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CONTROLLING THE COST OF IMPORTED MEDICINES

A CASE STUDY: TUNISIA



Regulatory Support Series, No 10



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Controlling The Cost Of Imported Medicines
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SUMMARY

The Tunisian pharmaceutical sector has a number of unique features, notably regarding the importation system for medicinal drugs and its regulation.

Tunisian pharmaceutical policy has long been based on a strong public sector. Regulatory and control structures with precisely defined roles co-exist with public procurement structures that centralize the importation of medicines for both the public and private sectors.

Centralization of all pharmaceutical imports is a major feature of the Tunisian system, which controls the prices of imported medicines, thereby reducing drug procurement costs in public hospitals and making retail prices in private pharmacies more affordable for the bulk of the population.

Given the current absence of universal health insurance in Tunisia, most of the population must pay the full price of the medicines they obtain from pharmacies. However, measures designed to keep retail medicine prices as stable as possible from year to year cushion the effects of this situation on drug accessibility.

Price stability is achieved through two mechanisms: first, increases in the prices of imported medicines are directly absorbed by the central procurement body; second, centralized purchasing and international tenders for the supply of medicines lead to greater negotiating power and reduce operating costs. This keeps retail prices relatively low without the need for state subsidies, while at the same time ensuring the economic viability of the public structures that manage drug importation.

The private sector is the main channel for drug distribution, working through a network of wholesalers and pharmacies. The economic activity of private operators is in no way restricted by the centralized import mechanism. The quantity of medicines imported is determined solely by the volume of prescriptions and consumption of non-prescription medicines, over which the centralized import structures have no influence.

This mixed public/private model combines effective public control of the drug supply chain with the flexibility of private distribution. In addition, by granting both private and public sectors clearly-defined roles as well as the right to review the other's operations, it helps to avoid conflicts of interest that might otherwise hinder the supply system.

This document describes how the Tunisian drug importation system manages to ensure satisfactory quality, safety, availability and affordability of pharmaceutical products. In this way, the system meets the public health needs of a country with relatively limited human and financial resources, while preserving the operating freedom of the different socioeconomic actors.

THE TUNISIAN HEALTH AND WELFARE CONTEXT

In 2001 the Tunisian population was estimated at 9.6 million, with about 3.3 million people in employment. Tunisia is classified as a middle-income country at an intermediate level of development (World Bank,¹ UNICEF, WHO)².

Overall, Tunisia's health indicators are reasonably satisfactory. One of the key indicators of progress in public health is the infant mortality rate, which fell from 132 per 1000 in 1960 to 25.8 per 1000 in 2000.

Life expectancy at birth is now 72.2 years (70.1 years for males, 74.2 years for females), and has increased by more than three years in the last 15 years.³ These data reflect the demographic and epidemiological transition that Tunisia is currently undergoing.

The Tunisian state has always considered public health and education as national priorities, and has provided substantial funding.⁴ Thus, in 2000, 8.5% of the national budget was spent on public health and 16% on education.

Tunisian national health policy is aimed at ensuring equitable access to health care, both geographically and financially. While cost containment is a key element of policy implementation, the overriding objective is to meet the needs of the entire Tunisian population.

Public vaccine policy ensures that more than 90% of Tunisian children less than one year of age are immunized, notably against diphtheria, tetanus, pertussis, polio, measles and tuberculosis (BCG).

Tunisian health services initially developed within the public sector, but the participation of the private sector has substantially increased since the beginning of the 1990s.

The public sector is the main health care provider, especially in terms of first-line and preventive medicine and hospital treatment. The public sector accounts for about 40% of total Tunisian pharmaceutical consumption. It is organized in three basic tiers:

- *Basic health care centres* ensure basic treatment and prevention. District hospitals and maternity units are part of this first level of health care.
- *Regional hospitals*, generally located in the capital city of each governorate,⁵ provide at least the following services: general medicine, general surgery, obstetrics, paediatrics, ENT and ophthalmology.
- *Teaching hospitals* mainly provide highly specialized care, and are located in Tunisia's principal cities.

About 90% of the population is located within 5 km of a public health care centre. However, there are real disparities between urban and rural areas, some of them qualitative, in terms of the availability of health services.

Alongside the public sector, a relatively large "parapublic" sector has also developed in Tunisia. It comprises polyclinics run by the National Social Security Fund (CNSS) for private sector employees, the autonomous medical services of certain companies, and the health services of certain ministries (Interior, Defence, etc.).

¹ From the website of the World Bank:

<http://devdata.worldbank.org/external/CPPProfile.asp?SelectedCountry=TUN&CCODE=TUN&CNAME=Tunisia&PTYPE=CP>, consulted on 20 January 2003

² From the website of Réseau d'Économie et Systèmes de Santé au Maghreb (RESSMA):

<http://www.ressma.com/fichier/tunisia.pdf>, consulted on 20 January 2003

³ National Statistics Institute, Tunis

⁴ Boukef K. Étude de la réglementation des médicaments en Tunisie. Study on Medicinal Drug Regulation in Tunisia. *Essaydali*, No 76. June 2000.

⁵ The governorate is the main administrative area in Tunisia.

The private sector consists of a network of general practitioners and specialists, wholesalers, community pharmacies, medical laboratories, and a number of private hospitals or clinics. The private sector accounts for 7% of paramedical personnel, 48% of medical staff, 83% of pharmacists and 72% of dentists.⁶ The clinics account for about 11% of the overall hospital bed offer, but represent a very marked geographical disparity because they are located chiefly in coastal regions and relatively wealthy areas.

The cost of some treatments provided mainly or exclusively by private structures, such as haemodialysis, is fully covered by public health insurance.

Medical, paramedical and pharmaceutical training capacity has been expanded, leading to a marked rise in the number of trained health care personnel in recent years. Tunisia has four faculties of medicine, one faculty of pharmacy, one faculty of dentistry, three health colleges and 19 training schools for other health professions.

Table 1. Total numbers of trained medical and pharmaceutical personnel

Category	1990	1995	1998	2001
Physicians	4424	5965	6819	8278
Dentists	809	1038	1276	1380
Pharmacists	1240	1499	1623	1998
Paramedical staff	23743	25874	26676	30392

Source: Ministry of Public Health/DEP⁷.

In 2001 there was one doctor per 1167 inhabitants (52% of doctors worked in the public sector), and one pharmacist per 4835 inhabitants. Most pharmacists work in private pharmacies.

In 2000, total health spending in Tunisia was 1489 million dinars, which corresponds to 156 dinars (114 US dollars⁸) per inhabitant and 5.6% of the gross domestic product (compared to 3.2% in 1980).

⁶ Ratios calculated from data supplied by the Pharmacy and Drugs Directorate (PDD) for the year 2001.

⁷ DEP – Directorate for Studies and Planning, Ministry of Public Health, Tunis

⁸ The exchange rate was calculated on the basis of 1 US dollar = 1.3707 Tunisian dinars (the mean exchange rate in 2000 – according to IMF's *International Financial Statistics Yearbook 2002*).

Table 2. Evolution of national health expenditure as a percentage of GDP

	1980	1985	1990	1995	2000
National health expenditure (million dinars)	138	285	578	938	1489
% of GDP	3.2	4.2	5.3	5.5	5.6

Source: Ministry of Public Health/DEP.

These data reflect the continuing growth in both costs and demand. The proportion of GDP allocated to the health sector in Tunisia has largely exceeded 5% during the past decade, but remains well below that in industrialized countries (in France, for example, expenditure on health goods and services was estimated at 8.7% of GDP in 2001⁹).

