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15667

Distr.
LIMITED

PPD.46
14 August 1987

UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

ENGLISH

TARIFF AND NON-TARIFF MEASURES IN THE WORLD TRADE OF PHARMACEUTICAL PRODUCTS

(prepared by the UNCTAD secretariat for UNIDO)

Sectoral Working Paper Series

No. 59

Sectoral Studies Branch
Studies and Research Division

V.87-88651

SECTORAL WORKING PAPERS

In the course of the work on major sectoral studies carried out by UNIDO, Studies and Research Division, several working papers are produced by the secretariat and by outside experts. Selected papers that are believed to be of interest to a wider audience are presented in the Sectoral Working Papers series. These papers are more exploratory and tentative than the sectoral studies. They are therefore subject to revision and modification before being incorporated into the sectoral studies.

This paper was prepared for UNIDO by Karen McCusker under guidance of the UNCTAD secretariat. The views expressed do not necessarily reflect the views of the UNIDO secretariat.

Preface

This paper has been prepared by the UNCTAD secretariat for UNIDO's Studies and Research Division, Sectoral Studies Branch, in connection with its ongoing activities in the area of the pharmaceutical industry, a sector in which developing countries are expected to play an increasingly important role in the world's production and trade.

The report reviews recent changes in world trade, discusses tariff and non-tariff obstacles to trade and includes an analysis of the potential effects of tariff removal on the market of pharmaceutical products from developing countries.

The UNCTAD secretariat prepared this paper with the assistance of Ms. Karen McCusker. UNIDO expresses its appreciation for this valued inter-agency co-operation.

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References to dollars ($) are to United States dollars, unless otherwise stated.

...	indicates that data are not available or are not separately reported;
-	indicates that the amount is nil or negligible;
blank	indicates that the item is not applicable;

In tables totals may not add exactly because of rounding.

Abbreviations

CPE	Centrally planned economies;
DME	Developed market economy countries;
EFTA	European Free Trade Association;
GSP	Generalized system of preferences;
GSTP	Global system of trade preferences;
MFN	Most favoured nation
NTMs	Non-tariff measures
SITC	Standard International Trade Classifications;
UNSO	United Nations Statistical Office

Country Groupings

Developed market economies:

North America:	Canada, United States and United States Territories
West Europe (North):	Austria, Belgium, Denmark, Federal Republic of Germany, Finland, France, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Sweden, Switzerland, United Kingdom
West Europe (South):	Greece, Malta, Portugal, Spain, Yugoslavia, Israel
Japan:	Japan
Other:	Australia, New Zealand, Republic of South Africa

Developing countries:

Latin America:	South and Central America and the Caribbean, except Puerto Rico and the U.S. Virgin Islands
Tropical Africa:	All of Africa South of the Sahara, except for the Sudan and the Republic of South Africa

Developing countries: (cont'd)

North Africa:	Rest of Africa except for the Republic of South Africa
West Asia:	The Arab countries of Asia, and Iran, Turkey and Cyprus
South Asia:	Afghanistan, Bangladesh, Bhutan, Burma, India, Nepal, Pakistan, Sri Lanka
East Asia (Mfg):	The area of Hong Kong, Republic of Korea, Philippines, Singapore, Thailand
Southeast Asia:	Rest of Asia except CPE Asia, Taiwan Province of China and Japan, plus the South Pacific Islands

Centrally planned economies:

Asian:	People's Republic of China, Democratic Kampuchea, Democratic People's Republic of Korea, People's Democratic Republic of Lao, Mongolia, Viet Nam
European:	Albania, Bulgaria, Czechoslovakia, German Democratic Republic, Hungary, Poland, Romania, Union of Soviet Socialist Republics

1. INTRODUCTION

Drugs, or pharmaceuticals, are an essential personal and public good. Like adequate nutritional levels, the availability of primary health care and essential drugs are critical to human welfare; secure supply of safe and effective drugs at reasonable cost is a social responsibility and should be a priority goal of public authorities.

Global health care expenditures are unevenly distributed; industrialized countries are estimated to account for over 90 per cent of the world total.[1/] On the other hand, the developing countries, containing three-quarters of the world population, account for twenty-five per cent of the world drug bill.[2/] Thus, the share of pharmaceuticals in health care expenditures is considerably higher in developing than in industrialized countries: one-third to one half versus one-sixth.[3/] This may be partly due to the low ratio of medical personnel to the overall population in the developing countries, as well as low salaries, and the fact that health care workers are concentrated in the urban areas with limited access to the majority of the population in the rural areas. The drug industry will undoubtedly continue to grow rapidly along with the aging of the population in the industrialized countries and the increase in population and level of economic development in developing countries. How production and trade in the world pharmaceuticals industry will evolve depends to a certain extent on the policy responses to structural changes in the industry.

Although not exceptional compared to other high-technology industries, a principal feature of the industry is the dominant share held by the leading drug producers. The world's fifty largest privately owned drug companies account for nearly two-thirds of the world (excluding centrally planned economies) pharmaceutical sales.[4/] The concentration in the industry, more particularly in therapeutic submarkets, results from economies of scale in the considerable and rising research and development expenses, as well as in quality control and marketing costs.[5/] Promotional efforts in the industry are directed towards the decision maker, usually the prescribing physician, who has no incentive to economize, rather than the end user. Generally, in

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1/ UNCTAD, "Guidelines on technology issues in the pharmaceutical sector in developing countries", UNCTAD/TT/49, United Nations, New York, 1982, UN Sales No.E.82.II.D.15, page 36.

