# ENSURING QUALITY AND SAFETY OF MEDICINAL PRODUCTS TO PROTECT THE PATIENT*

**Joint Statement betweenThe International Pharmaceutical Federation (FIP) and theInternational Federation of Pharmaceutical Manufacturers Associations (IFPMA)*

FIP and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) have a common goal to protect the well-being of patients in all parts of the world by ensuring that all medicinal products are of good quality and proven safety and efficacy. Both industry and the pharmaceutical profession also recognise the need for a regulatory and marketing environment which encourages investment in new innovative medicines and allows their timely introduction and availability to patients world-wide.

FIP and IFPMA give priority to the need for effective regulatory safeguards to ensure that the patient is protected from the hazard to health of poor quality, substandard and counterfeit medicines.

Governments have an obligation to protect their citizens and therefore must ensure that medicinal products, whether manufactured locally or imported, meet recognised international standards of quality, safety, bioavailability and efficacy. The same principles for standards must be applied by Governments for both branded and generic products and for both the private and public sectors. Achievement of high standards depends upon a combination of the commitment of manufacturers to Good Manufacturing Practice, satisfactory legislation, effective and comprehensive regulatory procedures and effective inspection and enforcement arrangements, together with the political will to implement them.

To assist countries to ensure the quality of imported products, the World Health Organization has developed the WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce. This seeks to establish an internationally standardised mechanism under which the competent regulatory authority within the exporting country can certify at the request of the importing country, whether a specific product is authorised for sale on its domestic market and whether it has been manufactured in accordance with defined standards of Good Manufacturing Practice. The Certification Scheme is a standardised administrative mechanism that makes it possible to ascertain the regulatory status of a product in the exporting country, the strength of which depends on the capacity of the regulatory authority in the exporting country to perform effective regulatory work. Full guidance on the potential and limitations of this scheme has been published by WHO (Ref.)

**Statement**

All governments should take steps to ensure the quality, safety and efficacy of all medicinal products available in their countries in accordance with recognised international standards. This applies whether they are branded or generic products, to both the private and public sectors, and to both imported and locally manufactured products.

If generic substitution is adopted by governments, then pharmacists and industry together, particularly in developing and newly emerging countries should stress to governments that in the interest of public health, such substitution should be introduced only when the necessary recognised international regulatory standards including bioequivalence are in place to ensure the quality of all products on the market. If an adverse event occurs in a case where product substitution has been carried out, the pharmacist must make available information relating to the source of the product, according to the pharmacist's professional responsibilities.