
STATUTORY INSTRUMENTS

2012 No. 1916

The Human Medicines Regulations 2012

PART 12

Dealings with medicinal products

CHAPTER 3

Exemptions

Exemptions in relation to specific kinds of product

Exemptions in respect of certain herbal remedies

241.—(1) Regulations 220 and 221 do not apply to the sale or supply, or offer for sale or supply by a person (“A”) of a herbal medicinal product if—

- (a) the product does not contain a substance listed in Part 1 of Schedule 20;
- (b) the product does not contain a substance listed in column 1 of Part 2 of that Schedule, unless the product is sold or supplied—
 - (i) in the case of a product for which there is a corresponding entry in column 2 of that Part, in or from containers or packages labelled to show a dose not exceeding the maximum dose or maximum daily dose specified in that entry, and
 - (ii) in the case of a product for which there is a corresponding entry in column 3 of that Part, with the percentage of the substance in the product not exceeding that specified in that entry;
- (c) the sale or supply, or offer for sale or supply, takes place on premises occupied by A and from which A can exclude the public; and
- (d) the product is for administration to a person (“B”) and A has been requested by or on behalf of B and in B’s presence to use A’s judgment as to the treatment required.

(2) A reference in this regulation to a substance listed in either Part of Schedule 20 is a reference to a substance that is obtained from any botanical source listed in either Part.