

Essential Laws for Medicines Access: A Pilot Study on National Legislation

Report to the WHO-EMP Department
on work undertaken in Geneva, June-August 2010

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This paper is the report on a pilot study on national laws in support of essential medicines access undertaken in Geneva, June-August 2010 in the WHO Department of Essential Medicines and Pharmaceutical Policies (EMP). The information included in this report reflects the situation in December 2010, after which date no new information was added. However, web links and references were updated and last checked on 7 May 2014..

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Status of this report

This is a report on research activities carried out for the WHO Department of Essential Medicines and Pharmaceutical Policies. The contents of this document and the opinions expressed by the authors are published under their personal title and do not necessarily reflect the opinions or policies of the World Health Organization.

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Executive Summary

Studies demonstrate that many factors affect universal access to essential medicines. To date, little qualitative and comparative analysis has been directed to the laws that support or impede medicines access. The objective of this pilot study was to create a format for collecting national laws in a uniform manner, so that these may be categorized, typed and analyzed into an evidence base, which is currently not available. The underlying hypothesis is that in countries with good access to essential medicines, a particular body of law or legal infrastructure exists that supports such access. This study was designed to identify such supportive laws, with the ultimate goal to identify, through comparative legal analysis, model *essential laws for medicines access* (ELMA).

Data on access to medicines and legal provisions were collected for a large number of countries (Annex 2). Four countries in different stages of economic development were then selected with national laws in a digital format that could be easily retrieved via on-line libraries and databases. These countries were Australia, The Netherlands, South Africa and Tonga. For these countries a series of queries were conducted on the relevant laws of each. Summary country profiles were made describing the overall structure of each government and health system and the national laws of these four countries were identified and compared (Annexes 3-6).

The results of this pilot study show that Australia and The Netherlands have a comprehensive, consistent and integrated body of substantive laws. The laws and regulations governing medicines access are interrelated and work together in coordinated systems that support all areas covered by the selected progress indicators. Evidence of government commitment and relevant legislation is less comprehensive in our two examples of middle-income countries, South Africa and Tonga. Of these, only South Africa is committed to health at the constitutional level, but not specifically to access to essential medicines.

Our study confirms an earlier general impression that a constitutional mandate committing the government to providing essential medicines is not an essential condition for success. Other legal paths can also achieve the desired result if these frameworks commit the government and if financial provisions are being made. The pilot also confirms that the methodology provides sufficient data and allows for comparison and analysis of multiple different types of legislative provisions from different legal systems. However, information on legal support for price control policies and on evidence-based selection of medicines for reimbursement was difficult to obtain in practice and some more indicators with greater specificity to essential laws for medicines access are needed.

It is anticipated that more country studies will be performed following the same protocol; and that these data will first be collected by researchers, and then interpreted as needed by local lawyers, submitted to a central analysis team and retained in a global data base. It is recommended that the legal information collected this way be made freely accessible to researchers and the public. Such a collection will help ensure a greater level of legal information transparency, improve governance in health, hopefully reduce health disparities and promote the rule of law.

It is our hope that this new collection of model legislation will assist other countries in developing and implementing sound legislation in support of universal access to essential medicines.

Introduction

The right to the highest attainable standard of health (in short: the right to health, RtH) is one of the fundamental human rights anchored in several international, regional and national legal documents. No government can ensure the realization of the right to health without ensuring access to essential medicines. Essential Medicines (EM) are those medicines that satisfy the majority of health care needs of a population. If the RtH is to be satisfied, EMs must be available in appropriate amounts, at all times, of good quality, and at affordable prices. Up to 2 billion of the world's population face a lack of access, poor quality and irrational use of EMs. Even with adequately funded health systems, access to medicines can be compromised by a number of factors such as lack of rational selection, high prices, lack of funding, inefficient procurement, corruption, poor supply management, irrational use by prescribers and patients and uncertainty about the quality of medicines.

This study focuses on the legal dimensions of medicines access beyond those found in international and national human rights law. This work goes beyond earlier work of WHO that focused on the regulation of pharmaceuticals in developing countries (Jayasuriya, 1985). There are also WHO guides on developing national drug policies, but with very limited content on legislation (WHO, 2001).

What is absent from the literature is an evidence-based guide on all sectors of the national system that contribute to medicines access, such as tariffs and their waivers, the justiciability of the right to health, and limitations on supply chain margins among others. In the present study a new method is designed and tested, to systematically identify the relevant laws in countries where citizens enjoy the right to medicines and access, with the ultimate objective to build an evidence base on which legislative best practices can be articulated. Given the breadth of subjects that could in theory be covered, this pilot study focuses only on the new progress indicators for access, as established in the WHO Medicines Strategy for 2008-2013.

The methodology is based on our hypothesis that in countries with good medicine access, the rule of law is also well-established. In this context, we refer to the rule of law as defined by four parameters: (1) government accountability; (2) fair processes; (3) access to justice; and (4) laws that are clear, publicized, stable and fair, and that protect fundamental rights. The focus of this work is on the composition of the body of law relevant to the means and mechanisms by which access is accomplished.

If the hypothesis is correct, eventually this study approach will help defining which means and mechanisms must be in place to accomplish the goal of medicines access. The long-term aim of this study is to find evidence to verify the requisite elements of laws in countries with access. From this evidence, good legislative elements and model texts can be defined and a set of legal indicators on access can be crafted. Moreover, these legislative tools and the assessment process of this study serve country stakeholders – including lawyers, legislators, civil society and regulators – to establish a strong legal foundation for medicines access.

Methods

Data on access to medicines and legal provisions were collected for a large number of countries. On the basis of these data, four countries in different stages of economic development were selected with national laws in a digital format that could be easily retrieved via on-line libraries and databases. Of these four countries a summary country profile was made, describing the overall structure of each government and health system. The relevant national laws of these four countries were then identified and compared.

Country overview table

The WHO progress indicators and targets, the Human Development Index and the Rule of Law Index were collected for 59 countries. (Annex 2).

WHO Progress Indicators on access to essential medicines

The report *Implementing the third World Medicines Strategy 2008-2013* describes progress indicators and targets. These data were collected as part of the WHO Medium-Term Strategic Plan for 2008-2013. Seven indicators represent five aspects of access: government commitment, rational selection, affordable prices, sustainable financing, and reliable systems (Box A). These five aspects represent government commitment and actions to make essential medicines available to all. Some of these indicators lend themselves to a legal inquiry, such as whether legal provisions exist that allow and/or encourage generic substitution. Others indicators require some adjustment, such as whether there is an updated national list of essential medicines. The legal query for this indicator had to be adjusted to search for any provision in the law relevant to a national list of essential medicines or a reasonable facsimile such as a reimbursement list.

