EUROPEAN ECONOMIC COMMUNITY
OFFICIAL SPOKESMAN
of the Commission

23, avenue de la Joyeuse Entrée
Brussels 4
Telephone 35.00.40

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PRESS RELEASE

Third Directive on drugs.

The EEC Commission has submitted to the Council a proposal for a third directive on the harmonization of Member States' laws and regulations governing drugs. The directive covers coloring agents which can be added to pharmaceutical products. The first directive, adopted by the Council on 26 January 1965, covered the sale and labelling of drugs, and the second, submitted as a proposal to the Council in February 1964 but not yet adopted, was concerned with quality control.

The dismantling of customs duties and other restrictions on imports would not suffice if the flow of trade were still to be obstructed by disparities in the laws and regulations on specific types of merchandise. Provisions of this kind are prevalent in the field of drugs on grounds of public health and safety. Efforts made so far to bring them into line have produced these two directives, both of which concern proprietary drugs. Most drugs now sold are in fact of this type, and they already account for a substantial share of intra-Community trade in pharmaceuticals. It has become clear that trade in these items can also be hampered by differences in statutory provisions not covered by the first two directives - if, for instance, a drug manufactured in one member country contains a dye that is prohibited in another. The disparities between Member States' laws on dyes used in drugs constitute such a barrier to trade that the Commission thinks it essential that they should be harmonized.

The proposal that has now been worked out closely follows the directive on food coloring adopted on 23 October 1962 (in the 25 October 1965 version), but it includes a list of dyes that may be used in proprietary drugs only, and not in food. The new directive follows the pattern of the measures concerning dyestuffs in food and takes advantage of the work of other international organizations. The Commission has taken as its main criterion the effective protection of public health. Economic requirements and the views of the drug industry have been given proper consideration.

In selecting the permitted coloring agents, the Commmission took into account the latest toxicological findings in order to guarantee the harmlessness of the drugs. Certain other coloring agents are to be permitted for three years ; these are in current use and have not been shown to be toxic in the short term, but information on long-term toxicity is still inadequate. The names of the permitted and provisionally permitted dyes are given in two annexes to the Commission's proposal. A third annex sets out the general and specific purity standards to be adhered to in all six countries in deciding whether a dye is toxic.

Within eighteen months of being notified of the directive, the proposal provides that the Member States will be required to align their statutory provisions accordingly. Firms will be given a further six months to conform to its provisions.

Finally, with a view to preventing laws on drugs from again diverging in the future, the Member States will be required to inform the Commission of all laws and regulations they propose to enact in the fields covered by the directive.