POLICY STATEMENT ON COUNTERFEIT MEDICINES

During the 1998 FIP Congress, the Section of Laboratory and Medicines Control held a symposium on the dangers of counterfeit medicines. This followed the adoption of a resolution at the World Health Assembly in 1988 and international meetings cosponsored by WHO and the International Federation of Pharmaceutical Manufacturers' Associations.

The FIP is seriously concerned about the risk to public health represented by counterfeiting, particularly in countries where legislation governing the manufacture and distribution of medicines, or the enforcement of legislation, is ineffective.

Counterfeit medicines are difficult to detect. They can escape all controls and so contribute to the burden of substandard and fake medicinal products that are undermining

the credibility of the public health services in many countries. Counterfeiting is attractive because relatively small quantities of counterfeit medicines can provide huge profits to the counterfeiter; and trading in them is seen to carry less risk than trafficking in the field of addictive drugs. Counterfeiting is undertaken for both long established and innovative medicines.

The key to the reduction in the availability of counterfeit medicines is the integrity of the manufacturing and distribution channel for medicines. Unfortunately, pressure on margins at the pharmacy and wholesaling levels can lead to purchases of medicines from outside the normal supply channel, increasing the risk of purchase of counterfeit medicines. This should be recognised by national authorities.

A separate joint FIP/IFPMA statement entitled "Ensuring the quality and safety of medicinal products to protect the patient" was adopted at the 1998 FIP Congress. That statement emphasises the need for effective regulatory safeguards to ensure that the patient is protected from the hazards of poor quality, substandard and counterfeit medicines. This FIP Policy statement on counterfeit medicines is complementary to the 1998 statement.

Definition

In this statement, counterfeiting in relation to medicinal products means the deliberate and fraudulent mislabelling with respect to the identity, composition and/or source of a finished medicinal product, or ingredient for the preparation of a medicinal product. Counterfeiting can apply to both branded and generic products and to traditional remedies. Counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging.

FIP

- Expresses its firm support for, and co-operation in, initiatives by international bodies including WHO, UNICEF, WTO, Interpol and IFPMA and national regulatory and pharmacopoeial authorities, to promote co-ordinated activities to detect and eliminate counterfeit medicines.

- Urges national administrations

- To recognise the serious risk to public health represented by counterfeit medicines and to ensure that the public are made aware of these risks through information in the media

- To recognise the safeguards provided by the traditional manufacturer/pharmaceutical wholesaler/pharmacy/ patient, supply channel for medicinal products and minimise the risk by promoting the use of this traditional supply channel

- To put in place, with adequate funding, within the overall national quality assurance system for medicines, effective measures to detect and prevent the circulation of counterfeit medicines including training programmes for pharmacists on detection of counterfeits; and

- To adopt and implement WHO guidelines for the development of measures to combat counterfeit medicines. (WHO/EDM QSM/99/1)
- To provide financial support and/or technical expertise to assist charitable organisations to ensure that effective quality assurance checks are carried out before any medicinal product is purchased or used for humanitarian purposes
- Urges charitable organisations to ensure that effective quality assurance checks are carried out before any medicinal product is purchased or used for humanitarian purposes
- Commits itself to informing Ordinary Members of FIP of any detected circulation of counterfeit medicines
- Expresses its willingness to assist developing countries, on request, to identify a source of expert advice on the implementation of an effective system for the detection and elimination of counterfeit medicines
- Endorses the imposition of punitive sanctions for manufacturing or trading in counterfeit medicines

Obligations of National Pharmacy Organisations

National organisations representing pharmacists should:

- Develop, implement and monitor effectively, Good Pharmacy Practice in accordance with WHO/FIP guidelines.
- Report to national regulatory authorities, WHO and FIP any instances where it is suspected that counterfeit medicines have been offered or supplied in their country and request that the information be widely disseminated.
- Include in their Code of Professional Practice and Ethics for pharmacists, a requirement for co-operation with government and other regulatory authorities and manufacturers in the detection of the circulation of counterfeit medicines and in measures designed to prevent such circulation.

Obligations of Pharmacists

Pharmacists in all fields of practice should

- Implement Good Pharmacy Practice in accordance with WHO/FIP guidelines.
- Purchase medicinal products only from reputable sources, paying regard to the storage conditions before purchase and subsequent chain of supply of the medicines concerned.
- Be alert to differences in quality of packaging, labelling or leaflets and in physical appearance of medicinal products.
- Report to the national regulatory authority for medicines and the national pharmaceutical organisation any instance where it is suspected, because of absence of expected therapeutic effect or for any other reason, that counterfeit medicines have been offered or supplied, isolate and withhold from supply any such medicinal product and co-operate in investigations to detect the source.