Box A

Progress indicators on access to essential medicines

1. Access to essential medicines/technologies as part of the fulfillment of the right to health, recognized in the constitution.
2. Existence of a published national medicines policy that has been updated within the last 10 years.
3. Existence of a published national list of essential medicines that has been updated within the last 2 years.
4. Legal provisions to allow/encourage generic substitution in the private sector
5. Median consumer price ratio of 30 selected essential medicines in public and private health facilities is below four times the world market reference price
6. Public/Private per capita expenditure on medicines as a country specific value.
7. The average availability of 30 selected essential medicines in public and private health facilities meets a target value of 80%.

National constitutional text: Data on the recognition of the right to medicines in national constitutions were taken from a WHO study by the Katrina Perehudoff (Perehudoff, 2008).

The Human Development Index: The Human Development Index (HDI) measures development by combining indicators of life expectancy, educational attainment and income into a composite human development index. The HDI is a single statistic for social and economic development.

The selection of HDI as an indicator relevant to medicines access assumes that countries with a higher HDI are more likely to have national policies, including laws and regulations that protect the right to health and provide access to essential medicines.

The World Justice Project Rule of Law Index: The Rule of Law Index measures the extent to which states adhere to the rule of law on a scale of 0 to 1. The Index evaluates how nations apply their laws in practice according to the four main elements of the rule of law (Figure 1). As noted earlier, Element 2 is highly relevant to our hypothesis and question: which laws are present in the countries in which citizens enjoy access to medicines? Element 2 looks to the status of laws – are they clear, publicized, stable and fair, and do they protect fundamental rights?

Other data: Data on World Bank income level, WHO region and WHO Country rankings in the World Health Report 2000 were also collected.

Legal Research

The legal research was conducted in two phases: first, an overview of the structure of the government was collected, followed by a second phase of reviewing the laws related to the health system. Selections were based on obvious relevance, and because chapter and sections titles were specific to each health system. Next, detailed legal information reflecting the progress indicators was collected.

Legal research and analysis of the laws of a country was limited to statutory and legislative materials and ratified international conventions, if applicable to a progress indicator. Research followed a typical legal hierarchy, commencing with primary source material whenever possible, such as international conventions, national legislation and other relevant source materials, such as ministerial declarations and presidential decrees that, under national law, have equal weight to legislative provisions. Particular attention was paid to tables of contents of laws and to giving preference to primary source documents and official translations. Research questions were standardized to allow for future comparisons over time and between countries. These questions were:

A. Member State's structure of government and legal system

- a. Type of legal system? (civil law/common law/Sharia, other?)
- b. What is the hierarchical structure of laws?
- c. Is there a controlling document, such as a constitution?
- d. How are laws written and passed? How are they amended?
- e. What is the form of government? Democracy, monarchy or other?
- f. What effect do national legislative enactments have on provincial, state, local or other governmental subdivisions?

B. Health care delivery system

- a. Is the system public or private or mixed?
- b. What role, if any, does private health insurance have?
- c. Is health care delivery the responsibility of the national government or of a subdivision such as a province or state?
- d. Which laws by their title and section headings contain health legislation?

C. Sources

- a. Government websites from the relevant jurisdiction
- b. The CIA Fact book

- c. Oceana Online – Constitutions of the Countries of the World
- d. Online legal primers
- e. The Ministry of Health or other government websites related to health, and WHO publications
- f. Westlaw, LexisNexis or other online legal research program
- g. GLIN (Global Legal Information Network)
- h. Lexadin
- i. ILO's NATLEX
- j. The U.S. Library of Congress online jurisdiction specific guides.

D. Progress Indicators

To understand how the law addresses (or fails to address) each progress indicator, each indicator was reframed as a legal question and the law was queried accordingly. For the purpose of developing a uniform tool for evaluation of national laws, a set of questions as given below was developed for the four indicators of (1) government commitment; (2) rational selection; (3) affordable prices; and (4) sustainable financing. WHO staff provided invaluable input on the technical components of each indicator. This input helped to define the scope of the legal questions:

a. Government Commitment

1. Did the country ratify or sign any international treaty with health provisions, such as the International Covenant on Economic, Social and Cultural Rights?
2. Is there constitutional or legislative language that gives international treaties or covenants constitutional or legislative force within the Member State's legal system?
3. Is there a provision within the national constitution that explicitly creates a right to pharmaceuticals and/or essential medicines?
4. Is there mandatory language that requires the State to provide pharmaceuticals and/or essential medicines?
5. If there is no mandatory language, is the commitment to provide pharmaceuticals and/or essential medicines otherwise present?

b. Rational selection

1. Is there a legislative enactment that gives a Minister of Health or other government authority discretion to develop an essential medicines list or schedule for reimbursement?
2. Are there any evidence-based criteria, within a legislative enactment, defining which medicines are on the essential medicines list (or pharmaceuticals that are otherwise eligible for state reimbursement)?

c. Affordable prices

1. Is there a legislative enactment that encourages and/or provides for the use of generic medicines?
2. Are there any price control mechanisms?

d. Sustainable financing

1. What system, if any, is in place through a legislative enactment that provides payment of pharmaceuticals to individuals within the general population as well as individuals who cannot otherwise afford to pay for pharmaceuticals?

E. Country profile format and database

A country profile format for the presentation of results was designed, containing summaries of the results and references to relevant legal texts and country specific documents.. The four country profiles are given in Annex 2. Original legal information was collected in digital format as much as possible, and presented in each country profile.

Results

The overview table of countries is presented in Annex 2. Australia, Netherlands, South Africa, and Tonga were identified for this pilot study. These countries represent a range of WHO regions, income levels and progress with regard to access to medicines. This variation between countries was intended to test the methodology and possibly provide information for further refinements. The four country profiles and the core legal texts of each are presented in Annexes 2-5.

Government Commitment

Government commitment was measured by the status of international human rights conventions, the presence of constitutional language, and whether constitutional and statutory language mandated actions. Government commitment is important as in most countries the national government is responsible for providing for the health care of citizens.

International Covenant on Economic, Social and Cultural Rights (1970)

In the 1970s, both **Australia** and **The Netherlands** signed and ratified this covenant, which embeds the right to enjoy the highest attainable level of physical and mental health. **South Africa**, however, merely signed the Covenant in the 1990s, but has not ratified it. **Tonga** has neither signed nor ratified the covenant.