Health service funding comes from three main sources, namely the State, social security organizations, and households.

Over the past 15 years the relative importance of these three sources has changed profoundly: in particular, the proportion funded by the State has fallen, while private expenditure by households has increased from 34% to nearly 50%.

Table 3. Evolution of health expenditure by funding source from 1985 to 2000 (million dinars)

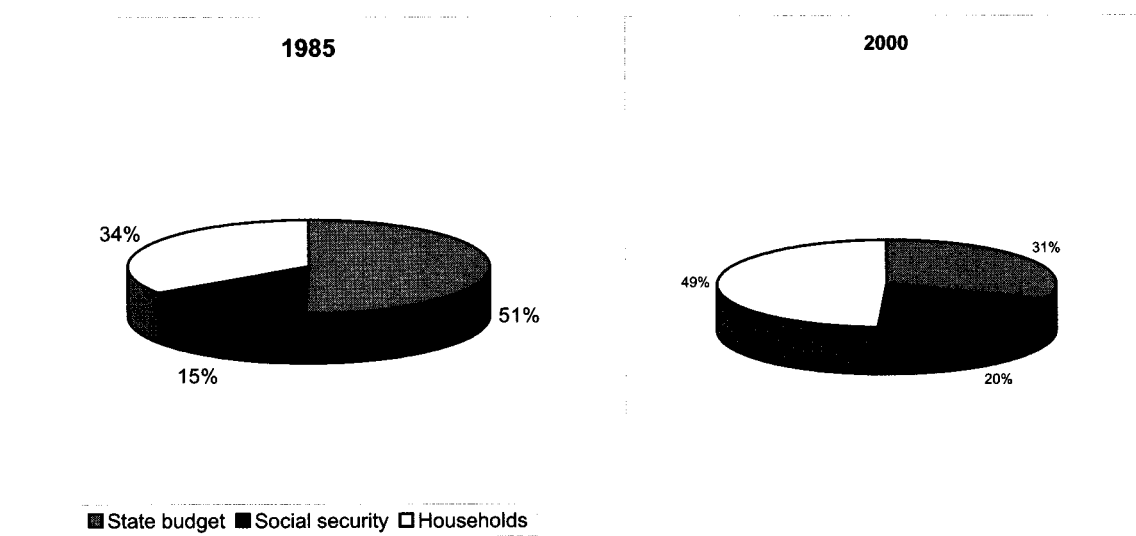
Source \ Year	1985	1990	1995	2000
State	143	218	349	461
Social security	44	89	146	297
Households	98	271	443	731
Total spending				
million dinars	285	578	938	1489
million US dollars ¹⁰	381	658	992	1086

Source: Ministry of Public Health/DEP.

⁹ Source: Les comptes de la Santé en 2001, France, <http://www.sante.gouv.fr/drees/etude-resultat/er-pdf/er187.pdf> consulted on 20 January 2003.

¹⁰ Dollar conversions are based on the mean dinar-US dollar exchange rate for the year in question.

Fig 1. Changes in the percentage contribution of funding sources to total health expenditure, 1985 and 2000



Patients' drug costs are covered in two main ways:

- in public hospitals, patients who do not receive free health care (reserved for the poorest members of the population) usually pay a fixed contribution giving them global access to health care; this sum covers hospitalization, health care procedures, and drugs;
- in private pharmacies, drug purchases are almost exclusively paid for by the patient; reimbursement by the social security system is very limited, and few patients have private health insurance.

CHARACTERISTICS OF THE PHARMACEUTICAL SECTOR

The Tunisian pharmaceutical sector has a number of unique features in the way it works and, the respective roles of public and private structures. The principal characteristics can be summed up as follows:

- the pharmaceutical sector is governed by various public regulatory and control structures, each of which has well defined functions;
- drug importation is centralized within public supply bodies (Central Pharmacy of Tunisia and the Tunis Pasteur Institute);
- local drug manufacture by private companies (with local and foreign investment) has been growing strongly since the early 1990s;
- drug distribution is ensured by a comprehensive network of small private wholesalers/distributors;
- the network of private pharmacies is growing rapidly.

Public regulatory and control structures

- The Pharmacy and Drugs Directorate (PDD). This is a technical and administrative body of the Ministry of Public Health. It is responsible for designing, applying and monitoring national drugs policy. PDD issues all the authorizations required for pharmacy and drugs, including marketing authorizations and customs release certificates for imported drug batches.
- The National Pharmacovigilance Centre (NPC) collects and analyses all national pharmacovigilance data, issues alerts on newly identified health problems, carries out health surveillance activities at the international level, and conducts literature searches on adverse effects of drugs.

- The Pharmaceutical Inspectorate (PI) manages all inspections of manufacturers, wholesalers, private pharmacies, and all health establishments possessing a pharmacy (or holding drug stocks).
- The National Pharmaceutical Control Laboratory (NPCL) controls the quality of drugs, medical devices, and cosmetic, personal hygiene and dietary products sold in Tunisia. It also participates in the evaluation of applications for marketing authorization.
- The National Agency for the Control of Health and Environmental Products (NACHEP). This recently created agency coordinates the health and environmental product-control activities of the relevant public bodies.
- Customs. All imported drugs must pass through Tunisian customs, which verify the legality of all imported drugs and health products; merchandise can only be released after being granted specific authorization for each batch, which is issued by PDD (customs release certificate).

Public drug supply bodies

The Central Pharmacy of Tunisia (CPT) is the key element in the pharmaceutical supply system. CPT originated from a simple warehouse created by decree in 1938 at the Hôpital Civil Français (now called Hôpital Charles Nicolle) with the name "Pharmacie Centrale des Hôpitaux de Tunisie". The current name, Central Pharmacy of Tunisia, was adopted in 1958. Faced with major drug availability problems in the late 1950s (supply problems with products frequently out of stock and highly uneven geographical distribution of community pharmacies), CPT was given the following principal roles:

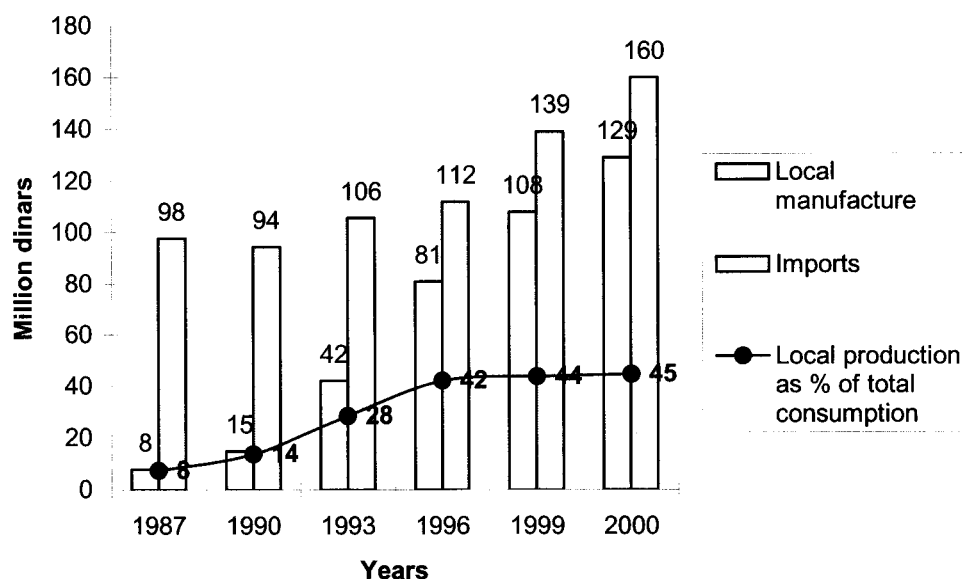
- Ensuring country-wide access to drugs: in 1957, drug depots called "agences pharmaceutiques" were opened in towns and villages that lacked private pharmacies. These depots, which had no commercial monopoly, were gradually eliminated as private pharmacies opened nearby. Only seven such agencies, located in particularly remote regions, have not been taken over by the private pharmaceutical sector because they are not financially viable. Their presence ensures that the inhabitants of these regions continue to benefit from these drug supply points.
- Importation of all medicinal products: centralization of drug imports by CPT, on behalf of both the public and the private sector, remains a specific feature of the Tunisian pharmaceutical system.

