EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Industrial affairs: Consumer goods industries
Pharmaceuticals and cosmetics

PHARM 287

49th PHARMACEUTICAL COMMITTEE
22. - 23. 3. 2000

Subject : Interpretation of Directive 78/25/EEC on colouring matters in medicinal products;

Background:

At the 43rd meeting of the Pharmaceutical Committee on 11.6.1997, a document (PHARM 170 – copy attached) with a proposed Commission interpretation of the above Directive was discussed. Several Member States expressed concern that this proposed interpretation would be too restrictive and exclude the use of certain colourants which could be safely used in medicinal products.

Following this discussion, the Commission services decided to submit the following question to the Scientific Committee on Medicinal Products and Medical Devices (SCMPMD): *"Is there a consumer health/safety concern to exclude the use of the "colours permitted for certain uses only" listed in Annex IV of Directive 94/36 (in particular: E 123 Amaranth, E 127 Erythrosin, E 161g Canthaxatin, E 173 Aluminium, E 174 Silver and E 175 Gold) in medicinal products ?"*

Following this request, the SCMPMD delivered scientific opinions on *E 123 Amaranth, E 127 Erythrosin, E 161g Canthaxatin, E 173 Aluminium* (copies attached), and concluded that it seems "*paradoxical to prohibit*", respectively "*reasonable to allow*" the use of these colourants in medicinal products.

Concerning *E 174 Silver and E 175 Gold*, the SCMPMD noted that there appeared to be little data on these products, and that it seemed that these products are not now utilised as colouring agents in medicinal products..

Proposed way forward:
Based on the scientific answers of the SCMPD one might consider to interpret the references in Directive 78/25 in a way which would permit the use in medicinal products of all colourants mentioned in Annex I of *Directive 94/36 on colours for use in foodstuffs*.

Rue de la Loi 200, B-1049 Bruxelles/Wetstraat 200, B-1049 Brussel - Belgium - Office: AN 88 1/40.
Telephone: direct line 299 21 80, exchange (+32-2)299.11.11. Fax: 296.15.20.
Telex: COMEU B 21877. Telegraphic address: COMEUR Brussels.

In the interest of legal certainty it seems, however, appropriate to amend Directive 78/25 accordingly and to replace the outdated references by clear new references. – Pending the review of this Directive, agreement on a harmonised application of the old text should be achieved.

Action to be taken:

For discussion and agreement on a way forward