

### **The World Medicines Situation**



World Health Organization

# THE WORLD MEDICINES SITUATION



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### INTRODUCTION

This second review of the world medicines situation (first published in 1988 as *The World Drug Situation*) presents the available evidence on global production, research and development, international trade and consumption of pharmaceuticals. In addition, it draws on the most recent surveys and studies in WHO Member States to examine the state of national medicines policy. The aim is to provide an easily accessible source of information on the pharmaceutical situation at global and national levels.

Although the text is based on and around the available data, these data pose several challenges. For example, reliable data on the large pharmaceutical markets in the world's most populous countries, the People's Republic of China and India, are in short supply. Trade, production, expenditure and consumption data all come from different sources. In addition, the use of monetary values, rather than an indicator of volume, gives a distorted picture of production and consumption since it fails to reflect the scale of global consumption of traditional medicines and low-priced generics (both branded and non-branded).

Another problem is that certain key terms, such as "generic" medicines, are used differently by different parties, and usage is also changing. While 10 years ago the term "drugs" was widely used by WHO and other agencies, in today's usage this seems too vague and inclusive, and is increasingly understood to refer to illicit substances. As a result, the term "pharmaceuticals" is now increasingly used (meaning both medicines and vaccines) or alternatively "medicines". All three terms are used in this report, with explanations given when needed, and this is reflected in the change in title from the 1988 report.

Meanwhile, the pharmaceutical industry itself is difficult to define. Its products extend from first aid and cough remedies which are on sale to all, to highly specialized medicines for use only by hospital specialists. Some definitions bundle veterinary medicines and vaccines, bulk ingredients, medical devices and diagnostic products with finished pharmaceutical products. The Standard International Trade Classification (SITC Rev 3) distinguishes pharmaceuticals from medicaments and itemizes 57 four- and five-digit sub-items of these two commodities. Within these classifications the main focus of this report is medicines for human consumption, including those available only on prescription and those which can be purchased over the counter. However, in Chapters 1 and 3, the broader industrial and trade classifications are used.

The manufacturers of pharmaceuticals are numerous and diverse. At one end of the spectrum are the many firms of all sizes which collect and process herbs and medicinal plants for use in traditional medicine. No data are available on the volume of products involved. At the other end of the spectrum are large, "integrated" transnational corporations, with the capacity to develop new molecular entities and to manufacture, market and distribute medicines to most parts of the globe. Situated in between is a wide range of manufacturers differing in size, the kind of pharmaceuticals produced and in manufacturing and marketing techniques. In India, for example, 20 000 pharmaceutical manufacturers have been inventoried, but only 250 of these are in the "organized" sector, and they account for 70% of the country's total output of branded generics. Elsewhere, China's

rapidly growing pharmaceutical industry has an estimated 7500 manufacturers but, according to one source, only 87 of these have internationally accepted Good Manufacturing Practice certification.<sup>1</sup>

Finally, the pharmaceutical markets of the high-income countries differ widely from those in developing countries. Not only is per capita spending on health and medicines many times higher in high-income countries, but a much greater share of the medicines bill is publicly subsidized. In the lowest-income countries, spending on medicines comes largely from household resources and has to be paid for out of pocket at the time the person is ill. Markets also differ in the extent and effectiveness of regulation in areas such as medicine prices and safety. This report therefore covers a wide range of different products from multiple and varied sources, prescribed, purchased and consumed in very different domestic contexts.

The report does not attempt to deal in a comprehensive way with a number of key policy issues in medicines policy, such as parallel trade, intellectual property rights, counterfeiting, or corporate pricing strategy, around which vigorous debate continues at both the national and international level. Whilst WHO's concerns and policy positions are made clear at relevant points in the text, our primary aim is to provide an up-to-date set of basic information on the global medicines situation and on the current status of national medicines policies. It is hoped that these data will serve as a useful set of reference material for analysts, researchers and others concerned with the global pharmaceutical situation.

#### REFERENCE

<sup>1</sup> Patents, pills and public health. Can TRIPS deliver? PANOS Report No.46. London, PANOS Institute, 2002.



### WORLD MEDICINE PRODUCTION

#### SUMMARY

- Trends from 1985 to 1999 indicate that the value of medicine production has grown four times more rapidly than the world's income.
- Medicine production is highly concentrated in the industrialized countries, where just five countries – the USA, Japan, Germany, France and the UK – account for two-thirds of the value of all medicines produced.
- Large volume markets of lower-price medicines exist in the highly competitive domestic markets of China and India.
- A small number of transnational companies dominate the global production, trade and sales of medicines. Ten of these companies now account for almost half of all sales. This concentration has increased considerably since 1987.
- The 10 best-selling drugs account for 12% of the value of all medicine production.

#### 1.1

#### INTRODUCTION

This chapter summarizes available data on the pattern of global pharmaceutical production.<sup>i</sup> Production means the value added at each stage of the manufacturing process, whether it is the manufacturing of active ingredients in bulk from basic chemicals, the preparation of finished new medical entities, or the repackaging of imported generic ingredients to make finished branded or unbranded generic products. When measured in monetary terms, global production is geographically a highly concentrated activity, with over 90% of world production located in a few high-income countries. The relative market share of major producing countries has been fairly stable over the past decade.

Two-thirds of the value of medicines produced globally is accounted for by firms with headquarters in just five countries — the USA, Japan, Germany, France and the UK. Production is also concentrated in a few key products and in a relatively small number of

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