The Tunis Pasteur Institute (TPI) is responsible for importing vaccines, sera, allergens and other biological products. It has similar prerogatives to CPT but a narrower range of activities.

Local drug manufacture

In 1987 about 8% by value of total consumption was covered by local manufacturing. By 2000, the Tunisian pharmaceutical industry comprised 27 production plants, and covered 45% of the national market by value. This progression has not been constant.

Fig 2. Evolution of local drug manufacturing and importation, 1987 to 2000



The proportion of national consumption covered by local production has flattened out since the mid-1990s, for the following reasons. First, the prices of imported drugs have risen far more rapidly than those of locally manufactured drugs, most of which are old substances whose patents have lapsed. In parallel, consumption has shifted towards more recent and more costly imported drugs. Thus, the total volume of imports fell by about 14% between 1990 and 1999, reflecting increased local production, but this fall in volume was outweighed by the increased cost of imported drugs (a rise of 74% during the same period).

Table 4. Evolution of Tunisian drug imports (by volume and value), 1990 to 1999

Year	1990	1993	1996	1999
Imports				
Volume (metric tons)	7400	8100	4748	6380
Value (million dinars)	105	127.3	142.5	176.6

Source: National Statistics Institute, Tunis (1990 value and volumes in tons); CPT (other data)

Distribution

In Tunisia, wholesale distribution is partly ensured by CPT (drugs of chemical origin) and TPI (vaccines, sera and blood products), and partly by a network of private wholesalers and distributors. CPT has a monopoly on drug distribution to the public sector, but competes with private wholesalers for sales to the private sector.

Private wholesalers act as intermediaries between importers (CPT and TPI) and local manufacturers on the one hand, and private pharmacies on the other hand. The official price mark-up for wholesalers is 8%. Private wholesalers numbered 49 in 2000, and are present in almost all Tunisian regions, albeit with highly variable turnovers.

About 60% of all drugs consumed in Tunisia are dispensed by private pharmacies, the remaining 40% being dispensed in hospitals. Private pharmacies must belong to a qualified pharmacist, and a given individual can only own one pharmacy. Pharmacists' official price mark-up is inversely proportional to the price of the drug, and ranges between 24% and 30%. In 2002 there were 1272 "day pharmacies",

and 153 pharmacies open exclusively at night.¹¹ The number of pharmacies rose by 44% between 1990 and 2000.

PHARMACEUTICAL CONSUMPTION

In 2001, estimated total pharmaceutical consumption in Tunisia represented about 400 million dinars (US\$ 278 million), i.e, less than 0.1% of the world market (estimated at US\$ 364.2 thousand million in 2001).¹²

Pharmaceutical consumption per inhabitant climbed by 40% between 1995 and 2001, rising from 30 dinars to nearly 42 dinars in six years. This is low compared to industrialized countries (about 12 times lower than in France for example).

A feature of pharmaceutical consumption in Tunisia is the substantial use of drugs for the treatment of communicable diseases. Such consumption was valued at 19.6 million dinars (US\$ 22.3 million) in 1990. By 2000 it had tripled in current terms, reaching 63.5 million dinars (US\$ 46.3 million), and accounting for nearly 22% of the total pharmaceutical market (PDD Data).

Despite the continuing high consumption of anti-infective drugs, Tunisia is undergoing an epidemiological transition, reflected notably by a proportionate rise in consumption of drugs used in cardiology and angiology (the second most consumed drug category at 12% of the market), and also in metabolism and nutrition.

There has been a very marked fall in morbidity from infectious and parasitic diseases long endemic in Tunisia (schistosomiasis, trachoma, tuberculosis, infant diarrhoea, etc.), and a concomitant increase in morbidity from chronic and degenerative diseases. Cardiovascular disease was the third cause of death (about 10%) in the late 1960s, but became the leading cause of death (23%) in the early 1990s.

Prescription

The Ministry of Public Health has established official lists of drugs available in hospitals and private pharmacies, aimed at promoting rational prescription and use.

Table 5. Number of pharmaceutical items according to the dispensing site

Site	Number of items in 2000
Health care centres	332
Hospitals	1026 (108 reserved for specialists)
Pharmacies	1730

Source: Hospital nomenclature (2000), and PDD.

These data reflect the desire on the part of the Tunisian authorities to limit the number of drugs available in public health establishments.

The list of drug preparations approved for sale in private pharmacies is also relatively short (about 1730 products). The number of drugs available in Tunisian private pharmacies is therefore relatively small compared to community pharmacies in most European countries (in France for example, nearly 7250 products representing more than 4000 different drug substances are sold in pharmacies¹³).

The drugs included in these official lists are regularly re-evaluated. In addition, limitations are placed on prescribing choices according to the type of health establishment (primary health care centres

¹¹ Source: PDD, October 2002.

¹² Source: IMS Health

¹³ Website of the French wholesaler-distributor association www.csrp.fr consulted on 20/01/2003

versus hospitals) and the prescriber's qualifications (general practitioners versus specialists), which also reduces the risks of incorrect use.

Measures promoting the use and local production of generics

In financial terms, the market share of generic drugs has been fairly stable in recent years, although it has fallen significantly in hospitals over the past five years. The hospital sector is the main generics consumer: in 2001, 37.6% by value of drugs dispensed in hospitals were generics (compared to 16.4% in private pharmacies). In terms of number of items, more than half the drugs used in the hospital sector are generics.

Table 6. Use of generics in private pharmacies and in the hospital sector (percentage by value)

Year	Hospitals	Private pharmacies
1995	40.5	11.9
1997	47.4	10.4
1999	40.6	11.5
2001	37.6	16.4

Source: PDD.

For several years Tunisia pursued a policy of promoting the use of generics, through regulatory measures, encouragement of local generics manufacture, and international calls for tenders for the supply of generic pharmaceutical products, including drugs for private pharmacies.

The following measures were taken in the early 1990s to encourage local drug manufacture:

- Waiving of import duty on raw materials and packaging items; reduced import duty on equipment; advantageous rate of value added tax; and taxation of the corresponding imported products;
- Advantages granted to local manufacturers for public markets;¹⁴
- A "correlation" system: on request by a Tunisian manufacturer, importation of a drug similar to a locally produced drug can be suspended under certain conditions¹⁵ (in particular, if the applicant undertakes to maintain a minimum stock equivalent to the stock of the imported reference product that would otherwise be kept by CPT);
- Authorization of subcontracting, which permits cooperation between different companies and optimization of production capacity.

This policy of encouraging local production of pharmaceuticals, and particularly generics, through the correlation mechanism partly explains why, in 1997, about two-thirds of locally produced pharmaceuticals were generics.

