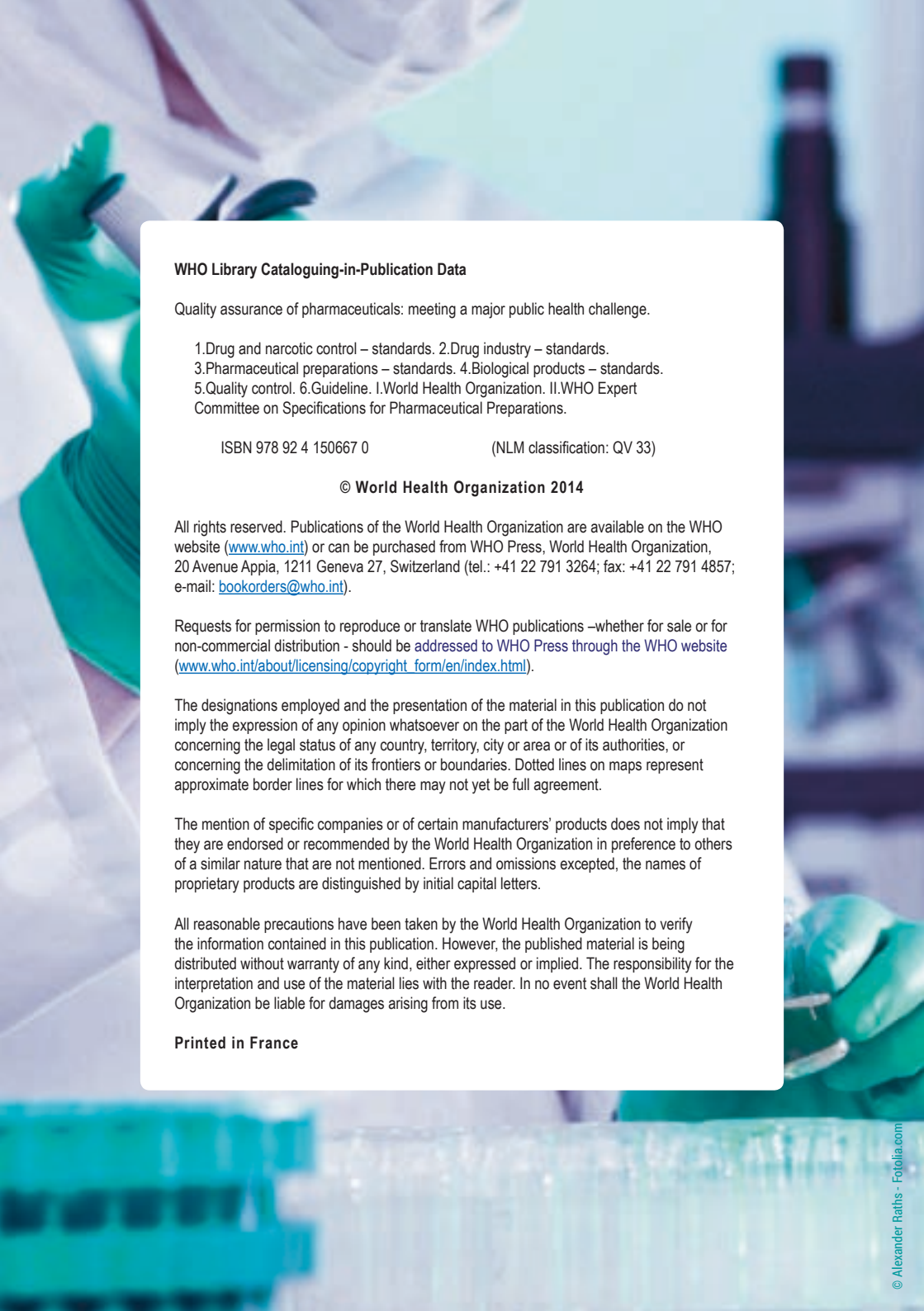
WHO EXPERT COMMITTEE

on Specifications for Pharmaceutical Preparations

Quality assurance of pharmaceuticals:

MEETING A MAJOR PUBLIC HEALTH CHALLENGE

World Health Organization



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INTRODUCTION

This booklet provides an overview of guidelines on pharmaceutical quality assurance as adopted by the Expert Committee on Specifications for Pharmaceutical Preparations in recent years.

