

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 15565

CERTAIN WORLD HEALTH ASSEMBLY ACTIONS RELATED TO PRODUCTION

AND USE OF DRUGS

- I. Pharmaceutical advertising -
Resolution WHA 21.41 (1968). Pg. 144 - Handbook of Resolutions and Decision - *Ethical and Scientific Criteria for Pharmaceutical Advertising.*
- II. "Principles of Pharmaceutical Quality Control" and "Good Practices in the Manufacture and Quality Control of Drugs (Technical Reports Series No. 418 and WHO Official Record No. 176 Annex 12, part 1) Resolutions WHA 22.50 (1969), WHA 23.45 (1970), WHA 24.56 (1971) Handbook of Resolutions and Decisions: pgs. 133 and 134
Also WHA 28.65 (1975) in Technical Reports Series 467.
- III. Evaluation of the safety and efficacy of drugs -
Requests Member States to communicate immediately to WHO: a) any decision to prohibit or limit the availability of a drug already in use, b) any decision to refuse the approval of a new drug, and c) any approval for general use of a new drug when accompanied by restrictive provisions; when these decisions a), b) and c) are taken as a result of serious adverse reactions. They are also requested to include in the communication as far as possible the reasons for the action taken and the non-proprietary and other names, and the chemical formula or the definition.
Resolution WHA 16.36 (1963) - Handbook Resolutions and Decision, pg. 139
See also Res. WHA 17.39 (1964) - Handbook Resolutions and Decision, pg. 140
- IV. "Monitoring of Adverse Effects of Drugs"
Resolutions: WHA 18.42 (1965), WHA 23.13 (1970). Handbook of Resolutions and Decisions - pgs. 140 and 141.
Technical Reports Series No. 498 - Role of national centres in international drug monitoring.
- V. Study on: a) the feasibility of an international system providing data on the scientific basis and the conditions of registration and withdrawal of individual drugs; b) practicable minimum requirements and on other efforts to develop a comprehensive approach to ensuring the quality, safety and efficacy of drugs, including the feasibility of implementing Article 21 (d) and (e) of the WHO Constitution.
Resolutions: WHA 25.61 (1972), Handbook of Resolutions and Decisions pg. 143; and WHA 26.30 and WHA 26.31. WHO Official Records No. 209 pgs. 14 and 15 and No. 210 pgs. 294 to 307.

WHO Constitution

Article 21 - The Health Assembly shall have authority to adopt regulations concerning:

d) - standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce;

d) - advertising and labeling of biological, pharmaceutical and similar products moving in international commerce.