However, generics have not yet had the success the Tunisian authorities had anticipated, for the following reasons:

- pharmacists are not allowed to substitute generics for trade-name prescriptions;
- price control mechanisms minimize the price difference between innovator pharmaceutical products and generics;
- most physicians use proprietary names instead of international nonproprietary names (INN) on their prescriptions;
- wholesalers and private pharmacists are remunerated by a fixed percentage of the retail price: the lower the price, the smaller their remuneration.

¹⁴ As part of the strict application of the general dispositions relating to Tunisian membership of the World Trade Organization to Tunisian regulatory texts, the preference granted to local products and the system of correlation (see next item) are being dismantled.

¹⁵ This mechanism exerts no inflationary pressure on the retail prices of the drugs concerned because these prices are determined before the decision to apply the correlation is made, and cannot be revised upwards.

In addition to prescription control by means of lists of officially approved drugs, and measures aimed at encouraging international procurement and local production of generics, the following measures have been adopted (or are being considered) to favour rational drug use in Tunisia:

- drawing up of therapeutic protocols which, in certain cases, are virtually compulsory (*références opposables*);
- drug classification in four categories (vital, essential, intermediate and "comfort") with decreasing rates of reimbursement, as part of the reform of the public health insurance system;
- authorization of generic substitution by dispensing pharmacists;
- tighter control of pharmaceutical information and promotion, through the participation and collaboration of health professionals and the public (in preparation);
- major awareness campaigns aimed at health professionals and patients, and a pharmaceuticals monitoring centre (in preparation).

CENTRALIZATION OF PHARMACEUTICAL IMPORTS

In Tunisia, medicinal products can only be imported by the Tunis Pasteur Institute (vaccines, sera, allergens and blood products) and the Central Pharmacy of Tunisia (all other types of drug).

Blood products, vaccines, sera and allergens only represent about 5% by value of all drug imports. Thus CPT imports the bulk of pharmaceuticals and, will be the focus of this analysis.

The evolution of drug imports by Tunisia over the past decade (1992-2001) is shown below.

Table 7. Evolution of drug imports by Tunisia between 1992 and 2001 (by value)

Value of Imports	1992	1993	1996	1999	2001
In million dinars	138.24	127.30	142.49	176.62	230.83
In million US dollars ¹⁶	156.31	126.83	150.99	148.90	160.45

Source: CPT.

The cost of drug imports thus rose by 67% over this 10 year period when expressed in Tunisian dinars, whereas it remained relatively stable when expressed in US dollars. The volume of imported drugs fell during the period (see section on local manufacture). The cost increase in dinars was due to depreciation of the Tunisian currency relative to the main international currencies (particularly the US dollar), and to sharp price increases, especially for new treatments, on the international market.

Table 8 shows that Tunisia imports most of its drugs from France.

¹⁶ The dollar conversions are based on the mean dinar-US dollar exchange rate for the year in question.

Table 8. Percentage of drug imports, by value, from the main supplier countries (1993 - 2001)

Supplier country	Percentage of imports, selected years			
	1993	1996	1999	2001
France	76.3	74.2	74.7	69.9
United Kingdom	2.6	5.4	7.4	7.4
Denmark	-	3.6	2.9	5.6
Jordan	1.8	3.0	2.2	1.8
Italy	5.0	1.6	1.8	1.3
Morocco	2.2	0.3	-	0.7
Switzerland	-	2.4	1.5	2.6
Others	12.2	9.5	9.4	10.8

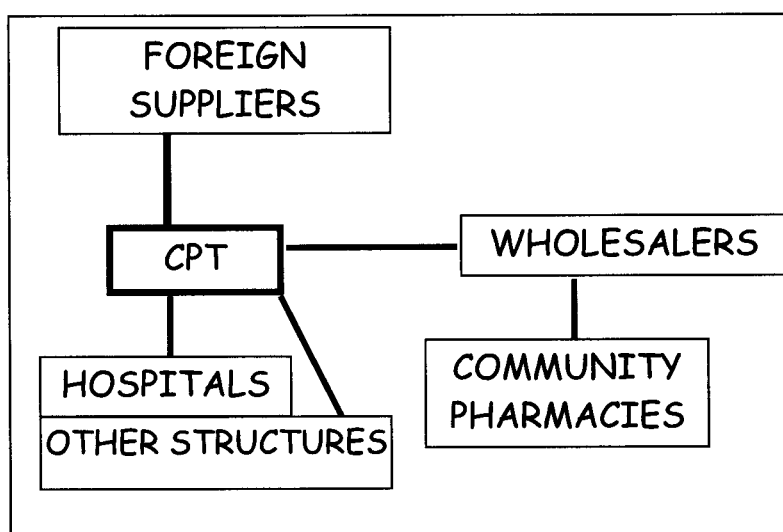
Source: CPT

This distribution of supplier countries is not the result of any preference on the part of the Tunisian health authorities, as no advantages are granted to one country or another as regards marketing authorization or the import procedure. It should be noted that Table 8 shows the supplier countries and not the countries of manufacture. Drug companies, no doubt for practical reasons, tend to export their products to French-speaking countries through their French subsidiaries.

The Central Pharmacy of Tunisia

CPT is a public economic and commercial body. Like public pharmaceutical procurement bodies worldwide, CPT is responsible for guaranteeing supplies to all health structures dependent on the Ministry of Public Health. In its position as sole Tunisian drug importer, it negotiates all international supply contracts for both the public and the private health sector. It centralizes all orders for drugs that are not locally produced, negotiates the contracts, and handles the reception and, in part, the distribution of imported drugs.

Fig 3. Routing of orders for imported pharmaceuticals



CPT also negotiates contracts with local manufacturers, which account for about 25% of its total pharmaceutical purchases. However, the private sector is not obliged to use CPT in order to acquire locally produced drugs, and the local pharmaceutical industry can use private distribution networks competitively.

CPT storage and distribution activities

CPT has very substantial warehouse facilities in Tunis (about 20 000m²) for the products it distributes. A further four large drug warehouses are located around the country, at Sfax, Sousse, Gafsa and Le Kef. These depots rapidly supply all drug distribution networks, and also keep stocks of drugs close to the local populations.

CPT also distributes drugs directly to public hospitals and to all other health care facilities dependent on the Ministry of Public Health. For public sector facilities, drugs are invoiced at prices reflecting true purchase and distribution costs. In the private market, price structures do not always correspond to actual costs because of the effects of the compensation system (see section on "Compensation principle" below).

CPT supplies the private pharmaceutical sector through wholesalers, but also supplies private pharmacies directly through three dedicated points of sale. This direct distribution is marginal, because, it represents only about 10% of all drug purchases by private pharmacies. However, the direct sales help CPT to improve its analysis of trends in pharmaceutical consumption by the private sector. They also provide useful information on pharmaceutical demand, allowing CPT to anticipate possible supply problems and stock ruptures which could not be detected solely on the basis of orders placed by wholesalers.