2/ World Development, Vol. 11, No. 3, March 1983, p. 197.

3/ Ibid, p. 170.

4/ United Nations Centre on Transnational Corporations, "Transnationals and the Pharmaceutical Industry", New York, 1979, UN Sales No. E.79.II.A.3, page 3.

5/ These have also risen as a proportion of overhead with the demand for more detailed scientific information.

the drug industry loyalty to brand name products identified with superior quality,[6] rather than price considerations, determine demand. On the supply side, the regulatory environment, patent protection and trademarks raise entry barriers and curtail competition.

Product or process patent protection induces socially beneficial research that might otherwise not be undertaken. The degree of this protection varies considerably between countries and where it exists its effects are often mitigated by compulsory licensing. However, the lifetime of many patents has now expired and much of drug technology, particularly for essential drugs, is in the public domain.[7] These so-called mature products are more likely to compete on price. Still, pharmaceutical technology requires considerable skills, capital and access to relevant information and the pricing policy must allow for ongoing investment in research.

Where patent protection leaves off, trade marks[8] pick up leading to imperfect substitutability between comparable products. Product differentiation, a key factor in the competitive strategy of the drug industry, aims to assure a certain price elasticity of demand. The appeal of brand name drugs, based on a manufacturer's reputation, may allow for excessive pricing sustainable when the buyer is not involved in the choice and justified by the producer in order to finance research costs.

While preference patterns based on price insensitivity and demand for quality assurance are characteristic of innovative industries, it is apparent that true innovation has slowed radically in the pharmaceuticals industry in the last two decades. Yet the need to bring new products to the market has resulted in a proliferation of sometimes unnecessary drugs. An obvious impact of product differentiation is its hampering effect on substitution of brand name with generic (non-proprietary) drugs, although, it may be noted, that prescribing generic drugs is not a sure form of price competition as it simply transfers the product choice from the physician to the pharmacist (who may well obtain a higher profit margin on the branded drug). Indeed, limiting profit margins is one way countries control local selling prices. Price review, control and approval procedures also have been instrumental in reducing excessive pricing. These activities on the part of the manufacturers and the regulators inevitably lead to different prices in different markets affecting international trade by leading to parallel imports and transfer pricing irregularities.

6/ A false assumption since branded and generic drugs have been found substandard with about equal frequency, see UNCTAD/TT/49, p. 13.

7/ UNCTAD/TT/49, op. cit., para. 153.

8/ More than forty per cent of the trademarks used throughout the world are estimated to relate to pharmaceuticals and associated goods. (SCRIP, no. 618, August 1981).

Some of the slowdown in innovation in the industry has been attributed to the regulatory environment and the requisite administrative apparatus is burdensome even for the most affluent countries.[9/] Government regulations vary between countries, being more restrictive in northern than southern Europe and often quite lax in developing countries. Typical procedures in industrialized countries involve product approval and registration along with price reviews or controls. Thus, the Food and Drug Administration of the United States monitors the developmental phase of research and development, approves drugs for safety and efficacy and controls advertising practices. Norway's "need clause" reduces the assortment of products by limiting registration to products "which are medically justified and which are considered to be needed."[10/] The registration procedure in France ensures that all drugs are manufactured there, while products to be marketed in Japan must undergo clinical testing in that country.[11/] These product approval measures effectively limit imports of finished products.

9/ WHO, Conference of Experts on the Rationale Use of Drugs, Nairobi, 25-29 November 1985, "The role of WHO in the transfer and dissemination of information on drug quality, safety and efficacy", see WHO/CONRAD/WP/1.2, para. 6.

10/ WHO, Action Programme on Essential Drugs and Vaccines, DAP/84.4, para. 121.

11/ UNCTC, op. cit., pp. 70-71.

2. INTERNATIONAL TRADE IN PHARMACEUTICALS

Between 1970 and 1984, world exports of pharmaceuticals rose from $US 6.7 billion to $US 17 billion in constant 1980 prices. Developed market economies continue to account for over 90 per cent of exports and nearly 70 per cent of imports (see tables 1 and 2). While industrialized countries, both market and centrally planned economies, account for the bulk of the pharmaceutical production and exports, developing countries produced 11 per cent of world pharmaceuticals in 1980[12/] and accounted for 6.3 per cent of world exports.

Within the traded pharmaceuticals sector, preparations account for over two thirds of the value of exports trailed by antibiotics with a 10.7 per cent share of world pharmaceutical exports. As of 1984,[13/] developing countries accounted for 3.8 per cent of world exports of medicaments and pharmaceutical goods, but 30.5 per cent of world imports, 5.2 per cent of global exports of antibiotics, but 21 per cent of global imports, and 9.7 per cent of exports of hormones, down from 27 per cent in 1970, presumably due to competition from innovation in biotechnology.

The developing regions of Latin America and East Asia are particularly important in the exports of pharmaceuticals from developing countries. In Latin America, the Bahamas, Panama, Brazil, Argentina and Mexicc are leading exporters, while in Asia, Singapore, the area of Hong Kong, the Republic of Korea and to a lesser extent India and Indonesia, account for much of the export supply. Indonesia and Zaire are solely exporters of alkaloids, while the other exporters are more diversified. In recent years, since 1980, there seems to have been an alarming decline in exports from developing countries, particularly in hormones and antibiotics, although some of this may be explained by under-reporting of trade between developing countries,[14/] which accounts for approximately 60 per cent of developing country exports (see table 3). However, while overall exports of medicaments and pharmaceutical goods from developing countries have declined between 1980 and 1984, the decrease has been in Latin America, while East Asia's exports, mainly those from the Republic of Korea and Singapore, have grown rapidly, some of this increase coming from trade with Japan, traditionally a significant importer of pharmaceuticals.[15/]

In many cases, export flows of developing countries have shifted from other developing countries to industrialized regions, as imports of the former have slowed. This may be attributable to saving measures, following balance of payments difficulties, which in many countries took the form of limiting non-essential imports and raising trade barriers. Other possible reasons for the drop in exports include new drug technologies which would tend to give the industrialized countries a trade advantage or the impact of additional standards and more restrictive policies implemented in the last few years.

