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PHARMACEUTICALS: RESTRICTIONS IN USE AND AVAILABILITY

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Essential Drugs and Medicines – Quality Assurance and Safety of Medicines
Health Technology and Pharmaceuticals
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PHARMACEUTICALS:
RESTRICTIONS IN USE AND AVAILABILITY

Prepared within the context of the United Nations publication

"Consolidated List of Products whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or Not Approved by Governments"

Update of the Sixth Issue – March 2001

Essential Drugs and Medicines – Quality Assurance and Safety of Medicines
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This text is the second update to the Sixth Issue of the United Nations Consolidated List of Products whose Consumption and/or Sale have been Banned, Withdrawn, Severely Restricted or Not Approved by Governments - Pharmaceuticals (UN General Assembly Resolutions 37/137, 1982; 38/149, 1983; 39/229, 1984; 44/226, 1989). It is offered as a service to drug regulators, the pharmaceutical industry, and to everyone interested in assuring the safe and rational use of drugs. It complements and consolidates other drug-related information issued by the World Health Organization, including the WHO Rapid Alerts, WHO Pharmaceuticals Newsletter and the quarterly subscription journal WHO Drug Information.

Scope and presentation

This volume presents information on new national regulatory decisions, and on voluntary withdrawal of products by manufacturers on grounds of safety, that were reported to WHO up to December 2000.

Products are listed alphabetically within sections; International Nonproprietary Names (INNs) have been used whenever possible. Each product entry includes, where available, the Chemical Abstracts Service registry number (CAS number); synonyms including other generic names and chemical names; the effective date on which the regulation came into force; a summary of regulatory measures taken by governments; brief explanatory comments where necessary; and legal and bibliographical references.

While the information cannot be regarded as exhaustive, either in terms of products or regulatory measures, it covers regulatory actions taken by a total of 41 governments on 76 products. It should be noted, none the less, that decisions taken by a limited number of governments on a specific product may not be representative of the positions of other governments. Moreover, the fact that a given product is not listed as regulated by a country does not necessarily mean that it is permitted in that country; it may mean that the relevant regulatory decision has not been communicated to WHO or that the product has not been submitted for registration. The efficacy of products listed is not addressed, but is an aspect that may be crucial when a government is considering regulatory action.

Criteria for the inclusion of products in the Consolidated List (see next page) were developed in 1985 and revised in the light of the comments received from governments. However, governments' interpretation of the criterion "severely restricted", in particular, continues to vary widely, leading to considerable unevenness in reporting. When necessary, additional information and/or clarification has been requested from governments; products which clearly do not meet the criteria have been omitted after consultation with governments. Information received from non-governmental organizations has, in each case, been verified with governments.

The information provided also includes references to relevant legal or statutory documents that enable the user to ascertain the legal context and scope of the regulations. Such references cannot be given for most entries relating to specific pharmaceutical products since the relevant licences are often made or amended by an administrative decision which is not published. Brief explanatory comments also appear, where necessary, to clarify certain regulatory actions and put them into broader context.

Criteria for the inclusion of pharmaceutical products in the UN Consolidated List

a) ***Banned product***

A product that has been withdrawn from use and/or sale nationally in one or more countries by order of the competent national authority, having regard to its safety in relation to its intended use.

b) ***Voluntary withdrawal***

A product that has been withdrawn from use and/or sale nationally in one or more countries by voluntary action of the manufacturer, having regard to its safety in relation to its intended use.

c) ***Severely restricted***

A product containing:

(i) a substance that is controlled more rigorously than is provided for under the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances or that is subject to analogous control at the national level before it has been considered for international scheduling.

(ii) a substance that may be incorporated in pharmaceutical dosage forms only within the specific limits determined by statute.

(iii) a substance that is approved by a competent national authority and is subjected to restrictions that exclude its use in a substantial proportion of the potential target population of patients having regard to its safety. A substance which from the outset has been severely restricted in its indications having regard to the known balance of safety and efficacy is excluded.

d) ***Not approved***

A product that has been formally submitted for registration by a manufacturer to a national competent authority and which has been rejected on grounds of safety.

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