Fig 4. Distribution paths for imported drugs

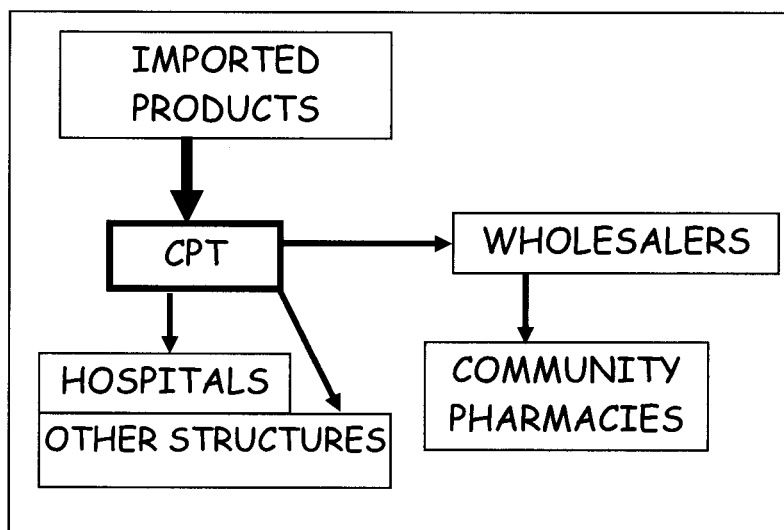
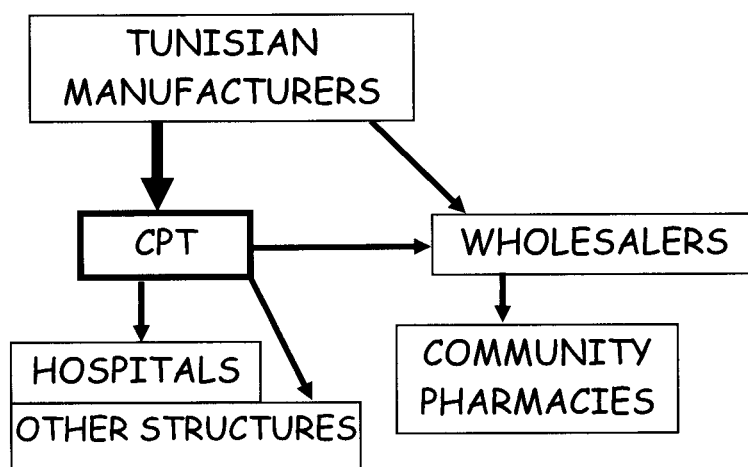


Fig 5. Distribution paths for locally manufactured drugs



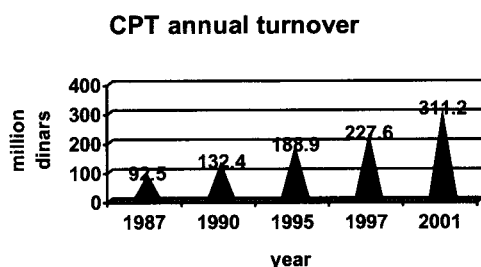
CPT has established procedures for all its drug storage and distribution activities, and ISO certification is under way to validate the quality assurance system.

CPT administration

CPT is a public body overseen by the Ministry of Public Health and managed by a board of directors. The chairman and chief executive officer is appointed by governmental decree. A purchasing commission assists the chairman, especially on questions relating to the pricing of imported drugs and to tenders. A markets commission negotiates the quantities and conditions of supply.

CPT has about 800 staff. In 2001 its turnover was 311.17 million dinars (about US\$ 216 million).

Fig 6. CPT's annual turnover, 1987-2001 (million dinars)



Source: CPT

In 2001, CPT turnover by product origin was as follows:

Table 9. CPT turnover in 2001 according to product origin

Category and origin	Turnover (million dinars)
Imported drugs	217.23
Locally manufactured drugs	60.48
Other imported products ¹⁷	20.55
Other local products	12.90
Total	311.17

Source: CPT

Operational aspects of pharmaceutical importation

Pharmaceutical importation by CPT is governed by clearly defined rules within a functioning system. Following these rules ensures a constant supply of good-quality imported drugs to both public and private dispensers.

Prior Marketing authorization

CPT can only purchase drugs that have already been granted marketing authorization in Tunisia by the Ministry of Public Health. The only exception to this rule is limited importation of drugs for named patients¹⁸, which is controlled by PDD. Apart from this procedure which represented about 6% of the cost of all imported drugs in 2001, CPT uses two standard purchasing methods contracts by mutual agreement and calls for tenders.

Contracts by mutual agreement

Negotiations are conducted directly between CPT and the firm holding the Tunisian marketing authorization for the drug. During these negotiations, the purchasing commission fixes the appropriate purchase price from the exporter. This means that the price is determined only once the marketing authorization procedure has been completed. Social security structures are not involved at this level of the process.

It is generally agreed that the maximum C&F price must not exceed the ex-tax wholesale price of the product in its country of origin minus 12.5%, a percentage which represents the CPT negotiating fee. The purchase price is valid until it is re-negotiated with the purchasing commission, generally at the request of the company concerned.

For the supply of private pharmacies, CPT generally negotiates mutually agreed contracts without being able to choose its suppliers. The only negotiations conducted by CPT with foreign manufacturers concern the price. Once the purchase price has been agreed between CPT and the foreign supplier, CPT become a simple neutral intermediary between the private market and the foreign company. CPT handles orders and stocks for the private pharmaceutical sector, which is therefore freed from this costly and financially risky task. Companies are free to promote their drugs to the private sector, and the volume of CPT purchases is therefore dependent solely on drugs' "commercial success". Thus, when new drugs are marketed in Tunisia, CPT imports and stocks a certain quantity without knowing how rapidly the stock will be sold.

There are no limits or quotas on the volumes purchased by the public purchasing commission, as these volumes are determined solely by demand from the private sector and by free competition among companies.

¹⁷ Medical devices, chemical products, laboratory reagents etc.

¹⁸ Drugs imported without Tunisian marketing authorization, but that are legally available in their country of origin, generally concern few patients and correspond to the general definition of products for compassionate use. Approval by the Pharmacy and Drugs Commission is essential for their importation, and is only granted if there is a fully justified medical prescription.

Calls for tenders

CPT issues international calls for tenders for the supply of generic drugs to the public sector and of a few drugs that are heavily consumed in the private sector. Calls for tenders are published.

CPT issues calls for tenders for drug products which meet one or more of the following criteria:

- cumulative purchases exceeding 1 million dinars in the previous year;
- the in-pharmacy retail price of the original imported drug is very substantially "compensated" by CPT (see Compensation Principle below),
- the product is a range extension of another product which meets one of the above criteria (e.g. a little-used 500-mg dose strength, the 250-mg version of which represented sales of more than 1 million dinars in the previous year. In this case both products are purchased through a call for tenders, in order to avoid distortions in prescription or pricing patterns),
- all other products having the same indication are already purchased through calls for tenders. Inclusion in the list of calls for tenders means that companies do not focus their commercial promotion on the only substance that is not included on the list¹⁹.

Calls for tenders are based on INNs or generic names. As a result, a single product from a single source is selected and made available in pharmacies during the following year, from among the different proprietary products with valid marketing authorization.

Drugs for the private sector have been purchased through calls for tenders for about the last 10 years. This practice is mainly justified on financial grounds: CPT can reduce its purchasing costs (and, thus, the level of compensation), and maintain low retail prices for generics with large sales volumes. This also has two indirect consequences:

- on drug promotion: drug companies have no reason to spend money on publicity, as they are not sure their products will be selected through the call for tenders and hence be available on the Tunisian market;
- on manufacturers: companies eliminated from the Tunisian market through the application of tender procedures may subsequently be prompted to manufacture their products (or to have them manufactured) directly in Tunisia in order to re-enter the market. In some cases they may be granted some of the same advantages (for example higher prices, or the possible suspension of imports of competing drugs) that are granted to local products in the CPT purchasing system.

Lastly, calls for tenders are easy to manage because of the limited number of products meeting the eligibility criteria. During the past decade, no more than 70 drug substances have been included in the annual calls for tenders.