12/ UNCTAD, "Guidelines...", op. cit., para. 42.

13/ See note to table 1.

14/ For many developing countries, trade information can be several years late in reporting.

15/ UNIDO trade matrix.

Table 1. Pharmaceutical exports, 1970, 1980 and 1984 (millions of constant[a/] 1980 dollars)

Product group	Year	World	Developed market economies	Developing countries	Centrally planned economies
Vitamins	1970	378	363	6	7
	1980	861	824	8	29
	1984	1,103	1,061	4	37
Antibiotics	1970	639	575	39	24
	1980	1,515	1,286	138	84
	1984	1,777	1,587	92	97
Alkaloids	1970	517	446	49	22
	1980	601	530	37	34
	1984	710	620	42	49
Hormones	1970	289	208	79	22
	1980	630	529	91	9
	1984	595	530	58	8
Glycosides, glands and vaccines	1970	301	279	17	5
	1980	951	889	43	19
	1984	1,151	1,085	39	27
Medicaments and pharmaceutical goods	1970	4,532	4,255	215	61
	1980	9,784	8,685	573	517
	1984	11,716	11,147	445	124
Total	1970	6,657	6,127	405	120
	1980	14,343	12,745	893	693
	1984	17,052	16,030	680	342

a/ UNIDO Fisher type price indices.

Source: UNSO Trade tapes using partner-reported data.

Note: 1984 data should be considered preliminary as reporting is not yet complete.

Table 2. Pharmaceutical imports, 1970, 1980 and 1984 (millions of constant[a/] 1980 dollars)

Product group	Year	World	Developed market economies	Developing countries	Centrally planned economies
Vitamins	1970	424	327	80	16
	1980	967	701	218	48
	1984	1,203	930	230	43
Antibiotics	1970	647	457	186	3
	1980	2,070	1,487	545	36
	1984	2,559	1,970	548	41
Alkaloids	1970	492	404	74	13
	1980	640	514	126	10
	1984	780	641	129	11
Hormones	1970	208	162	40	4
	1980	653	490	146	16
	1984	728	581	131	16
Glycosides, glands and vaccines	1970	320	220	94	5
	1980	879	660	192	21
	1984	1,047	830	201	16
Medicaments and pharmaceutical goods	1970	4,904	2,814	1,916	115
	1980	10,008	5,676	3,572	742
	1984	12,166	8,173	3,706	381
Total	1970	6,995	4,384	2,390	156
	1980	15,217	9,528	4,799	873
	1984	18,483	13,025	4,945	508

a/ UNIDO Fisher type price indices.

Source: UNSO Trade tapes using partner-reported data.

Note: 1984 data should be considered preliminary as reporting is not yet complete.

Table 3. Commodity structure of selected trade flows in pharmaceuticals, 1980 (percentages)

Product group	Developed market economies exports to:			Developing country exports to:		
	Other developed market economies	Developing countries	Centrally planned economies	Other developed market economies	Developing countries	Centrally planned economies
Vitamins	75.6	19.6	4.8	35.1	64.6	-
Antibiotics	70.6	25.4	4.0	76.2	23.8	-
Alkaloids	77.3	17.5	5.2	72.3	11.2	16.5
Hormones	74.0	23.2	2.8	68.6	31.5	-
Glycosides, glands and vaccines	76.5	20.8	2.7	63.5	34.3	2.0
Medicaments and pharmaceutical goods	58.8	35.8	5.4	13.2	74.1	12.4
All	63.8	31.3	4.9	29.7	60.5	9.6

Source: UNSO Commodity Trade Tapes, Series D.

3. RESTRICTIONS TO TRADE IN PHARMACEUTICALS

For industrialization plans of developing countries to achieve their economic objectives a most important investment criterion is an evaluation of the international trading environment, especially where domestic markets are too small to support a given industry.

The trade environment in the pharmaceutical industry is particularly complex. Patent protection and trademarks, product approval procedures and price controls all influence the structure of the international market. Given that safety, efficacy and quality are at least as important as price in determining demand, pharmaceutical products that can offer assurance of their therapeutic value will tend to be favoured over cheaper drugs which may be perceived as being somehow less reliable. Countries lacking a comprehensive and fully independent system of drug control are limited in their capability to assure adequate standards.

The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, adopted in 1975, imposes obligations on exporting countries regarding the enforcement of internationally recognized standards of manufacturing practices. In the long run, this will have the effect of making products, regardless of source, more competitive. However, the effective operation of the scheme is impeded by numerous problems such as ambiguities because drug regulation of licensing differs conceptually or operationally in different countries.[16/] With regard to efficacy, various international codes and UN resolutions have stressed the need for full disclosure of scientific information.

Thus, in addition to restrictions such as tariffs and non-tariff measures, differences in national health policies and regulations, administrative costs to meet minimum international standards, as well as lack of market transparency, are formidable obstacles to international trade.