Constitution

Australia's Constitutional Act includes no mention of a right to health, yet uses mandatory language giving the Parliament power to “make laws for ... the provision of ... pharmaceuticals...” The Constitution of **The Netherlands** includes mandatory language to promote and improve health without including any specific mention of a right to health or a right to pharmaceuticals. The constitution of **South Africa** does include a right to health and states that the government has the duty to provide health care services to those who cannot afford them. However, it does not contain any specific reference to medicines or pharmaceuticals. The constitution of **Tonga** contains no mention of a right to health, health care, health insurance, pharmaceuticals, or medicines, nor any mandate to the government.

Government mandates

The constitutional act of **Australia** mandates the government to certain actions by using the term “shall”. This is also the case for pharmaceuticals: “*The Parliament shall... make laws... with respect to... the provision of ... pharmaceutical[s]*”. It also requires the government to provide pharmaceutical benefits. The national legislation of **The Netherlands** creates a framework that appears to exactly implement the constitutional requirement of promoting the health of the population, but does so in language establishing rights of citizens rather than government obligations. This framework sets out that: 1) all citizens are eligible for government provided health insurance for unforeseen medical costs, such as long-term hospital or nursing home stays; 2) all citizens are required to purchase basic health insurance from private companies; and 3) this basic health insurance must include coverage for pharmaceutical benefits. Therefore, The Netherlands government ensures by legislation that citizens have insurance for pharmaceuticals.

Despite difference in their constitutions, **South Africa** and **Tonga** have similar language in legislation. The legislative mandates to provide health care services are fulfilled by placing the

obligation on the State to provide health care services; each country implements the mandate by creating risk sharing between citizens, the government and insurance companies. Each country also legislatively limits this government commitment in two ways. First, the national legislation gives discretion to a Minister of Health to determine which services are included. Second, each has a legislative provision that limits the State's obligation to provide health care to services which are possible within the available financial resources.

Sustainable Financing

There are two subsections of the sustainable financing indicator: the framework of a state reimbursement scheme and the governmental allowance for state subsidy. Sustainable financing is an essential aspect of affordability of access, and an important signal of government commitment.

The state reimbursement scheme for **Australia's** National Health Act includes a specific provision that prohibits pharmacists, hospitals, etc... *"from receiving any form of payment, other than from the Commonwealth, for pharmaceutical benefits in order to protect the integrity of pharmaceutical benefit programs and the Commonwealth Medicare."* In **the Netherlands** the government subsidizes all costs of care covered by the basic health insurance, which includes pharmaceuticals. The exception of this full coverage is a so-called "individual risk" or co-payment: the insured pays a certain amount out-of-pocket before the insurer covers the remainder. **South African** law contains a state reimbursement scheme for free primary health care, but it is limited by certain prerequisites and does not explicitly include pharmaceuticals. The government of **Tonga** considers it to be the duty of each medical officer, a government employee to afford free medical health services within his or her district. This service includes pharmaceuticals.

In **Australia**, the state subsidy takes the form of a framework of concession cards and a safety net. When an individual had paid the full co-payment amount for pharmaceuticals, the insurance covers the rest. In **the Netherlands** individuals pay a monthly premium to private insurers. Persons with an income below a certain level may receive a state subsidy to pay the insurance premium. The Minister of Health of **South Africa** may, after mandatory consultation of the Minister of Finance, determine who is or who is not an eligible person to receive free medical treatment. This ministerial discretion is bound by several markers, which the Minister is required to take into account. The law, however, does not specifically enumerate who qualifies as an eligible person. In **Tonga**, pharmaceuticals are free of charge. This benefit is limited, however, in that the Minister of Health has discretion to implement a system of co-payments for specific health care services, provided that individuals who are unable to pay such co-payments are not denied essential health care services. Other than this limitation, full discretion is given to the Minister of Health in determining who qualifies as an eligible person. The Minister of Health may also exempt certain categories of people, e.g., the disabled or the elderly), from making co-payments, if the exemption is published in the national Gazette.

Rational Selection

Rational use of medicines requires that *"patients receive medications appropriate to their clinical needs, in doses that meet their own requirements, for an adequate period of time, and at the lowest cost to them and their community."* Rational selection is a prerequisite for rational use. Selection

occurs in product registration, procurement, treatment protocols, the national essential medicines lists and ultimately in the national reimbursement lists. Best practice indicates that supply and reimbursement follow a national essential medicines list, following the approach of the WHO Model List of Essential Medicines, published bi-annually. A national list of essential medicines, created by the parties noted above, must be maintained by regular, e.g. biannual revisions and serve as the basic reference document for public pharmaceutical procurement or reimbursement.

Through legislation, **Australia** requires the Minister of Health to set forth a list of medicines covered by state reimbursement, which are presented in the regulations as schedules. **The Netherlands** use regulation, rather than legislation, to establish the list of medicines reimbursed within the scope of the obligatory basic health insurance. Both **South Africa** and **Tonga** include a specific provision in national legislation that places the responsibility to develop a list of medicines for reimbursement on the Minister of Health and the National Drugs and Medical Supplies Committee. The South African Department of Health publishes its list as a policy document. Legislation in **Tonga** establishes a mandate to create a list of medicines for reimbursement; the text of the law itself does not contain such a list.

Affordable Pricing

The promotion of the use of generic medicines is used as a proxy indicator for government commitment to the affordability of medicines. Affordable pricing is related to the use of generics, because these are usually less costly than branded products. Affordable pricing and generic medicines promotion are connected through legal provisions that increase coverage for generic use and increase the co-pay for branded products.

Australia's reimbursement framework distinguishes brand name and generic pharmaceuticals, and promotes the use of generics by covering them with a greater level of reimbursement. **The Netherlands** requires that anyone with insurance should always have access to one of the medicines out of a group with the similar active ingredients, but if an insured opts for the higher-priced (often a branded) product, that person pays more out-of-pocket. By legislation, **South African** pharmacists are required to inform people that generics and branded products are interchangeable. If a patient opts for a generic medicine, the pharmacist must note the brand name for the patient on the prescription. The law also includes a provision that explicitly disallows pharmacists from dispensing generics if the prescriber has written "no substitution" on the prescription. In **Tonga**, the legislative provisions addressing the promotion of generic medicines use is sparse. There are no specific provisions that set requirements for medicines classification, nor are there legal provisions that set an encouraging or promoting generic medicines use policy. Pharmacists, however, are required to list a generic name on all prescriptions.

Discussion

Australia and The Netherlands present with a comprehensive and integrated body of substantive laws. The laws and regulations governing medicines access are interrelated and work together in coordinated systems that support all areas covered by the selected progress indicators. We can conclude that government commitment is demonstrated and is consistently reflected in the laws we identified in relation to the access indicators. In other words, the laws require the government to deliver the actions necessary to fulfill the patient's right to access to essential medicines. For example, legally binding laws or regulations commit the government to a state subsidy or reimbursement for medicines; health care financing is legally based on rational selection of a list of medicines covered under health insurance or state reimbursement, and affordability is supported by a generic policy. These possible relationships need more study but the pilot observations suggest there are in fact correlations to be identified and duplicated.