Table 10 shows the evolution of total CPT purchases on behalf of the private sector.

¹⁹ For example, if only azithromycin was purchased through a call for tenders, this could create a risk of prescribing distortions, because companies could concentrate their promotional activities on the brand name of an equivalent drug, such as clarithromycin, which would not be included in the call for tenders. This distortion could be avoided by also purchasing clarithromycin through a call for tenders.

Table 10. Evolution of total CPT purchases on behalf of the private sector, 1993-2001 (million dinars)

Year	1993	1996	1999	2001
Drug imports for private pharmacies				
Contractual agreements	} 78.53	} 81.90	107.51	141.99
Calls for tenders			6.82	8.04
Total				
million dinars	78.53	81.90	114.32	50.03
million US dollars ²⁰	78.24	86.79	96.38	104.29

Source: CPT.

The dinar value of CPT imports on behalf of private pharmacies nearly doubled between 1993 and 2001, showing that the introduction of international calls for tenders failed to stop import costs from rising. In 1999 and 2001, the value of drugs imported through the bidding process only represented 5% and 6% respectively of total pharmaceutical imports.

Compensation principle

The retail prices of imported drugs are decided, during the initial importation process, by a commission representing the relevant ministries. This decision is based on the import price agreed between CPT and the supplier. The commission applies coefficients that take into account the mark-ups of the different players (CPT, wholesalers, pharmacies) before finally fixing the retail price.

Once fixed, retail prices are rarely re-adjusted, even if the cost of importation changes (generally upwards) because of two main factors:

- fluctuation of the Tunisian dinar relative to the foreign currencies used to pay for imported drugs;
- periodic reassessment of the purchase price, which the purchasing commission is obliged to re-negotiate if requested by the foreign supplier.

The compensation principle means that CPT must absorb and "compensate" for all increases in import prices in order to maintain both retail prices and wholesalers' and pharmacists' mark-ups at the same level.

This compensation principle reflects the Tunisian Government's political choice of ensuring that drug prices are more accessible to the population especially in pharmacies where patients must themselves meet the cost of their drugs (reimbursement by social security and private health insurers remains very limited in Tunisia).

The vast majority of the essential drugs that are imported and sold in private pharmacies are old compounds. Their public sale prices are heavily "compensated", making them more affordable for the population.

Because of the compensation mechanism, the CPT's profit margin on imported drugs is gradually falling. Some of the oldest products imported on behalf of private pharmacies, which are highly compensated, may even be sold at a loss by CPT.

The cost of the compensation mechanism has more or less stabilized in recent years, at about 18-20 million dinars annually (see Table 11). This loss is covered by revenues derived chiefly from sales of non-priority drugs (e.g. multivitamins) and similar products sold by CPT. Moreover, as a state body endowed with a public health mission from its creation, CPT is not intended to make a profit.

Table 11. Evolution of the cost of retail price compensation between 1988 and 2001

²⁰ The dollar conversions are based on the mean dinar-US dollar exchange rate for the year in question.

Cost of compensation	1988	1991	1993	1994	1995	1997	1999	2001
In million dinars	12.18	14.72	14.66	7.61	9.87	18.36	20.35	19.12
In million US dollars ²¹	14.31	15.92	14.61	7.52	10.44	16.60	17.16	13.29

Source: CPT.

There are several reasons why the cost of the compensation mechanism has stabilized in recent years:

- some old drugs are no longer imported because they are no longer used or have begun to be manufactured locally (with the related consequence that the prices of locally produced generics, fixed partly on the basis of "compensated" prices, are not always sufficiently remunerative for their manufacturers);
- some more recent (and thus less "compensated") drugs are imported in the place of older drugs;
- price increases are occasionally authorized for heavily compensated drugs that are not public health priorities;
- calls for tenders result in savings on the global import cost of generic products.

The figures in Table 11 show that application of the compensation principle has been kept under control without confronting CPT with an unmanageable financial imbalance.

The advantages of centralized drug importation

CPT has been the sole drugs importer in Tunisia for 40 years, and also the principal regulator of the country's drug supplies. CPT has thus acquired a good working knowledge of the world drugs market and of contract negotiation, which is a major advantage for the Tunisian pharmaceutical system.

For a country the size of Tunisia, a centralized drug supply system offers real negotiating power with the increasingly consolidated international pharmaceutical industry. Centralization offers clear advantages in terms of efficiency, costs and planning of orders to avoid stock ruptures or over stocks). As shown in Table 12 below, centralization ensures advantageous prices relative to the French market, for example. It should not be thought that centralized importation is the principal explanation of the data in Table 12. However, Tunisia remains one of the few developing countries where the retail prices of imported drugs are not based on the retail prices in the country of origin multiplied by a fixed coefficient. The Tunisian system permits true price negotiation by a public centralized importation structure.

In addition, centralized drug importation allows CPT to offer public services that are not provided by the private sector:

- Price control: CPT, through the compensation mechanism, maintains retail price stability in private pharmacies. The financial resources absorbed by the compensation mechanism simply represent the profit that CPT would make if it were a private enterprise.
- Importation of little-used drugs: CPT is not influenced by commercial considerations when deciding which drugs to import. This ensures that all imported drugs are made available at the lowest possible price, including little-used drugs that a private importer would not find sufficiently profitable.
- Maintaining strategic stocks: for emergency interventions in catastrophes. These stocks are distributed throughout country and cover about three months' consumption. Holding them immobilizes about 70 million dinars.
- Ensuring drug availability: throughout Tunisia seven CPT pharmaceutical agencies continue to ensure drug supplies in poor and sparsely populated regions where private pharmacies would be unprofitable.

²¹ The dollar conversions are based on the mean dinar-US dollar exchange rate for the year in question.

It is important to note that these public service missions are carried out at no extra cost to the State, as they are supported by CPT's global budget. Thus these operations are financed through the profit margin generated by CPT's overall drug and related import and distribution activities. It is unlikely that these services could be provided by one or more private operators.

In conclusion, the mechanism in place seems financially sound and viable, and contributes to ensuring the continuity of CPT's public service functions.

Table 12. Comparison of French and Tunisian retail prices of certain drugs widely used in Tunisia

INN	Dose	Dosage form	Drugs available in Tunisia		Drugs available in France		Tunisia		France		French price/ Tunisian price
			Proprietary product	Cheapest product	Proprietary product	Cheapest product	Retail price per box ²²	Unit price	Retail price per box ²³	Unit price	
Lysine acetylsalicylate	1000 mg	Powder for oral solution	Aspegic (20 sachets)	-	Aspegic (20 sachets)	-	-	2.964	2.30	4.09	1.78
Niflumic acid	700 mg	Suppositories	Nifluril, box of 8		Nifluril, box of 8			2.505	1.95	2.64	1.36
Amoxicillin	500 mg	Capsules	Clamoxyl, box of 12	Niflumic, box of 5	Nifluril, box of 8			1.600	1.24	2.64	1.33
Carbocysteine	100 mg	Syrup	Bronchokod, 125 ml bottle		Clamoxyl, box of 12			4.080	3.12	2.68	0.86
Paracetamol + dextropropoxyphene	400 mg + 30 mg	Capsules	Diantalvic, box of 20		Bronchokod, 125 ml bottle			1.536	1.19	1.88	1.58
Famotidine	20 mg	Tablets	Pepdine 20, box of 30		Diantalvic, box of 20			3.007	2.34	2.97	1.27
								2.174	1.69	2.44	1.44
								21.992	17.09	18.83	1.10
								13.200	10.26	18.83	1.84

²² PDD data.