3.1 Tariffs

A tariff is a tax placed on a product as it enters the country, calculated either as a monetary amount in relation to the volume of goods entered, or as a percentage of the value of the goods as assessed at the point of entry. Comparing levels of tariff protection in various countries is complicated by a lack of detailed computerized tariff-line data on tariffs and trade for many countries. Such information is readily available for most developed market economies only. For those countries for which detailed information is available, weighted average tariff rates have been calculated.[17/] That is, a tariff average for each tariff line is calculated using actual trade weights together with the import duty; subsequently, the

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16/ See WHO, Conference of Experts on the Rationale Use of Drugs, 25-29 November 1985, Nairobi, "The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce", WHO/CONRAD/WP/2.6, para. 25.

17/ The tariff rates used are 1983 applied rates weighted by 1983 trade weights.

average rate for each tariff line is aggregated to the product group level using weights based on the tariff line's importance in the total imports of a product group. Such an average is widely considered to give an unduly low reflection of the tariff situation since imports will tend to be inversely related to tariff levels; however, a simple unweighted average gives a less meaningful picture.

For those countries for which the required information is available in UNCTAD's Trade Information System,[18/] trade-weighted average tariffs of developing countries on imports from industrialized countries range from 9.5 per cent on glycosides, glands and vaccines to as high as 15.9 per cent on vitamins. Vis-à-vis developing countries, tariffs are even higher with a low of 11.6 per cent on alkaloids to 19.6 per cent on antibiotics. With respect to individual developing countries, Indonesia, Malaysia, Singapore, Sri Lanka, Saudi Arabia, Tunisia, Algeria and Egypt exhibit the lowest degree of tariff protection (duties lower than 10 per cent) and Singapore applies no import duties on any pharmaceutical products.

In the major developed market economies (DMEs), tariff rates are applied differentially in accordance with trade agreements such as the Generalized System of Preferences (GSP), European Free Trade Association (EFTA) agreements and others. Industrialized countries have been allowed to grant tariff preferences to developing countries under the Generalized System of Preferences since 1971. The margin of preference applied to developing countries varies considerably between individual importing markets (see table 4 and 5a) with the highest weighted average applied tariff rate occurring in the EEC and the lowest in the United States. It is also apparant from table 4 that, irrespective of source, tariffs on imports of medicaments and pharmaceutical goods are noticeably higher than on other products in the majority of markets and in a number of European markets are higher against developing countries. This suggests that tariff escalation,[19/] i.e. protection increases at higher levels in the processing chain, also occurs in the pharmaceutical sector and may inhibit the process of industrialization.

For the aggregate of the twenty developed market economies (including the 10 EEC countries) considered (table 5), a slight overall preference in total pharmaceutical products imported from GSP beneficiaries is apparent, 2.7 per cent versus 3 per cent. (It should be noted that because of tradeweighting, a higher rate against GSP beneficiaries may occur if imports mainly fall under those product groups or tariff-line items subject to higher duties.) By individual product group (table 5b), GSP beneficiaries face lower tariff rates than non-preference receiving countries on antibiotics, hormones and glycosides, glands and vaccines, but higher rates in alkaloids, 4 per cent versus 2 per cent and medicaments and pharmaceutical goods, 3.6 per cent versus 3.0 per cent.

18/ A UNDP supported project related to economic co-operation between developing countries. Information is being expanded, but at present relatively little information is held on preference rates under regional trade agreements.

19/ See UNCTAD, "The Kennedy Round: estimated effects of trade barriers", TD/6/Rev.1, New York.

Table 4. Weighted average applied 1983 tariff rates facing imports of pharmaceuticals from (1) preference receiving, and (2) non-preference receiving countries

Product group	Australia (1)	Australia (2)	Austria (1)	Austria (2)	Canada (1)	Canada (2)
Vitamins	0.0	0.0	0.0	0.0	3.0	7.4
Antibiotics	0.0	0.0	0.0	0.0	1.5	4.3
Alkaloids	0.0	0.0	0.0	0.0	1.1	1.9
Hormones	0.0	0.0	0.0	0.3	2.4	8.2
Glycosides, glands and vaccines	0.0	0.0	10.2	2.1	0.7	0.4
Medicaments and pharmaceutical goods	0.8	1.3	13.5	0.2	6.6	10.1

Product group	EEC (1)	EEC (2)	Finland (1)	Finland (2)	Japan (1)	Japan (2)
Vitamins	4.0	1.3	0.0	0.0	2.3	5.0
Antibiotics	5.0	5.1	0.0	0.0	2.4	4.8
Alkaloids	5.3	1.1	0.0	0.0	4.0	5.7
Hormones	5.3	5.3	0.0	0.0	2.3	5.8
Glycosides, glands and vaccines	5.2	2.4	0.0	0.0	1.4	3.1
Medicaments and pharmaceutical goods	4.8	1.8	1.5	0.0	2.9	4.6

Product group	New Zealand (1)	New Zealand (2)	Norway (1)	Norway (2)	Sweden (1)	Sweden (2)
Vitamins	0.0	4.8	...	0.0	0.0	0.0
Antibiotics	0.0	4.3	...	0.0	0.0	0.0
Alkaloids	0.0	2.3	0.0	0.0	0.0	0.0
Hormones	0.0	0.0	...	0.0	0.0	0.0
Glycosides, glands and vaccines	0.0	2.0	0.0	0.0	0.0	0.0
Medicaments and pharmaceutical goods	4.5	18.8	2.9	0.6	2.9	1.7

Product group	Switzerland (1)	Switzerland (2)	United States (1)	United States (2)
Vitamins	0.6	0.1	0.4	3.3
Antibiotics	0.1	0.1	0.0	3.9
Alkaloids	0.2	0.1	0.1	3.5
Hormones	0.1	0.0	0.3	5.2
Glycosides, glands and vaccines	0.3	0.1	0.1	3.1
Medicaments and pharmaceutical goods	0.7	0.0	0.0	4.2

Note: ... denotes no trade.