Evidence of government commitment is less comprehensive in the legal systems of our two examples of middle-income countries, South Africa and Tonga. Only South Africa is committed to health at the constitutional level, but not specifically to access to essential medicines. The respective national laws do not commit the government to action for all the indicators used in our study. South Africa provides free access to essential medicines as part of free primary health care services. In the national legislation of Tonga, pharmaceuticals are included as a part of free health services, perhaps reflecting a philosophy that is not stated in the constitution but is practiced in fact. Both countries restrict their obligations within the limitations of government resources. Both countries show a lower percentage of total government expenditure on medicines, and both have not incorporated the mandatory promotion and use of generics into their national systems.

Our detailed study of four countries confirms that a constitutional mandate that commits the government to provide essential medicines is not an essential condition for success. But is there a link between legal means and mechanisms for access and national ratification of the International Covenant on Economic, Social and Cultural Rights (ICESR)? In our study, only Australia and The Netherlands have ratified the ICESR. These are exactly the two countries that provide for comprehensive government financing of health services for all citizens through state reimbursement and subsidies and have no legal texts that limit government obligations. In contrast, South Africa has not yet ratified the Covenant and Tonga has not even signed it; these two countries have weaker legal systems for access, lower levels of financing and restrictions on government financing. These differences raise the question of what elements comprise a sufficient body of law, thus a legal framework that ensures access to essential medicines?

Our study also found a few interesting differences in the use of terms. First, none of the four countries had a legal mandate specifically requiring the establishment and use of an "essential medicines list"; but all make reference to a list of medicines for reimbursement. This focus on reimbursement reflects one of the most important uses of the essential medicines concept. Secondly, there appears to be differences in the use of the term "generic". In Dutch legislation, the term "generic" is mentioned, though not consistently; some provisions describe generics as "medicines out of a group with the similar active substance – less expensive similar pharmaceuticals." In South African law, generics are defined as "interchangeable multi-source medicines." Both Australia and Tonga use the term generic medicines.

Methodology

Any comparative legal analysis is restricted by the fact that this pilot study only included four countries. The most important outcome of this study is therefore the proof of concept: it is indeed possible to collect important legal texts, other than national constitutions, that have a potential impact on access to essential medicines.

Two components of the original progress framework proved difficult to use in practice. Information on price control policies (D.a.2) and on the procedures for evidence-based selection of medicines for reimbursement list (D.b.2) was difficult to obtain in practice. The future use of these indicators must be reviewed. One of the reasons for this is that often a technical standard such as a medicines reimbursement list is documented in a regulation or other subnational legal instrument or in a non-legal instrument. It is very difficult to find sub-national legal instruments and non-legal technical instruments through existing databases.

The lack of easily available and comprehensive legal information was and will continue to be a serious barrier to this work. There is no such database of health laws in existence. Many countries continue to maintain their laws for all sectors in paper format and thus are not searchable with ease even assuming the researcher is fully familiar with the system.

Limitations of the study

Apart from the limitations related to the few countries studied, it is important to state that all findings are exploratory and preliminary. Secondary legal sources such as decrees, administrative and judicial rulings were not used to diagram the full legal framework underlying the progress indicators. Thus, it is unknown whether a secondary legal source can explain why, in the absence of national legislation or a constitutional mandate, a country like Tonga scores so high on public expenditure on medicines. This level of analysis can only be done by a practitioner in the law of Tonga, armed with the study methodology and a solid understanding of the sociological dimensions of the country.

Next steps: Essential Laws for Medicines Access (ELMA)

It seems that countries whose governments provide a large percentage of overall financing for pharmaceuticals are the countries with more developed laws that work together in a legal system that supports access to essential medicines. These countries also have the highest Rule of Law Index scores. The hypothesis that there is a correlation between high levels of rule of law and higher indicators on medicines access needs further testing. In this regard we have coined the concept of essential laws for medicine access (ELMA).

The next step is to study the legislative texts in other countries. The raw or primary and comparative legal information collected in the future must be stored somewhere and hopefully this location will be open to the public without charge. This information will be of great utility, as it will allow any number of research questions to be analyzed. Understanding how other countries have addressed the same legal issues will be particularly important for low- and middle-income countries undergoing health reform in the medicines sector. Moreover, such a collection of full bodies of law will help ensure a greater level of legal information transparency, improve governance in health, hopefully reduce health disparities and promote the rule of law. It would be unfortunate to miss the opportunity to capture such data for wider use.

Conclusions

The results of this pilot study of four countries show that Australia and The Netherlands have a comprehensive, consistent and integrated body of substantive laws. The laws and regulations governing medicines access are interrelated and work together in coordinated systems that support all areas covered by the selected progress indicators. Evidence of government commitment and relevant legislation in support of access to essential medicines is less comprehensive in the two examples of middle-income countries, South Africa and Tonga. Of these, only South Africa is committed to health at the constitutional level, but not specifically to access to essential medicines.

Our study confirms an earlier general impression that a constitutional mandate that commits the government to provide essential medicines is not an essential condition for success. Different legal paths can provide the desired result if these frameworks commit the government and if financial provisions are being made. The long-term goal of this study is therefore to identify and collect model legislation on essential laws for medicines access and indicators therefore. Countries could use these to benchmark existing and proposed local laws governing medicines.

This pilot study created a new format to systematically collect country legal information, so that these data can be compared and analyzed. The methodology provides sufficient data and allows for comparison and analysis of multiple different types of legislative provisions from different legal systems. Information on legal support for price control policies and on evidence-based selection of medicines for reimbursement was difficult to obtain in practice; some more indicators with greater specificity to essential laws for medicines access are therefore needed.

The potential correlation between high levels of rule of law and higher indicators on medicines access needs further testing. In this regard we have coined the concept of Essential Laws for Medicine Access (ELMA). The next step is to study the legislative texts in other countries, with the ultimate goal to collect examples of best practice and model legal texts.

The legal information collected must be stored in a location open to the public without charge. Such a collection will help ensure a greater level of legal information transparency, improve governance in health, hopefully reduce health disparities and promote the rule of law.

Annex 1

Practical recommendations by student researchers

1. Include legislation from industrialized countries

The value of the legal provisions of high income, high-rank countries should not be discounted. Identifying the legal provisions of these countries serves a significant purpose. These high scoring countries will serve as a guide for ELMA. Countries with less developed laws on access may use this information to help answer the important question of which laws are *not* present.