²³ Vidal 2002 and Sempex 2002.

²⁴ Conversion based on 1 dinar = 0.777 euros.

Nifedipine	20 mg	Tablets CR	Adalate retard, box of 20		Adalate retard, box of 30		6.215	4.83	0.24	8.58	0.29	1.19
			Nifedipine LP, box of 50		Several Nifedipine LP G, box of 30		2.759	2.14	0.04	6.31	0.210	4.88
Omeprazole	20 mg	Capsules	Mopral, box of 14		Mopral, box of 14		39.392	30.61		25.90		0.85
				Risek, box of 14	Mopral, box of 14	-	21.157	16.44		25.90		1.58
Paracetamol	500 mg	Tablets	Doliprane, box of 16		Doliprane, box of 16		1.190	0.93		2.21		2.39
				Analgan, box of 20	Paracetamol EG, box of 16		0.807	0.63	0.03	1.48	0.09	3.00
Piroxicam	20 mg	Capsules	Feldene, box of 15		Feldène, box of 15		9.892	7.69		9.13		1.19
				Roxam, box of 14	Piroxicam EG, box of 15		5.800	4.51	0.32	5.34	0.36	1.11
Roxithromycin	150 mg	Tablets	Rulid, box of 10		Rulid, box of 10		10.525	8.18		14.09		1.72
				Roksolit, box of 10	Rulid, box of 10		12.590	9.78		14.09		1.44
Spiramycin	1500 IU	Tablets	Rovamycin, box of 16		Rovamycin, box of 16		6.420	4.99		10.29		2.06
				Spira 1.5 MIU box of 16	Rovamycin, box of 16		4.950	3.85		10.29		2.68
Mean												1.74

Factors in the efficient functioning of centralized drug importation

Political will

The Tunisian Government stresses the importance of drug supplies and their accessibility for the majority of the population. This is a key role of the public sector, and cannot be left exclusively to the private sector or to market forces. Tunisia is not yet able to offer universal health and welfare coverage, but measures such as centralized drug importation through CPT and the price compensation mechanism have improved drug availability and affordability.

However, if it is to be efficient and transparent, CPT must not be the sole decision-maker. The existing system, based on the distinct roles and responsibilities of public institutions and a strong presence of the private sector, makes all these entities interdependent, which in turn leads to closer monitoring and increased transparency of each activity.

For example, the separation of drug purchasing by CPT and drug evaluation by PDD gives each of these public bodies the right to review the other's work. Thus CPT is not responsible for the choice of which drugs to import, which is based on marketing authorizations granted by PDD. This rules out possible conflicts of interest and allows CPT to criticize, if necessary, the quality of the drugs purchased.

Drug companies and distributors, whose income is dependent on the efficiency of CPT, represent the transparency and social control mechanism which obliges CPT to provide services that match the requirements.

Price regulation

In Tunisia, the law establishes the principle of freedom to fix the prices of goods, products and services, with the exception of certain sensitive goods and services, particularly in the fields of health, medicinal products and medical procedures.

Import controls

CPT exerts its operational and decision-making autonomy within a regulatory system based on marketing authorizations and import licences issued by PDD. In practice, this means that:

- CPT cannot initiate marketing authorization application procedures. Thus, only drugs that have already received marketing authorization can be purchased or included in CPT negotiations.
- The Tunisian drug registration system managed by PDD follows procedures that are comparable to those used in industrialized countries. A WHO analysis of the functions and activities of PDD in February 2001 showed that the current system permits satisfactory evaluation of drug quality, safety and efficacy.
- An imported drug batch cannot leave the customs zone of Tunisian ports and airports unless it is accompanied by a "document of conformity" issued by PDD (customs release certificate). Using a dedicated computer system, PDD checks the supplier's invoice, verifying that the product conforms to the marketing authorization file and that the invoiced price is that agreed. In case of non-conformity, a batch can be moved from the customs area and quarantined in suitable CPT storage facilities, pending resolution of the problem (or rejection). PDD generally takes only 24 hours to check the necessary documents, and procedures are sufficiently flexible to distinguish between a real problem of conformity and a relatively minor problem such as modification of the primary packaging. Thus PDD is able to block the purchase or introduction of drugs whose Tunisian marketing authorization has been suspended or withdrawn subsequent to CPT confirmation of the contract.

Cooperation with customs

The Tunisian drug import control system is based on effective coordination between customs, CPT and the Tunis Pasteur Institute (the sole purchasers of imported drugs) and PDD (which issues

customs release certificates). Thus the customs services only release drugs after receiving written instructions from PDD.

Official publication of prices

CPT plays a key role in determining drug prices, and publishes bimonthly updates for health professionals.

All the actors in the pharmaceutical supply chain (CPT, wholesalers and private pharmacists) keep a watch on each other, ensuring that official prices are respected.

In addition, certain administrative control structures (the Pharmaceutical Inspectorate and the Prices and Competition Office of the Trade Ministry) employ inspectors to monitor prices throughout the country. Finally, Tunisia has a number of active nongovernmental organizations, such as the Consumer Protection Association, which also ensure that official prices are respected.

The Tunis Pasteur Institute

The Tunis Pasteur Institute (TPI) is briefly presented here in its role as sole importer of vaccines, sera, allergens and other biological products. TPI's role is similar to that of CPT for all the other products.

This import exclusivity implies that TPI must control the sale and use of the products it imports, notably by ensuring the traceability of biological products (including blood products). Since 1998, TPI has imported all its vaccines from competing producers prequalified by WHO. Calls for tenders are organized by the supply department, and candidate suppliers are selected by a purchasing committee which issues the contracts. TPI receives biological products directly, and then distributes them to hospitals and other dispensing structures.

TPI's import activities conform to a mechanism tried and validated over many years by CPT (albeit with larger numbers of suppliers and bigger volumes). Independent evaluators mandated by WHO in February 2001 found that the centralized supply system functions efficiently. It is computerized, well documented and managed by competent staff. It executes its supply role very effectively, while respecting both quality and cost criteria.

TUNISIA'S INTERNATIONAL COMMITMENTS: FUTURE OF THE CENTRAL PHARMACY OF TUNISIA

Two major international agreements have been signed by Tunisia during the past decade: accession to membership of the World Trade Organization (WTO) in 1994, and an association agreement with the European Union in 1995. These two agreements were concluded on the basis of broad liberalization of international trade in goods and services and, more generally, an opening of national economies. They may have an impact on the availability and affordability of drugs in Tunisia in the future.

The consequences of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) automatically accepted on accession to WTO membership are relatively well known to developing countries, which are required to adopt tighter legislation on drug patent protection.^{25, 26} Tunisia has prepared for this change, and its legislation on the subject, which already recognized certain types of patents, is now fully in line with the TRIPS Agreement. Application of these new measures at the end of the transition period on 1 January 2005 should not lead to substantial changes in the functioning of the Tunisian pharmaceutical system, and particularly CPT.

In contrast, the association agreement with the European Union is more specific and warrants closer scrutiny.

²⁵ World Trade Organization. Agreement on Trade-related Aspects of Intellectual Property Rights. Geneva, WTO, 1997.

²⁶ Velásquez G, Boulet P, Globalization and access to drugs – Perspectives on the WTO/TRIPS agreement, Geneva, WHO, 1999.

Association agreement with the European Union and state monopoly

Article 37 of the association agreement with the European Union negotiated in 1995 stipulates that structural adjustments must gradually extend to all state monopolies in order to ensure, after the fifth year following entry into force of the agreement, absence of discrimination concerning the import and trading conditions on goods and services between Tunisia and the European Union.

