L.N. 474 of 2004

MEDICINES ACT
(ACT NO. III OF 2003)

Colouring Matters in Medicinal Products for Human Use Regulations, 2004

IN exercise of the powers conferred by article 106 of the Medicines Act, 2003, the Minister of Health, the Elderly and Community Care has made the following regulations:–

Title and scope.

1. (1) The title of these regulations is the Colouring Matters in Medicinal Products for Human Use Regulations, 2004.

(2) The objective of these regulations is to transpose Directive 78/25/EEC as amended by Directive 81/464/EEC.

Permitted colouring matters.

2. (1) The only colouring matters that shall be permitted for the colouring of medicinal products for human use shall be those under Annex I, Sections I and II, to the Directive of the 23rd October, 1962, as subsequently amended, as long as such colouring matters satisfy the general and specific criteria of purity laid down under Annex III to the Directive of the 23rd October, 1962.

(2) No distinction shall be made between colouring matter for both mass and surface colouring, and colouring matter for surface colouring only.

(3) The Licensing Authority shall adopt methods of analysis to verify that the general and specific criteria of purity under Annex III to Directive of the 23rd October, 1962 are satisfied.

Application of a colouring matter.

3. Where a colouring matter is deleted from Annex I to the Directive of the 23rd October, 1962 but the marketing of foodstuffs containing this colouring matter is permitted to continue for a limited period, this provision shall also apply to medicinal products. This limited period of use may, however, be amended for medicinal products according to the procedure laid down in Article 6 of Directive 78/25/EEC.

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