

Recent Publications

WHO Expert Committee on Specifications for Pharmaceutical Preparations: Thirty-fourth report

This report sets out a series of twelve international guidelines and other recommendations intended to assist national drug regulatory authorities and manufacturers in the quality control of pharmaceutical products. Concerns addressed include the need to ensure that pharmaceutical products moving in international commerce are of acceptable quality, that generic drugs are therapeutically equivalent to innovator products, and that drugs retain their quality, safety, and efficacy throughout their designated shelf-life, particularly under the extreme climatic conditions often found in developing countries. The report also responds to the need to extend previously issued WHO guidelines for good manufacturing practices (GMP) to cover several special circumstances.

Although the report has universal relevance, its guidance is of particular importance in countries attempting to establish or strengthen a regulatory framework for pharmaceutical products. All recommendations share the ultimate goal of assisting regulatory authorities to safeguard the health of patients by protecting them from substandard or counterfeit products.

Two of the guidelines focus on premarketing studies, covering the technical data that should be included in the registration dossier when applying for a marketing authorization. The most extensive guidelines, on multisource pharmaceutical products, address the need to ensure that generic drug products satisfy the same standards of quality, efficacy and safety as those applicable to the originator's product and that adequate comparative studies have been conducted to verify whether the products are interchangeable. Presented in seven parts, the guidelines provide global standards and requirements for the regulatory assessment, marketing authorization, documentation of therapeutic equivalence, and quality control of multisource products.

The second guidelines, on stability testing of pharmaceutical products containing well-established drug substances, specify the tests needed to predict the stability of a drug product and determine its shelf-life and storage conditions in various climatic zones. The availability of these WHO guidelines is considered to be of special importance for testing products for use in the more extreme climatic conditions found in many developing countries, because such advice is lacking in other guidelines.

The report also contains revised guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, including standardized format and contents for product and batch certificates to be issued by the drug regulatory authority of the exporting country and the manufacturer.

Three guidelines supplement previously issued advice on good manufacturing practices (GMP), and cover the validation of the manufacturing processes, the manufacture of investigational products for clinical trials in humans, and the manufacture of herbal medicinal products. The resurgence of interest in herbal medicines is further reflected in guidelines for assessing their quality, safety and efficacy and for approving product labelling and package inserts. Other information includes updated lists of International Chemical Reference Substances and International Infrared Reference Spectra, supplemented by recommendations for the preparation and use of infrared spectra in pharmaceutical analysis. The report also contains extensive guidelines for the standardized graphic representation, whether hand-drawn or computer-assisted, of chemical formulae.

The report concludes with detailed guidelines on import procedures intended to promote efficiency in applying relevant regulations, to simplify the checking and handling of consignments in international transit, and to provide a basis for collaboration between the various regulatory, trade, customs, and port authorities. Full details of the

special controls required for narcotic drugs and psychotropic substances are also included

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Good pharmacy practice (GPP) guidelines

All practising pharmacists should be committed to their profession and ensure that the service they provide to each patient is of appropriate quality. A recent WHO document sets out the four basic principles of good pharmacy practice (GPP).

The *Good pharmacy practice guidelines* have been drawn up with a view to encouraging national pharmaceutical organizations to focus the attention of pharmacists in both the community and hospitals on developing the elements of the service they provide. Conditions of practice vary widely from country to country and each national pharmaceutical organization must decide what can be achieved. Such organizations should be particularly active in ensuring that pharmaceutical education is designed to equip pharmacists for the roles they have to undertake in hospital and community practice.

The present document is updated from the International Pharmaceutical Federation's (FIP) text of "good pharmacy practice" which was originally adopted during the World Congress of Pharmacy and Pharmaceutical Sciences in Tokyo in 1993. It sets out to provide a framework for the development of standards which follow closely the philosophy of good pharmacy practice. After a clear description of the framework of GPP, requirements are proposed covering health promotion and ill-health prevention, supply and use of prescribed medicines, and influencing prescribing and rational use of medicines.

These guidelines are recommended as a set of professional goals in the interest of patients and end-users at the pharmacy. All national pharmaceutical organizations are urged to implement them at the earliest opportunity.

Good pharmacy practice (GPP) in community and hospital pharmacy settings. PHARM/DAP/96.1. World Health Organization, Geneva. Available on request from Regulatory Support, Division of Drug Management & Policies, WHO, 1211 Geneva 27, Switzerland.

International Nonproprietary Names (INN) for pharmaceutical substances: cumulative list No. 9

This publication groups together the 6567 international nonproprietary names published by WHO up to December 1995. The list features INNs presented in alphabetical order under the Latin name and each entry includes equivalent names in English, French, Russian and Spanish. Also listed is the molecular formula and the corresponding Chemical Abstracts Service (CAS) registry number.

Three separate indexes allow retrieval of the INN equivalent in relation to the national name; the name of the substance from knowledge of its formula; or the name according to its CAS registry number. INNs for substances which are no longer marketed or which were abandoned before marketing are listed in an annex.

Procedures for the selection of recommended INNs, as well as the general principles for guidance in devising INNs, are also explained in length.

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