International Pharmaceutical Federation
Fédération internationale pharmaceutique

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FIP STATEMENT OF POLICY
PHARMACIST'S AUTHORITY IN PRODUCT SELECTION
THERAPEUTIC INTERCHANGE AND GENERIC SUBSTITUTION

This statement was adopted by the Council of the International Pharmaceutical Federation (FIP) at its Council meeting in Vancouver on 5th September 1997.

Introduction

(1) In 1992 FIP issued a statement concerning the quality of medicinal products calling on all countries to ensure their adequate quality. The statement reads, in part:

"All countries must ensure that medicinal products, whether manufactured or imported, meet satisfactory standards of quality, safety, bioavailability, bioequivalence and efficacy. The same principles for standards must be applied by governments for both branded and generic products. Achievement of high standards depends upon a combination of satisfactory legislation, efficient and comprehensive regulatory procedures and effective inspection and enforcement arrangements, together with the political will to implement them."

(2) This statement of FIP policy on product selection can only be implemented if the country concerned has the infrastructure and regulatory authority in place to ensure that all medicinal products available in that country - whether manufactured locally or imported - meet satisfactory standards of quality, safety and efficacy including regulatory and pharmacopoeia standards.

(3) Until recently, the marketing of some medicinal products was based on the premise that the brand-name product is different from its competitors in scientifically and clinically important ways. However it is now clear that, with appropriate exercise of medical and pharmaceutical judgement, medicinal products within a pharmacological class may be interchanged according to defined criteria and the needs of the patient without significant compromise of patient outcome.

(4) In May 1994 the World Health Assembly passed a resolution considering the role of the pharmacist. Amongst other points it urges action by all governments, in collaboration with national pharmaceutical associations to make full use of the expertise of the pharmacist at all levels of the health care system.

Definitions

The following terms are defined as indicated:

(1) Generic alternatives: Medicinal products, intended for administration by the same route and the same dosage form, containing the same amount of the same active ingredients and meeting the required regulatory and pharmacopoeia standards, the same satisfactory standards of quality, safety and efficacy and are bioequivalent;

(2) Generic substitution: The act of dispensing a generic alternative, as defined in (1) above, for the medicinal product prescribed, on the basis of available evidence including professional literature, bioequivalence and/or clinical studies, information from the manufacturer, drug recalls, manufacturer reputation and other pertinent factors including information from regulatory bodies;

(3) Therapeutic alternatives: Medicinal products containing different active ingredients but which are of the same pharmacological class, and which have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses;

(4) Therapeutic substitution: The act of dispensing a therapeutic alternative for the medicinal product prescribed without prior consultation with the prescriber; thus therapeutic substitution is a unilateral act;

(5) Therapeutic interchange: The act of dispensing a therapeutic alternative, as defined in (3) above, in accordance with a protocol previously established and agreed between prescriber and pharmacist, or after individual prior consultation with the prescriber. Therapeutic interchange may be within or outside a formulary system. Thus therapeutic interchange is a collaborative action between prescriber and pharmacist designed to achieve maximum therapeutic benefit for the patient and to ensure the safest, most effective and economic use of medicinal products.

Taking into account this introduction and these definitions, it is the policy of FIP that:

(1) Where generic substitution is allowed by legislation or the prescriber indicates that a generic alternative is acceptable, the responsibility for selection of the generic medicinal product will be that of the pharmacist and should be made within the criteria in definition (2) above, having regard to value for the patient and payer.

(2) If appropriate, the use of generic names for professional communications should be encouraged.

(3) Regulatory authorities and manufacturers should provide to pharmacists and prescribers, bioavailability and other relevant data relating to all medicinal products, where these are important factors relative to efficacy, in a format standardised in agreement with the professions.

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(4) The concept of therapeutic substitution, as defined in definition (4) above, should not be supported except in cases of emergency.

(5) The concept of therapeutic interchange, as defined in definition (5) above, using the relevant expertise of the pharmacist and the prescriber should be promoted.

(6) The dialogue with WHO, international organisations representing the medical profession, other prescribers and pharmaceutical manufacturers regarding the role of the pharmacist in product selection should continue and this should be encouraged at national level.

(7) All national associations representing pharmacists, prescribers and pharmaceutical manufacturers should be urged to collaborate by working on quality improvement programmes and by providing continuing education to ensure safe and effective practice of generic substitution and therapeutic interchange and to enable practitioners to offer sound advice to professional colleagues and patients.