MEETING A PUBLIC HEALTH CHALLENGE

Quality assurance of pharmaceuticals has become a major public health challenge. Diseases know no borders; to combat the effects of diseases, countries need medicines that are manufactured to the same standards of safety and effectiveness so that they can be relied on everywhere. And as international demand for medicines grows, substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products have been found in both developing and developed countries. Such products are at best ineffective, resulting in the growth of drug resistance and prolonged or ineffective treatment for patients, and at worst they are dangerous, putting lives at risk, even resulting in death.

Medicines that are ineffective or harmful not only damage lives but also waste public resources. The Constitution of the World Health Organization (WHO) states that one of the Organization's primary functions is "to develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products". WHO provides global standards for pharmaceutical ingredients, good manufacturing practices (GMP), testing of products, regulatory guidelines for authorization of marketing, and correct storage and distribution practices.

THE EXPERT COMMITTEE ON SPECIFICATIONS FOR PHARMACEUTICAL PREPARATIONS

The development of norms, standards and guidelines for the quality assurance and quality control of pharmaceuticals is an essential global task. As a fundamental role of WHO, this task has been endorsed by many resolutions of the World Health Assembly. It is a task that WHO is uniquely suited to carry out.

Thus, guidelines on the quality assurance of pharmaceuticals are prepared in consultation with the 70-member WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations and are then evaluated by the WHO Expert Committee on Specifications for Pharmaceutical Preparations. The Expert Committee's original role of developing *The International Pharmacopoeia* has expanded over time and in light of new technologies. The Committee's rigorous consultative process involves WHO Member States, national authorities and international agencies such as the United Nations Children's Fund (UNICEF).

The Expert Committee is convened annually to decide on adopting the guidelines as international standards. The report of each meeting includes the newly adopted guidelines in its annexes.

VITAL TOOLS FOR GOOD-QUALITY MEDICINES

Through the quality assurance tools and systems developed under the auspices of the Expert Committee, WHO aims to ensure that all essential medicines, including those used in treating large populations, meet identical standards of quality, safety and efficacy.

Not only the health services and national medicines regulatory authorities (NMRAs) of WHO Member States worldwide, but also pharmaceutical manufacturers, international bodies – such as the Global Fund to Fight, AIDS, Tuberculosis and Malaria – and procurement agencies all depend on the Expert Committee's international guidelines, specifications and nomenclature. The output of the Expert Committee additionally supports global initiatives such as the WHO Prequalification of Medicines Programme, the Medicines for Malaria Venture, and Stop TB.

This brochure aims to give an insight into the Expert Committee's work by summarizing some of the vital tools for ensuring pharmaceutical quality that were discussed and approved in recent years. All current WHO quality assurance guidelines adopted by the Expert Committee on Specifications for Pharmaceutical Preparations, together with related training materials, are available in a structured format on CD-ROM and on the Internet. A list of current guidelines is included at the end of this document.

THE INTERNATIONAL PHARMACOPOEIA

The International Pharmacopoeia (Ph.Int.) is a collection of quality specifications for pharmaceutical substances (active ingredients and excipients) and dosage forms, together with supporting general methods of analysis. Its texts can be used or adapted by any WHO Member State wishing to establish legal pharmaceutical requirements.

The Ph.Int. is based primarily on medicines included in the current WHO Model List of Essential Medicines (EML). In recent years, priority has been given to medicines of importance in developing countries, including child-friendly dosage forms. International health funders and implementers of treatment programmes to combat AIDS, tuberculosis (TB) and malaria also rely heavily on the Ph.Int.

WHO collaborates with other organizations worldwide towards harmonization of pharmacopoeias. An Index of national, regional and international pharmacopoeias is maintained on WHO's website. In 2012 WHO hosted the first international meeting of world pharmacopoeias in Geneva and the forty-seventh Expert Committee endorsed the resulting recommendation to develop harmonized guidance on good pharmacopoeial practices under the aegis of WHO.