Table 5a. Weighted average applied 1983 tariff rates facing imports of pharmaceuticals in major developed market economies, by importer (percentages)

Importer	Imports from: GSP beneficiaries	Non-GSP beneficiaries
Australia	0.4	0.9
Austria	3.5	0.3
Canada	3.5	6.6
EEC (10)	5.0	2.6
Finland	0.6	0.0
Japan	2.4	4.6
New Zealand	3.5	16.7
Norway	2.8	0.0
Sweden	1.5	0.2
Switzerland	0.3	0.1
United States	0.2	3.7
Total	2.7	3.0

Table 5b. Weighted average applied 1983 tariff rates facing imports of pharmaceutical product groups in major developed market economies, by product group (percentages)

Product group	GSP beneficiaries	Non-GSP beneficiaries
Vitamins	2.6	2.5
Antibiotics	2.6	4.3
Alkaloids	4.0	2.0
Hormones	2.7	4.7
Glycosides, glands and vaccines	1.3	2.3
Medicaments and pharmaceutical goods	3.6	3.0
Total	2.7	3.0

Source: GATT trade and tariff tapes.

3.2 Non-tariff measures

While the role of tariffs as trade barriers has been declining due to a series of multilateral negotiations under the General Agreement on Tariffs and Trade (GATT) since 1948, the application of non-tariff measures (NTMs) and their restrictive effects has become more intensive in both absolute and relative terms. The concept of non-tariff measures embraces all types of governmental measures which have an actual or potential effect on trade flows. They introduce unequal treatment between domestic and foreign goods of the same or similar production, thereby actually creating distortions in trade flows. From the viewpoint of international price stability, a tariff is preferable to a quantitative restraint, since, under a fixed import quota, demand is rather insensitive to changes in world prices. Under tariffs, domestic firms are still faced with the threat of foreign competition if their prices become excessive. However, where a quota is applied, this competitive stimulus is missing since this sets a limit on the extent of potential entry of foreign firms.[20/] Furthermore, non-tariff distortions create uncertainty and curtail transparency in the international trading system; in general they are considered more detrimental than tariffs for the international community.

The NTMs for which information is stored in the UNCTAD Data Base on Trade Measures could be classified into at least three broad categories: price controls (to ensure that goods do not sell below a certain minimum level), volume controls (which include import authorizations and prohibitions), and technical barriers (intended to ensure that products meet certain domestic or international standards).

In pharmaceuticals, technical barriers to trade predominate in the form of health and safety regulations as well as packaging and advertising. However, these are rarely taken into account when analyzing protectionist trends. Technical barriers can impose considerable uncertainty costs on foreign exporters who may be unfamiliar with standards and methods of certification. On the other hand, the mere presence of industrial standards that differ from country to country creates international price differences that have nothing to do with barriers to trade.[21/]

In assessing the trade restrictive effects of non-tariff barriers or distortions, various measures can be employed. If the direct price effects can be determined, for example in the case of a minimum import price or variable levy, the ratio of the import charge to the final price of the product provides a fairly reliable estimate of the ad valorem equivalent of the non-tariff barrier. In cases where such ad valorem equivalents cannot be derived, other indicators must be used. The indicator used here is the trade

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20/ Yeats, A., "Trade barriers facing developing countries", London, Macmillan Press, 1979.

21/ Deardorff, A.V. and Stern, R.M., "Methods of measurement of non-tariff barriers", United Nations, UNCTAD, Geneva, 1985, UNCTAD/ST/MD/28, para. 115.

coverage index which gives the ratio of the value of trade affected by NTMs to the total value of trade in the product group. This index suffers from the fact that items which are subject to very restrictive trade measures are automatically accorded zero or very low weights in the overall index because of the resultant zero or low trade leading to a lower index value. In other words, any computation based on the observed volume or value of imports can be misleading since NTMs are applied with the precise aim of distorting volume or value of potential imports.[22/]

As can be seen from table 6, the developed market economies' imports of pharmaceutical products from each other are subject to percentagewise far more selected non-tariff measures than is the trade in all products (less fuels). The case is the opposite with respect to imports from the developing as well as socialist countries. It is striking that nearly one half of the world imports of medicaments and pharmaceutical goods is affected by non-tariff measures, and that the developed market economies encounter a greater degree of protectionism in their intra-regional trade than in their commerce with other regions. This is difficult to interpret since the high index number, instead of implying that other developed market economies are more affected, could imply that the actual level of imports from developing countries has been more successfully reduced by the restrictions. It should be noted that the NTMs considered do not include technical barriers, such as health and safety regulations, and that the indices apply only to price and volume controls. It should also be kept in mind that the data produced here are only for a limited number of developed market economies, as for several countries information on non-tariff measures in pharmaceuticals is not available.

