STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 5

Marketing authorisations

Consideration of application

Classification of UK marketing authorisation

62.—(1) A UK marketing authorisation must include a term that the product to which the authorisation relates is to be available—

(a) only on prescription;

(b) only from a pharmacy; or

(c) on general sale.

(2) In making a determination under paragraph (1), the licensing authority must have regard to the following in relation to the product—

(a) the maximum single dose;

(b) the maximum daily dose;

(c) the strength of the product;

(d) its pharmaceutical form;

(e) its packaging; and

(f) such other circumstances relating to its use as the licensing authority considers relevant.

(3) A UK marketing authorisation must be granted subject to a condition that the product to which the authorisation relates is to be available only on prescription if the licensing authority considers that the product—

(a) is likely to present a direct or indirect danger to human health, even when used correctly, if used without the supervision of a doctor or dentist;

(b) is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health;

(c) contains substances, or preparations of substances, of which the activity requires, or the side effects require, further investigation; or

(d) is normally prescribed by a doctor or dentist for parenteral administration.

(4) In deciding whether paragraph (3) applies to a product, the licensing authority must take into account whether the product—

(a) contains a substance listed in any of Schedules I, II or IV to the Narcotics Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention);

(b) contains a substance listed in any of Schedules I to IV of the Psychotropic Substances Convention (where the product is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 of that Convention);

(c) is likely, if incorrectly used—

(i) to present a substantial risk of medicinal abuse,

(ii) to lead to addiction, or

(iii) to be used for illegal purposes;

(d) contains a substance that, by reason of its novelty or properties, might fall within paragraph (c), but as to which there is insufficient information available to determine whether it does so fall;

(e) by reason of its pharmaceutical characteristics or novelty, or in the interests of public health, is reserved for treatments that can only be followed in a hospital;

(f) is used in the treatment of conditions that must be diagnosed in a hospital or in an institution with special diagnostic facilities (although administration and subsequent supervision may be carried out elsewhere); or

(g) is intended for outpatients but may produce very serious side effects which would require a prescription drawn up as required by a specialist and special supervision throughout the treatment.

(5) A UK marketing authorisation may include a term that the product to which the authorisation relates is to be available on general sale only if the licensing authority considers that the product can with reasonable safety be sold or supplied otherwise than by, or under the supervision of, a pharmacist.