2. Follow the methodology

The methodology should be followed as closely as possible to ensure substantially similar results from one researcher to the next. The fact remains, however, that every legal system will have its own unique intricacies that need to be understood for proper research to occur. Therefore, researchers who should be lawyers should use their legal competency in producing a thorough analysis.

3. Do not underestimate the time needed

Anyone beginning research under this study should not underestimate the amount of time necessary to fully explore the laws to produce the country report. Every country will take a different amount of time depending on the researcher's prior knowledge in that area, the development of the given legal system, the accessibility of laws, etc. At the outset of the three-month summer period, the research team planned to look at the laws of 12-15 countries; instead, due to the time it took to analyze each, only four countries were analyzed. This recommendation should also help with developing a long-term, multi-year plan for this research that is realistic and feasible.

4. Study the country as closely as possible

Researching the laws of any country can be difficult. The difficulty of this process is increased when research takes place from a location "remote" to the laws. As this study progresses it would be ideal to have students and their professors' work in situ to conduct the primary research and analysis. This work would then be integrated into the study by a review team after which the comparative results would be shared with country researchers and reviewed for accuracy of the interpretation.

We think this approach could open opportunities to access national and university libraries and to discussions on health legislation with department of health officials, WHO staff members, and local legislators. Furthermore, researchers could interview doctors and pharmacists about their prescribing habits, the trends they see, and the existence and application of any laws that limit, structure and mandate their practice. Interviews such as these may lead to an understanding of what factors exist that lead to access when no mandates exist in the laws.

A possible solution would be to recruit law students from around the world. This recommendation is not designed in any way to discount the value of working at the WHO headquarters. There is a great deal to be learned from full-time WHO staff members and having direct access to these individuals to ask questions has been essential. Therefore, any student who

will also be doing “field research” should also be required to spend time at the WHO prior to such research to ensure they are fully oriented with the study.

5. Access to paid sources of data is essential

Accessing laws of a country can be difficult at times for citizens of that country, let alone foreign researchers. Moreover, multiple countries were not included in the study simply because access to verifiable versions of their laws required a paid subscription to a legal research service (such as LexisNexis, Westlaw or other country-specific services). Free versions appeared to be unofficial documents and, therefore, unreliable for this survey. For this study to progress and continue to produce accurate results, access to these paid services will be essential. With the research continued by national teams of university professors and students access to these data bases is easier as it was in the pilot which relied upon the law library access of the lead investigator and student researchers.

6. Laws change, so regular updates are necessary

Legal systems are designed to regulate human behavior. As the needs of a society and the behavior of its citizens change, so too will the laws. This fact becomes important when research spans more than a year, as this study will have to in order to be completed. To maintain the integrity and quality of the study results, steps must be undertaken to check – and re-check – the laws of countries that have been previously analyzed by local legal persons. This procedure will help identify any relevant changes to legislative provisions included herein and ensure analysis is correct.

Annex 2

Overview of selected countries

Country	National Medicine Policy in place	National List of Ess.Meds updated <2yrs	Generic substitution encouraged	CPR <4x	Per capita expend- iture on medicines (pub)	Per capita expend- iture on medicines (private)	Constitu- tional provision Right to Health	Human Develop- ment Rank	Rule of Law Index		World Bank Index	WHO region	WH2000 ranking
Albania					4	4	Yes	70 - H	0.45	0.57	LM	EURO	86
Argentina	Yes		Yes		41	157	Yes	49 - H	0.51	0.6	UM	PAHO	49
Armenia	Yes	Yes	Yes		5	13	Yes	84 - M			LM	EURO	81
Australia	Yes	Yes	Yes		133	112	Yes	2 - VH	0.79	0.81	H	WPRO	12
Austria	Yes	Yes			227	97		14 - VH	0.77	0.85	H	EURO	10
Barbados	Yes	Yes	Yes		46	103		37 - VH			H	PAHO	38
Belarus	Yes	Yes	Yes		6	1	Yes	68 - H			LM	EURO	53
Bhutan	Yes	Yes	Yes		2		Yes	132 - M			LM	SEARO	144
Bolivia	Yes	Yes	Yes		3	10	Yes	113 - M	0.37	0.48	LM	PAHO	117
Botswana	Yes	Yes	Yes		23	23		125 - M			UM	AFRO	168
Bulgaria	Yes	Yes			13	4	Yes	61 - H	0.55	0.69	UM	EURO	74
Cameroon	Yes	Yes	Yes		1	7	Yes	153 - M			LM	AFRO	163
Cape Verde	Yes	Yes	Yes		12	7	Yes	121 - M			LM	AFRO	126
Colombia		Yes	Yes		6	13	Yes	77 - H	0.58	0.6	LM	PAHO	41
Croatia					61	10	Yes	45 - H	0.52	0.52	UM	EURO	36
Dom. Republic		Yes	Yes		5	18	Yes	90 - M	0.61	0.62	LM	PAHO	66
Ecuador	Yes	Yes	Yes		3	10	Yes	80 - H			LM	PAHO	107
Egypt	Yes	Yes	Yes		3	17	Yes	123 - M			LM	EMRO	110
El Salvador		Yes			6	39	Yes	106 - M	0.59	0.67	LM	PAHO	122
Ethiopia	Yes	Yes	No	Yes	1	1	Yes	171 - L			L	AFRO	186
France		Yes	Yes		273	148		8 - VH	0.69	0.74	H	EURO	6
Ghana	Yes	Yes	Yes		n/a	n/a	Yes	152 - M	0.57	0.6	L	AFRO	139
India	Yes	Yes			1	2	Yes	134 - M	0.5	0.65	L	SEARO	121
Indonesia	Yes	Yes		Yes		5	Yes	111 - M	0.55	0.51	LM	SEARO	106
Iran			Yes	Yes	20	19	Yes	88 - M			LM	EMRO	114
Italy	Yes	Yes	Yes		149	187	Yes	18 - VH			H	EURO	11
Japan	Yes		Yes		348	180		10 - VH	0.71	0.74	H	WPRO	1
Jordan	Yes	Yes			14	39		96 - M	0.48	0.54	LM	EMRO	84
Kenya			Yes	Yes		6		147 - M	0.35	0.43	L	AFRO	142
Kyrgyzstan	Yes	Yes	Yes		1	4		120 - M			L	EURO	135

