEDICINAL PRODUCTS (CONTROL OF PLACING ON THE MARKET) (AMENDMENT) REGULATIONS 2014


1. (1) These Regulations may be cited as the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2014.

(2) These Regulations shall be construed as one with the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2013 and may be cited together with those Regulations as the Medicinal Products (Control of Placing on the Market) Regulations 2007 to 2014.

2. In these Regulations “Principal Regulations” means the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007).

3. Regulation 3(1) (as amended by Regulation 3 of the Medicinal Products (Control of Placing on the Market) Regulations (Amendment) Regulations 2013 (S.I. No. 162 of 2013)) of the Principal Regulations is amended—

(a) by substituting for the definition of “2001 Directive” the following:


3OJ No. L 65, 8.3.2013, p. 17.
5OJ No. L 33, 8.2.2003, p. 30.
6OJ No. L 159, 27.6.2003, p. 46.
8OJ No. L 136, 30.4.2004, p. 34.

Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 28th March, 2014.

(b) by substituting for the definition of “Regulation (EC) No. 726/2004” the following:


(c) in the definition of “relevant Community provisions”—

(i) in subparagraph (i), by deleting “and”,

(ii) in subparagraph (j), by substituting “2010, and” for “2010;”, and

(iii) by inserting after subparagraph (j) the following subparagraph:


4. The Principal Regulations are amended by inserting after Regulation 13 the following Regulation:

“Urgent Action

13A. (1) Without prejudice to Article 31(1) of the 2001 Directive, the Board may, where urgent action is necessary to protect public health at any stage of the procedure initiated under Article 31 of the 2001 Directive, suspend a marketing

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12OJ No. L 174, 1.7.2011, p. 74.
authorisation and prohibit the use of the medicinal product concerned until a definitive decision is adopted under that procedure.

(2) Without prejudice to Article 107i(1) and (1a), 107j and 107k of the 2001 Directive, where, on the basis of concerns resulting from the evaluation of data from pharmacovigilance data, it considers that urgent action is necessary to protect public health, the board may suspend a marketing authorisation and prohibit the use of the medicinal product concerned until a definitive decision is adopted under the procedure laid down in Articles 107j and 107k of the 2001 Directive.

(3) Where the Board takes urgent action under paragraph (1) or (2), it shall inform the Commission, the Agency and other EEA States no later than the following working day of the reasons for its action.”

5. Regulation 15(6) (as amended by the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2012 (S.I. No. 272 of 2012)) of the Principal Regulations is amended—

(a) by substituting for subparagraph (h) the following:

“(h) if the medicinal product ceases to be placed on the market, either temporarily or permanently, notify the Board, no less than two months before the interruption in the placing on the market of the product or, in exceptional circumstances, less than two months before such interruption, and include in such notification the reasons for such action in accordance with Article 123(2) of the 2001 Directive”,

(b) in subparagraph (m), by deleting “and”,

(c) in subparagraph (n), by substituting “said request;” for “said request.”, and

(d) by inserting after subparagraph (n) the following subparagraphs:

“(o) notify the Board of any action taken by the holder to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation, certificate of registration or certificate of traditional-use registration, or not to apply for the renewal of such authorisation or certificate, together with the reasons for such action and a declaration as to whether such action is based on any of the grounds set out in Article 116 and Article 117(1) of the 2001 Directive;

(p) notify the Board, in the manner described in subparagraph (o), of any action equivalent to that referred to in that subparagraph taken by the holder in a state outside the EEA, where such action is based on any of the grounds set out in Article 116 or 117(1) of the 2001 Directive; and
(q) notify the Agency, where the action referred to in subpara-
graph (o) or (p) is taken on the basis of any of the grounds
referred to in Article 116 or 117(1) of the 2001 Directive”.

6. Schedule 2 (as amended by the Medicinal Products (Control of Placing on
the Market) (Amendment) Regulations 2012 (S.I. No. 272 of 2012)) to the Prin-
cipal Regulations is amended—

(a) in paragraph 1, by substituting “Subject to paragraphs 6, 7 and 8” for
“Subject to paragraph 6”, and

(b) by inserting after paragraph 7 the following paragraph:

“8. Paragraph 2 shall not apply in the case of urgent action taken by
the Board under Regulation 13A.”

GIVEN under my Official Seal,
26 March 2014.

JAMES REILLY,
Minister for Health.
EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations amend the Medicinal Products (Control of Placing on the Market) Regulations 2007 (S.I. No. 540 of 2007).


These Regulations may be cited as the Medicinal Products (Control of Placing on the Market) (Amendment) Regulations 2014.