Price controls, in the context of non-tariff measures, are not very significant in the industry except in the case of the United States where imports from certain other developed market economies face anti-dumping duties, primarily in vitamins and medicaments. The extent to which quantitative restrictions and technical barriers affect imports varies considerably from country to country and between product groups with the majority of the measures affecting medicaments. For antibiotics documented restrictions appear for only a few countries: Switzerland applies import licensing and Italy's imports from socialist countries are affected by country quotas. In the case of alkaloids, Japan applies import permits and global quotas and Canada employs the former measure. It should be noted, however, that alkaloids are dominated by codeine which is also a narcotic. As such it is subject to international control to which all countries have agreed. In the Scandinavian countries, a state monopoly controls all pharmaceutical imports of Norway and health and safety regulations dominate in Sweden, as they do in several countries, particularly for medicaments.[23/] For developing countries, import authorization seems to be the preferred non-tariff measure.

22/ UNCTAD, "Non-tariff barriers affecting the trade of developing countries and transparency in world trading conditions: the inventory of non-tariff barriers", TD/B/940, Geneva, 1983, para. 24.

23/ Official sources: Customs tariff for Japan, Switzerland and Sweden; D-19 Memos for Canada; GATT Report L/5265 for Norway; Trade Action Monitoring System for the United States and EEC Official Journal for Italy.

Table 6. Trade coverage index of non-tariff measures[a/] applied by major developed market economy countries[b/]

Product group	Against developed market economies	Against developing countries	Against centrally planned economies	Against world
Vitamins	13.8	0.0	0.1	13.0
Antibiotics	7.8	3.4	12.3	7.3
Alkaloids	23.4	15.4	10.8	21.7
Hormones	0.3	0.0	0.0	0.2
Glycosides, glands and vaccines	7.8	3.0	3.5	7.1
Medicaments and pharmaceutical goods	46.1	35.9	25.9	45.6
All pharmaceutical products	28.4	10.0	10.0	26.8
All imports (less fuels)	15.8	20.9	23.7	17.6

a/ Excludes para-tariff measures as well as, more importantly, technical barriers (i.e. health and safety regulations).

b/ Not available for most EEC members.

Source: UNCTAD Data Base on Trade Measures.

4. POTENTIAL TRADE EXPANSION EFFECTS FROM TRADE LIBERALIZATION

A study of trade barriers and the potential effects of their elimination has inherent limitations and may even distract attention from other, perhaps more important, issues of the health care sector. Despite a lack of detailed and comprehensive statistics on obstacles to trade, and given that price competition has an insignificant influence on trade in pharmaceuticals, a partial and tentative evaluation of the effects of trade liberalization is presented below, using UNCTAD's Trade Policy Simulation Model.[24/]

The estimate of potential expansion of imports into major developed market economies is based on a number of different scenarios. These include the following simulations: (i) removal of tariffs on all imports, i.e. elimination of all preferences by setting the MFN (most favoured nation) rate equal to zero for all products from all sources; (ii) elimination of preferences for developing countries by moving their preferential rates to the level of the MFN rate as applied in 1983, and (iii) full extension of preferences by reducing preferential rates to zero on all products in all importing markets. The latter two simulations then enable one to assess the actual and potential benefits of the Generalized System of Preferences.

In all of the simulations two distinct effects are calculated, trade creation and trade diversion. The trade creation (or loss) effect results from the change in domestic demand for imports as reflected by the domestic price change after the tariff change. The trade diversion effect results from the changes in the relative domestic prices of imported goods from preference receiving and non-preference receiving countries resulting from changes in the preferential margin.

As can be seen from table 7, the complete tariff removal on pharmaceutical imports on the part of major developed market economies would result in a $US 230 million, a four per cent, increase in imports from all trading partners. (N.B. Intra-EEC trade is not included in the import data.) Clearly, under this liberalization scenario because of trade diversion due to the erosion of preference margins, imports from non-preference receiving countries increase more (by 4.1 per cent) than do those from preference receiving countries (2.2 per cent) who no longer benefit from preferential treatment.

The EEC, the United States and Japan account for 90 per cent of imports from GSP beneficiaries (see table 8). The greatest expansion of imports from GSP beneficiaries takes place in the EEC market, 9.3 per cent. By contrast, imports from GSP beneficiaries by the United States would actually decrease by 4 per cent, indicating that the current preferential treatment by the United States in pharmaceutical products is particularly advantageous to developing countries.

As GSP beneficiaries enjoy the greatest margins of preference on antibiotics, hormones and glycosides, glands and vaccines, these product groups show the smallest percentage increase, and, in fact, imports of the

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24/ For a description of the model, see Laird, S. and Yeats, A. "The UNCTAD Trade Policy Simulation Model", UNCTAD Discussion Paper, forthcoming.

Table 7. Trade effects of simulated changes in tariff rates applied by major developed market economies to pharmaceuticals

Supplier	Total 1983 imports $1,000	Change in trade resulting from: Zero rate for all countries[a/] $1,000	%	Full extension of GSP[b/] $1,000	%	Elimination of GSP[c/] $1,000	%
GSP beneficiaries	368,277	7,930	2.2	21,929	6.0	-25,229	-6.9
Non-GSP beneficiaries	5,389,447	222,522	4.1	-7,324	-0.1	8,818	0.2
Total	5,757,724	230,452	4.0	14,605	0.3	-16,411	-0.3

a/ Elimination of all preferences by setting the MFN rate equal to zero for all products from all sources.

b/ Preference rate reduced to zero on all products in all markets.

c/ Complete elimination of preference for developing countries by moving their preference rate to the level of the MFN rate as applied in 1983.

Source: UNCTAD Trade Policy Simulation Model.