Liberia	Yes	Yes	Yes	n/a	n/a		169 - L	0.53	0.44	L	AFRO	187
Mexico	Yes	Yes		19	62	Yes	53 - H	0.62	0.55	UM	PAHO	51
Mongolia	Yes	Yes	Yes	2	1	Yes	115 - M			L	WPRO	136
Morocco		Yes		2	18		130 - M	0.48	0.52	LM	EMRO	94
Netherlands	Yes			123	80	Yes	6 - VH	0.75	0.83	H	EURO	8
Nigeria	Yes	Yes	No	1	2	Yes	158 - M	0.48	0.45	L	AFRO	184
Norway	Yes	Yes	Yes	147	125		1 - VH			H	EURO	3
Pakistan				3	2	Yes	141 - M	0.29	0.44	L	EMRO	133
Peru	Yes	Yes	Yes	5	18	Yes	78 - H	0.53	0.6	LM	PAHO	115
Philippines	Yes	Yes		1	13	Yes	105 - M	0.46	0.58	LM	WPRO	54
Poland	Yes		Yes	27	34	Yes	41 - H	0.58	0.71	UM	EURO	34
Moldova	Yes	Yes	Yes	1		Yes	117 - M			LM	EURO	91
Sierra Leone	Yes	Yes				Yes	180 - L			L	AFRO	191
Singapore		Yes	Yes	45	237		23 - VH	0.63	0.66	H	WPRO	27
Solomon Islands	Yes	Yes	Yes	2	1		135 - M			LM	WPRO	108
South Africa		Yes	Yes	6	25	Yes	129 - M	0.65	0.63	UM	AFRO	151
Spain	Yes	Yes		164	21	Yes	15 - VH	0.66	0.79	H	EURO	19
Suriname	Yes	Yes	Yes	10	22	Yes	97 - M			LM	PAHO	105
Swaziland	Yes	Yes	Yes	n/a	n/a	Yes	142 - M			LM	AFRO	164
Sweden			Yes	221	95		7 - VH	0.81	0.89	H	EURO	4
Tajikistan	Yes	Yes	Yes	1		Yes	127 - M			L	EURO	127
Tanzania		Yes	Yes	1	1		151 - M			L	AFRO	158
Thailand				13	8	Yes	87 - M	0.43	0.66	LM	SEARO	57
Tonga	Yes	Yes	Yes	11	10		99 - M			LM	AFRO	156
Turkey				34	21		79 - H	0.48	0.41	UM	EURO	96
Uganda	Yes	Yes	Yes		2	Yes	157 - M			L	AFRO	162
Ukraine				3	2	Yes	85 - M			LM	EURO	60
United States				99	442		13 - VH	0.69	0.75	H	PAHO	15
Yemen		Yes	Yes		8	Yes	140 - M			L	EMRO	146

Annex 3:

Australia

NB: This report reflects the situation in 2010.

Legal System

The legal system in Australia is structured as a constitutional Monarchy. Australia uses a common law system based on English common law. Australia also uses a federal structure that defines each state and territory as a separate, self-governing jurisdiction with its own court system and parliament. Laws passed by the Australian National Parliament are binding on the entire country.

Health Care System

Within Australia's federally structured government, provision of health care services is divided between the national level and the state/territory level. On the National level, the Federal government implemented Medicare – a health care delivery system that funds medical services and pharmaceuticals. Funding for Medicare comes from the Medicare Levy, a tax on all Australians based on their income. State and territory governments are responsible for actual provision of health care services for their localities. The Australian Department of Health and Ageing established the Pharmaceutical Benefits Scheme, which determines the particulars for provision and reimbursement of pharmaceuticals on a national level.

Constitution

Commonwealth of Australia Constitution Act 1990 (Cth) s 51xxiiiA: "The Parliament shall, subject to this Constitution, have power to make laws for the peace, order, and good government of the Commonwealth with respect to... the provision of maternity allowances, widows' pensions, child endowment, unemployment, *pharmaceutical*, sickness and hospital benefits, medical and dental services (but not so as to authorize any form of civil conscription), benefits to students and family allowances." (emphasis added).

Overview of Relevant Provisions

Indicator	National Legislation	National Regulation
Government Commitment Mandatory language	"Benefits shall be provided by the Commonwealth, in accordance with this Part, in respect of pharmaceutical benefits." <i>NHA 1953 (Cth) s 85(1)</i>	
Sustainable Financing State reimbursement scheme	"[a]n approved pharmacist, a medical practitioner or an approved hospital authority shall not demand or receive a payment (other than a payment from the Commonwealth) or other valuable consideration in respect of the supply of a pharmaceutical benefit." <i>NHA 1953 (Cth) s 85(1)</i> . "The object of this Part is to protect the integrity of the Commonwealth Medicare benefits and pharmaceutical benefits programs...." This provision is found within a section of the Health Insurance Act, which establishes a system to review professional services. <i>HIA 1973 (Cth) s 79A</i> .	
Sustainable Financing State subsidy	This provision sets out the eligibility requirements for state subsidized pharmaceutical benefits. <i>NHA Act 1953 (Cth) s 84C(1AA)</i> .	These regulations set out the details for the system of state subsidized pharmaceuticals. <i>NHR (Pharmaceutical Benefits) 1960 (Cth) pts IIAA, IIA</i> .
Rational Selection Essential medicines framework	This provision sets out that medicines covered for state reimbursement under the National Health Act are those set forth by the Minister of Health through legislative instrument. <i>NHA 1953 (Cth) s 85(2)</i> .	These regulations provide lists of pharmaceuticals that are covered for state reimbursement. <i>NHR (Pharmaceutical Benefits) 1960 (Cth) schs1-2</i> .
Affordable Prices Availability of generics	These legislative provisions set out the framework for distinguishing between brand name and generic pharmaceuticals. <i>NHA 1953 (Cth) ss 84AC-AE, 85AB</i> .	Within the lists of pharmaceuticals that are covered for reimbursement, these regulation sections divide the pharmaceuticals into the framework for generics the NHA provides. <i>NHR (Pharmaceutical Benefits) 1960 (Cth) schs 1-2</i> .

Comments

Australia's National Health Act contains a direct mandate for the State to provide pharmaceutical benefits. Although it is not called an essential medicines list, the regulatory provisions listed include a list of pharmaceuticals eligible for state reimbursement. There is a system in place for substitution of generics; however, the term "generic" is not used within the legislation or regulations.

Sources

Legal instruments

- Commonwealth of Australia Constitution Act 1990 (Cth).
- National Health Act 1953 (Cth), (NHA).
- National Health (Pharmaceutical Benefits) Regulations 1960 (Cth), (NHR (Pharmaceutical Benefits)).
- Health Insurance Act 1973 (Cth), (HIA).
- Social Security Act 1991 (Cth), (SSA).