Article 38 of the same agreement specifies that, with regard to public enterprises and enterprises which have been granted special or exclusive rights, it must be ensured that no measures perturbing exchanges between the European Union and Tunisia, or contrary to the interests of the two parties, are adopted or maintained beyond the fifth year.

As for the pharmaceutical sector, as medicines are not simple consumer products, the possible consequences of liberalizing this sector must be carefully considered.

The import exclusivity currently exercised by CPT and TPI guarantees constant supply of the Tunisian market at affordable prices. The Central Pharmacy of Tunisia and the Tunis Pasteur Institute have a legal exclusivity on the importation of drugs and other pharmaceutical products in Tunisia. However, while CPT, as a public body, naturally has the classical prerogatives of an exclusive central purchaser for the public hospital sector, its role towards the private sector is that of an intermediary between local market players and foreign drug manufacturers. CPT is neutral as regards the choice of imported drugs, but watches over their quality and availability. There are no limitations or quotas on the volume of drugs purchased by CPT in this system for the supply of drugs to the Tunisian private health sector, as these quantities are determined through free competition among drug companies.

This considerably lessens the scope for the possible application of the provisions of the association agreement, and particularly that of Article 36 (on abusive exploitation of a company's dominant position), on CPT activities. Indeed, even if CPT is effectively a "*public enterprise granted special or exclusive rights*", its activity does not perturb trade between the European Union and Tunisia. CPT's work as an intermediary does not negatively affect the interests of either party, but rather facilitates trade by setting a clear framework.

The following questions should be considered:

- *Does the Tunisian drug import system discriminate against European Union companies or Member States?*

As described elsewhere in this document, the Tunisian drug import system is based on the possession of already existing marketing authorizations and on free competition between companies holding such authorizations. The contents of the dossiers and the criteria used to evaluate and issue marketing applications are the same for all companies, regardless of the country of origin. There is therefore no discrimination at this level. Likewise, Tunisian pharmaceutical purchasing procedures do not create discrimination between imported drugs. Regarding contractual agreements, CPT must respect the choices and quantities requested by Tunisian wholesalers and pharmacists. During calls for tenders, CPT simply provides for competition between suppliers of interchangeable generic products. Finally, available data on the provenance of imported drugs clearly show that European Union companies and Member States are in no way penalized by this system.

- *Would the European Union and European drug companies really benefit from the dismantling of the current Tunisian drug import mechanism?*

Available data on trade exchanges between Tunisia and the European Union (see Table 13) show that the trade balance for pharmaceutical products has always greatly favoured the European Union. Dismantling of the current Tunisian system would have no real commercial or economic justification, as more than 90% of pharmaceuticals imported by Tunisia are of European origin (see Table 8). This leads to the conclusion that the current system does not discriminate against European suppliers in favour of other potential international suppliers. Conversely, dismantling of CPT would lead to the creation of numerous private import companies. Being small and therefore less soundly based financially, they might be tempted to seek new and cheaper supply sources,

possibly to the detriment of quality or continuity of supplies. This could have an impact on the share of supply quantities obtained from the different sources.

Table 13. Tunisia's trade balance with the European Union for medicinal products (1996-2001)

Country	Year	Exports to EU (€)	Imports from EU (€)
TUNISIA	1996	4 832 350	108 184 080
	1997	9 524 510	135 242 490
	1998	21 181 760	140 758 670
	1999	2 219 300	143 127 240
	2000	1 096 060	151 184 170
	2001	1 494 800	171 994 660

Source: <http://mkaccdb.eu.int/mkdb/stb/stat/comext.pl> consulted on 20 January 2003

What impact would the dismantling of the Tunisian drug import mechanism have on the Tunisian pharmaceutical system and on equitable access to drugs?

The regulatory system governing drug supplies in Tunisia has demonstrated its effectiveness in a pharmaceutical market of modest size and in a country with limited resources. Indeed, this system has had several benefits:

- It has avoided weaknesses in supply and distribution which could have caused difficulties in the availability and accessibility of drugs;
- It has reinvested the "profits" accruing from its commercial activities, in a socially useful way, using them to maintain retail drug price stability;
- It has optimized the use of public resources by assuring the quality and origin of imported products. The Tunisian market has thereby been protected from counterfeit products -- a ubiquitous problem, but especially in countries with a highly liberalized import and distribution system coupled with a public control system hampered by limited resources.

Dismantling of the CPT import monopoly would certainly greatly weaken the main operational structure of the Tunisian pharmaceutical system, hindering the fight against counterfeit drugs and compromising the accessibility of medicinal products for the majority of the population.

In conclusion, strict application of Articles 36, 37 and 38 of Tunisia's association agreement with the European Union to the pharmaceutical sector, and particularly any challenge to CPT's prerogatives, would be contrary to the spirit of this agreement. It would also be inconsistent with the fundamental principles of development and partnership embodied in the agreement, and in contradiction to the cooperation initiatives on health and welfare undertaken by European Union Member States with Tunisia.

Tunisia needs international cooperation in order to consolidate and further improve its health care system to bring it up to the level of the industrialized countries, but dismantling of the CPT import monopoly would certainly not be the best means of achieving that objective.

CONCLUSION: TUNISIA, A MODEL FOR DRUG IMPORTATION?

The most important benefit of the Tunisian drug import system is to keep retail drug prices as stable and low as possible using only the resources generated by the system itself, i.e. without outside intervention or significant state subsidies.

The system is based on close and effective collaboration between different actors, each with well defined roles: regulation and control structures, customs services, and the various operational structures for supply and distribution.

These different structures ensure the selection and importation of drugs of quality, group purchasing, real negotiation on purchase prices, and a well managed "compensation" mechanism to stabilize retail prices.

Centralized drug purchasing ensures a position of strength in negotiations with suppliers and offers advantages in terms of profitability, costs and planning of orders.

The compensation mechanism allows CPT to keep prices stable both to wholesalers and to the public for drugs available in community pharmacies. It is based on the absorption of all price increases of imported drugs by the central purchasing body, which directly reinjects any "profit" generated by its commercial activity into the supply system in order to ensure that essential drugs are accessible.

Clear separation of responsibilities between public control and regulatory institutions on the one hand, and public supply bodies on the other hand, avoids a monopoly in decision-making and ensures the proper functioning of the centralized drug import mechanism. Moreover, the private pharmaceutical sector exerts outside control on the efficiency of the public sector, through the interaction between the sectors.

Tunisia needs to consolidate and further improve its health system if it is to continue to offer equitable access to medical care, including drugs, and gradually to reach the level of health and welfare characteristic of countries of the European Union. The Tunisian drug import mechanism is clearly not the only element in the strategy to achieve these objectives. However, its dismantling would in no way improve the availability, affordability or rational use of medicinal products.

It is important to note that the existing Tunisian drug import mechanism is compatible with WHO resolutions on access to medicinal products, and particularly resolutions WHA49.14, WHA52.19, WHA54.11 and WHA55.14, which reaffirm that access to essential drugs is a main objective of WHO's drug strategy. These resolutions also call on governments to take the necessary concrete measures to guarantee equitable access to medicines, and to ensure that public health interests remain uppermost in their pharmaceutical and health policies.

The Tunisian drug import system combines price control, accessibility for the majority of the population, strong public structures, and freedom of action for private enterprise. As such, it is an effective model for countries which rely on imports for the majority of their drugs and which might be interested in developing a similar system.