Table 8. Potential trade expansion effects assuming zero-rate tariffs on all pharmaceutical imports

Origin / Importing market	All: 1983 imports $million	All: trade change $million	All: %	GSP beneficiaries: 1983 imports $million	GSP beneficiaries: trade change $million	GSP beneficiaries: %	Non-GSP beneficiaries: 1983 imports $million	Non-GSP beneficiaries: trade change $million	Non-GSP beneficiaries: %
All	5,757.7	230.5	4.0	368.3	7.9	2.2	5,390.4	222.5	4.1
of which:									
EEC	1,843.6	83.5	4.5	122.1	11.4	9.3	1,721.5	72.1	4.2
United States	834.8	44.3	5.3	84.9	-3.4	-4.0	749.9	47.7	6.3
Japan	1,215.1	34.9	2.9	124.4	0.2	0.2	1,090.7	34.7	3.2

Source: UNCTAD Trade Policy Simulation Model.

latter product group are actually reduced (see table 9). Ceteris paribus, the product groups that experience the largest increase from non-GSP trading partners are hormones and antibiotics. Imports of alkaloids from GSP beneficiaries, which receive no preferential tariff treatment (see table 5b), expand more than the rest of the world under complete tariff removal.

In order to explore in greater detail what the benefits in this industry are to preference receiving countries, it is instructive to look at table 10 which shows the decline in imports if preferences are eliminated, as well as the possible increase if preferential rates are reduced to zero on all products in all markets (the full extension of the GSP). One can surmise that actual preferences account for over $US 25 million, or nearly seven per cent, of the 1983 imports from developing countries. However, it is also apparent that a full extension of the GSP would boost pharmaceutical imports from developing countries by an additional $US 22 million, or six per cent. While the elimination of preferences would particularly affect imports of antibiotics and hormones, which currently enjoy strongly preferential treatment (mainly in the United States, Canadian and Japanese markets), under a full extension of preferences, medicaments and pharmaceutical goods would exhibit the largest percentage increase, 8.7 per cent.

Table 9. Changes in pharmaceutical imports by product group of major developed market economies simulating zero-rate tariffs on imports from all countries

Product group	GSP beneficiaries			Non-GSP beneficiaries		
	Imports 1983 $1,000	Change $1,000	%	Imports 1983 $1,000	Change $1,000	%
Vitamins	22,787	513	2.2	457,154	18,296	4.0
Antibiotics	111,495	2,148	1.9	840,849	56,014	6.7
Alkaloids	32,859	1,832	5.6	246,081	7,807	3.2
Hormones	71,869	1,412	2.0	202,614	15,826	7.8
Glycoside, glands and vaccines	64,313	-309	-0.5	621,747	20,294	3.3
Medicaments and pharmaceutical goods	64,954	2,334	3.6	3,021,002	104,286	3.5

Source: UNCTAD Trade Policy Simulation Model.

Table 10. Changes in pharmaceutical imports by product group of major developed market economies from GSP beneficiaries simulating elimination/full extension of GSP rates

Product group	Imports 1983 $US 1,000	Changes resulting from Elimination of preferences $US 1,000	%	Full extension of preferences $US 1,000	%
Vitamins	22,787	-1,488	-6.4	1,452	6.4
Antibiotics	111,495	-1,488	-7.2	6,277	5.6
Alkaloids	32,859	-1,831	-5.6	2.349	7.2
Hormones	71,869	-6,510	-9.1	4,549	6.3
Glycosides, glands and vaccines	64,313	-2,253	-3.5	1,677	2.6
Medicaments and pharmaceutical goods	64,954	-5,146	-7.9	5,624	8.7

Source: UNCTAD Trade Policy Simulation Model.

5. POTENTIAL TRADE EXPANSION AMONG DEVELOPING COUNTRIES

While local production of pharmaceuticals in developing countries is limited by scarce financial and technical resources, six developing countries with populations large enough to support domestic production have established vertically integrated industries (Argentina, Brazil, Egypt, India, the Republic of Korea and Mexico).[25/] A sizeable national population is imperative since developing countries, especially in the early stages of production, find it difficult to compete in the international market. Hence, policies to foster infant industries in developing countries often include the use of protective trade barriers. Among the developing countries, only a few like India, Brazil, the People's Republic of China and Mexico are in a position to offer technical advice and the hardware for drug formulation.[26/] Where it is not feasible to domestically produce pharmaceuticals, there are other ways to secure drugs at reasonable cost, many of which are key projects in the work programmes of the World Health Organization and other international bodies. One which bears directly on trade is centralized purchasing within economic zones of co-operation which improves the importer's bargaining power and is a powerful instrument for rationalizing drug use, an objective also being effected by increased emphasis on the use of generics to fill essential drug needs. Just the same, however, such economic co-operation could also constitute the economic rationale for regional production for regional markets.

With respect of pharmaceuticals trade among developing countries (imports from other developing countries account for only 12 per cent of developing countries' pharmaceutical imports), the proposed global system of trade preferences among developing countries (GSTP)[27/] would yield substantial benefits (see table 11). Using the UNCTAD Trade Policy Simulation Model for the limited number of developing countries for which data are available and simulating full preferences on imports from developing countries, South-South trade in pharmaceuticals would increase by $US 60 million or twenty per cent.[28/] This $US 60 million is a more impressive figure than the

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25/ World Development, op. cit., page 283.

26/ Muller. M. "The Health of Nations: A North-South Investigation", Faber & Faber, London, 1982.

27/ The proposal was made in 1976 to establish the GSTP in order to "promote the development of national production and mutual trade" among developing countries; since then, the UNCTAD secretariat has been active in collecting information and producing a number of studies on the potential of the GSTP.