Web links

- Department of Foreign Affairs and Trade, *Legal System*. Available at: http://www.dfat.gov.au/facts/legal_system.html
- Department of Foreign Affairs and Trade, *Australia's System of Government*. Available at: http://www.dfat.gov.au/facts/sys_gov.html
- Department of Foreign Affairs and Trade, *Health Care in Australia*. Available at: <http://www.dfat.gov.au/facts/healthcare.html>
- Department of Health and Ageing, *The National Medicines Policy Document*. Available at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/nmp-objectives-policy.htm>
- Department of Health and Ageing, *Pharmaceutical Benefits Scheme*. Available at: [http://www.health.gov.au/internet/main/publishing.nsf/Content/pharmaceutical+benefits+scheme+\(PBS\)-1](http://www.health.gov.au/internet/main/publishing.nsf/Content/pharmaceutical+benefits+scheme+(PBS)-1)
- Department of Health and Ageing, *Legislation Administered by the Minister*. Available at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-eta2.htm> Department of Human Services, *Medicare Australia*. Available at: <http://www.medicareaustralia.gov.au/>

Other

Hynd, A *et al.*, The Impact of Co-Payment Increases on Dispensings of Government-Subsidised Medicines in Australia, *Pharmacoepidemiology and Drug Safety* 2008.

Sweeny K, Key Aspects of the Australian Pharmaceutical Benefits Scheme, Working Paper no. 35, Centre for Strategic Economic Studies, Melbourne, 2007.

Appendix Australia

Government Commitment

Provision:

[NHA 1953 \(Cth\) s 85.](#)

Pharmaceutical benefits

1. Benefits shall be provided by the Commonwealth, in accordance with this Part, in respect of pharmaceutical benefits.
Note: The Commonwealth may also provide the drugs and medicinal preparations covered by subsection 100AA (1) under special arrangements made under section 100.
2. Subject to subsection (3), the drugs and medicinal preparations in relation to which this Part applies are:
 - (a) drugs and medicinal preparations that are:
 - i. declared by the Minister, by legislative instrument, to be drugs and medicinal preparations to which this Part applies, or
 - ii. included in a class of drugs and medicinal preparations declared by the Minister, by legislative instrument, to be a class of drugs and medicinal preparations to which this Part applies; and
 - (b) medicinal preparations composed of:
 - i. one or more of the drugs and medicinal preparations referred to in paragraph (a), being a drug or medicinal preparation that is, or drugs and medicinal preparations that are, included in a class of drugs and medicinal preparations declared by the Minister, by legislative instrument, to be a class of drugs and medicinal preparations to which this paragraph applies; and
 - ii. one or more of such additives as are declared by the Minister, by legislative instrument, to be additives to which this paragraph applies.

Comments:

This mandatory provision commits the Commonwealth (government) to provide pharmaceutical benefits. It specifically defines the term pharmaceuticals and extends the constitutional commitment of Australia to for see in pharmaceutical benefits.

Sustainable Financing

Provision:

[NHA 1953 \(Cth\) s 84C.](#)

Eligibility for concession and entitlement cards

- (1AA) A person who is both a general patient and an eligible person at any time during a relevant entitlement period is eligible to be issued with a concession card if:
- (a) the total of the amounts charged (otherwise than under subsection 87(2A)) to the person for supplies of pharmaceutical benefits (including supplies taken, because of subsection 99(2A) to be supplies otherwise than under this Part) and repatriation pharmaceutical benefits made to the person during the period and of the applicable amounts in relation to the supplies of out patient medication made to the person during the period; or
 - (b) the total of the amounts charged (otherwise than under subsection 87(2A)) to the person and to the person's family for supplies for pharmaceutical benefits (including supplies taken, because of subsection 99(2A) to be supplies otherwise than under this Part) and repatriation pharmaceutical benefits made to the person and the person's family during the period and of the applicable amounts in relation to the supplies of out patient medication made to the person and to the person's family during the period;
- is the amount of the general patient safety net (within the meaning of section 99F) or an amount that, together with the amount that the person may be charged under paragraph 87(2)(b), (c) or (e) (whichever is applicable) for the supply of a pharmaceutical benefit, would not be less than the amount of the general patient safety net.

Comments:

This provision applies to the "general population." In effect, any individual within the general population who pays a full co-payment for every pharmaceutical benefit they acquire will only have to pay a limited co-pay once they have spent the value of the general patient safety net (i.e. they 'earn' a concession card). Individuals may already qualify for concession cards via their status as a veteran or through the [Social Security Act 1991 \(Cth\)](#). These individuals, along with individuals from the general population who qualify for a concession card under the provisions above, pay a limited co-pay for pharmaceuticals until they reach the value of the concessional beneficiary safety net, at which point they qualify for an entitlement card. See [National Health Act 1953 \(Cth\) s 84C\(1C\)](#). This system of legislation provides a 'step-wise' process of state reimbursement, beginning with a higher co-payment for the general population and moving down to the point of full reimbursement by the Government. This system is intended to ensure that individuals do not pay too much for pharmaceuticals, while the co-payments help ensure the sustainability of the system. Arguments do exist that increases in the co-payments also have a negative effect (Hynd *et al.*, 2008).

Rational Selection

Provision:

[NHA 1953 \(Cth\) s 85\(2\).](#)

"(1) Benefits shall be provided by the Commonwealth, in accordance with this Part, in respect of pharmaceutical benefits.

(2) Subject to subsection (3), the drugs and medicinal preparations in relation to which this Part applies are:

- (a) drugs and medicinal preparations that are:
 - (i) declared by the Minister, by legislative instrument, to be drugs and medicinal preparations to which this Part applies; or
 - (ii) included in a class of drugs and medicinal preparations declared by the Minister, by legislative instrument, to be a class of drugs and medicinal preparations to which this Part applies; and
- (b) medicinal preparations composed of:
 - (i) one or more of the drugs and medicinal preparations referred to in paragraph (a), being a drug or medicinal preparation that is, or drugs and medicinal preparations that are, included in a class of drugs and medicinal preparations declared by the Minister, by legislative instrument, to be a class of drugs and medicinal preparations to which this paragraph applies; and
 - (ii) one or more of such additives as are declared by the Minister, by legislative instrument, to be additives to which this paragraph applies.

(2AA) The Minister may, by legislative instrument, revoke or vary a declaration under subsection (2) in relation to a drug or medicinal preparation.

(2AB) If:

- (a) under subsection (2AA), the Minister proposes to revoke or vary a declaration under subsection (2) in relation to a drug or medicinal preparation; and
- (b) the drug or medicinal preparation would cease to be a listed drug on and after the day the revocation or variation comes into force; then, before making the revocation or variation, the Minister must obtain the advice in writing of the Pharmaceutical Benefits Advisory Committee in relation to the proposed revocation or variation."