28/ This simulation is based on the assumption that (i) tariffs are completely eliminated amongst developing countries; (ii) NTBs are lifted sufficiently to permit the predicted expansion to take place; (iii) the developing countries can fully meet the rise in demand (perfectly elastic supply); and (iv) an elasticity of substitution between developed and developing countries equal to 1.5. For a discussion on this latter point, see Cline, et al, "Trade Negotiations in the Tokyo Round - A Qualitative Assessment", The Brookings Institution, Washington, D.C., 1978, pp.60-62.

approximately $US 25 million expansion in imports from developed market economies, but still constitutes only a fraction of annual research expenditures in industrialized countries.[29/]

Table 11. Potential trade expansion effects among developing countries simulating full preferences under the GSTP

Product group	Total imports $US million	Change $US million	Imports from developing countries $US million	Change $US million	%
Vitamins	207	1.5	7.9	2.7	34.2
Antibiotics	517	9.9	50.5	17.2	34.1
Alkaloids	84	0.4	2.7	0.8	29.6
Hormones	125	1.9	12.0	3.4	28.3
Glycosides, glands and vaccines	143	0.5	8.4	1.5	17.9
Medicaments and pharmaceutical goods	2,493	2.9	218.7	35.2	16.1
Total	3,569	17.1	300.2	60.8	20.3

Source: UNCTAD Trade Policy Simulation Model.

29/ World Development, op. cit., p. 262.

6. AREAS OF NORTH-SOUTH CO-OPERATION

The reduction or elimination of tariffs is an integral part of North-South economic co-operation and the expansion and diversification of exports from developing countries. The full extension of preferences by the developed market economies, i.e. the preferential removal of tariffs, would clearly boost pharmaceutical exports of developing countries. But non-tariff barriers, mainly volume controls and technical barriers, which curtial market transparency, create greater obstacles to trade. Non-tariff barriers, in the form of price and volume controls, particularly in medicaments and pharmaceutical goods, have an impact on both North-North and North-South trade. Their removal should be recognized as an important item in multilateral trade negotiations. Technical barriers, primarily national health and safety regulations, emanate from domestic rather than trade policy and are therefore not necessarily subject to international trade negotiations.[30/] Instead, information exchange, as provided by WHO, on drug acceptability and national regulations, is a means to improve market transparency. However, no mechanism for international exchange of regulatory information can operate effectively where there is no indigenous system of drug regulation.[31/] Furthermore, the internationalization of standards, such as the Certification Scheme mentioned above, is an important effort towards non-discriminatory trade relations.

At present the largest share of pharmaceutical exports of developing countries are traded intra-regionally even though tariffs between developing countries are comparatively high. Under the global system of trade preferences, a reduction of tariffs on pharmaceuticals by developing countries should be encouraged. At a minimum, efforts should be made to ascertain that tariffs do not inhibit imports of essential drugs.

30/ See Article XX of the General Agreement excepting measures "... to protect human, animal or plant life or health..."

31/ See WHO, "The Role of WHO in the Transfer and Dissemination of Information on Drug Quality, Safety and Efficacy", op. cit., para. 38.

7. SUMMARY AND CONCLUSIONS

Actual or potential trade is always determined by the structure of, and the structural changes occurring within, an industry. In pharmaceuticals, a rising proportion of research to production costs requires sustained capital investment and considerable skills. On the other hand, the growing number of so-called mature products allows for freer competition in the non-proprietary field. The trend, fueled by public concern, away from brand names to generics can reduce the cost as well as the number of existing drugs, but will not guarantee the continued financing of future research. Trade liberalization can only proceed as the standards of safety, efficacy and quality are understood and met. However, standards which are not uniform obfuscate market transparency thereby implicitly restricting trade.

Production and consumption of pharmaceuticals as well as the related trade is concentrated in the industrialized countries. With efforts on the part of the international community to improve access to essential drugs, international trade continues to grow despite many technical barriers to trade. Some of the more advanced developing countries are keeping pace. The developing countries represented by the group of GSP beneficiaries benefit from a slight preference margin on all pharmaceutical imports in major developed market economies where they account for approximately seven per cent of the imports. But these countries encounter higher tariffs in their own region. Excluding health and safety regulations, non-tariff measures applied by selected developed market economies occur primarily in the form of volume-restraining measures. These affect a higher percentage of imports from developed market economies, although this may suggest that restrictions are in fact more effective against the rest of the world.

Various scenarios for trade liberalization suggest that under complete tariff removal imports into the major developed market economies would increase by roughly $US 8 million and under a full extension of preferences by nearly $US 22 million (based on 1983 import levels). In the first case, the greatest absolute expansion would occur amongst medicaments and pharmaceutical goods and the greatest relative increase in alkaloids. In the second case, the greatest absolute expansion would occur in antibiotics and the greatest relative increase in medicaments and pharmaceutical goods. Potential trade expansion effects among developing countries is however even more impressive and would, under the global system of trade preferences, expand trade by $US 60 million, an increase of twenty per cent, with the largest gains again occurring in medicaments and pharmaceutical goods and antibiotics. Realization of this potential, however, rests on the dual assumptions of sufficiently elastic export supply and the removal of non-tariff barriers.

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Q U E S T I O N N A I R E

Tariff and non-tariff measures in the world trade of pharmaceutical products

		(please check appropriate box) yes	no
(1)	Were the data contained in the study useful?	/_/	/_/
(2)	Was the analysis sound?	/_/	/_/
(3)	Was the information provided new?	/_/	/_/
(4)	Did you agree with the conclusion?	/_/	/_/
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