The National Health (Pharmaceutical Benefits) Regulations 1960 contain 'schedules' that specifically enumerate the medicines that are covered under the National Health Act. Due to their length, those schedules are not listed here in their entirety; however, the following links can be used to view each schedule. See [NHR \(Pharmaceutical Benefits\) 1960 \(Cth\) ss 1\(F1\), 2\(F2\), 3](#).

Comments:

Australia appears to have an advanced framework for selection of pharmaceuticals for inclusion within the state reimbursement scheme. It should be noted, however, that Australia does not use the term "essential medicines list." In effect, this framework functions similarly to such a list. The regulations contain the specific pharmaceuticals covered for reimbursement (and divide the list by brand names (F1) and generics (F2)). Furthermore, the Minister of Health has discretion to determine which pharmaceuticals are included, but is required to seek independent professional advice from an Advisory Committee if he or she intends to change the list, either by variation of a pharmaceutical or removing a pharmaceutical.

Affordable Prices

Provision:

[NHA 1953 \(Cth\) s 85AB.](#)

"Minister may determine that a listed drug is on F1 or F2

- (1) Subject to subsection (5), the Minister may, by legislative instrument, determine that a listed drug is on F1 or F2.
- (2) The Minister may only determine that the drug is on F1 if the drug satisfies all the criteria for F1.
- (3) The Minister may only determine that the drug is on F2 if the drug does not satisfy one or more of the criteria for F1.
- (4) The criteria for F1 are as follows:
 - (a) there are no brands of pharmaceutical items that:
 - (i) have the drug; and
 - (ii) are bioequivalent or biosimilar; and
 - (iii) are listed brands of the pharmaceutical items on any day in the relevant period;
 - (b) there are no brands of pharmaceutical items that:
 - (i) have another listed drug that is in the same therapeutic group as the drug; and
 - (ii) are bioequivalent or biosimilar; and
 - (iii) are listed brands of the pharmaceutical items on any day in the relevant period;
 - (c) the drug was not on F2 on the day before the determination under subsection (1) comes into force.
- (5) This section does not apply to the drug if:
 - (a) the drug is in a combination item; and
 - (b) there are no brands of combination items that:
 - (i) have the drug; and
 - (ii) are bioequivalent or biosimilar; and
 - (iii) are listed brands of the combination items on any day in the relevant period."

Comments:

The legislative provisions in Australia that control classification of pharmaceuticals as either brand name drugs (F1) or generics (F2) are very complex and interconnected. The provision listed here lists the

requirements for a pharmaceutical to be considered for F1. The language used gives the Minister of Health the discretion to make this decision. However, the provision is written so that the Minister is limited as to what can qualify for F1. The result is a system that favors placing pharmaceuticals on F2. The other legislative provisions working together with this provision can be accessed through the links provided below. [NHA 1953 \(Cth\) ss 84AC-AE.](#)

Annex 4: The Netherlands

This annex reflects the situation in 2010.

Legal System

The Netherlands is a constitutional monarchy and based on a civil law system which embodies the French penal theory. The Constitution was adopted in 1815 and amended multiple times. It does not allow for judicial review of the States General enacted acts. National laws apply to all Dutch residents. Formal Dutch legal references are included, though legal texts are all translated.

National Health Care System

The Dutch National Health Care System was revised recently in 2006. In this new system the government complies passively with its duties. The duty to provide in health care services is predominantly carried out by private health insurers. The indirect carrying out of governmental legal duties to provide health care services is enshrined in the national enactment of the obligatory health insurance that all Dutch civilians must purchase. This is supported by the legal duty of insurers to accept all applications despite age, state of health, or any other ground of discrimination. Competition under private insurers is allowed up to a certain limit. They may never lack in their core duty to provide basic health care. Furthermore, the health insurance is build up out of a basic insurance and an additional (optional) insurance. A certain amount of health care costs are part of the uninsurable personal health risk. Medicines are part of this risk. I.e. an individual has to pay for its own health care costs up to 150 Euro; afterwards the costs fall within the scope of the basic insurance.

Constitution

Art. 22(1) Gw: De overheid treft maatregelen ter bevordering van de volksgezondheid. (The authorities shall take steps to promote the health of the population.)

Overview of Relevant Provisions

Indicator	National Legislation	National Regulation
Government Commitment Mandatory language	-All Dutch residents and those who work for The Netherlands are subject to the general health insurance provided by the Government. <i>Art 5 AWBZ.</i> -All persons who fall within the scope of the AWBZ are required to have a 'basic health insurance'. <i>Art 2 Zw.</i> -"[U]nder the health insurance insured risks are the need for: pharmaceuticals" <i>Art 10(C) Zw.</i>	Pharmaceutical care is explicitly defined in the Decision Health Insurance. <i>Art 2.8 Besluit Zv.</i>
Sustainable Financing State reimbursement scheme		-Health care expenses are subsidized by the insurers with exception of the "individual risk." (The insured pays a certain amount out of pocket before the insurer covers the remainder.) <i>Art 2.2 Besluit Zv.</i> -Medicines listed in the first appendix of the regulation on the Health Insurance Act are covered under the basic insurance. Medicines listed in the second appendix of this regulation are only covered by the basic insurance if complied with certain prerequisites. <i>Art 2.5 Regeling Zv.</i>
Sustainable Financing State subsidy	Persons who have a lower annual fee than the calculated average will receive a state subsidy up to the average fee. <i>Art 2 WZt.</i>	
Rational Selection Essential medicines framework		-Medicines listed in the first appendix of the regulation on the Health Insurance Act are covered under the basic insurance. Medicines listed in the second appendix of this regulation are only covered by the basic insurance if the meet certain

		prerequisites. Medicines listed in the first appendix are considered to be the most essential medicines. Art 2.5 Regeling Zv.
Affordable Prices Availability of generics		- The definition of generics is explicitly determined. Art 2.40 Regeling Zv. - Insured should always have access to one of the medicines out of a group with the similar active substance. Art 2.8.3 Besluit Zv. - Generics are categorized. Art 2.8.5 Besluit Zv. - Individuals must pay a certain contribution for medication of a higher expense if there are less expensive similar pharmaceuticals available. Art 2.8.6 Besluit Zv. The subsidy limit of the state regards the subsidy of generics is based on the general doses and the Defined Daily Dose. Art 2.41 Regeling Zv. (Ch2(2) Regeling Zv. elaborates on price-fixing of generics.)

Comments

Dutch legislation does not contain an explicit mandatory provision on the state's responsibility to allow people access to essential medication. The compulsory basic insurance system, however, covers all Dutch residents and includes pharmaceutical care as part of the insured risk. There is no general list of essential medicines such as the WHO model list of essential medicines. National regulations determine which pharmaceuticals are funded by the state. These regulations include the most essential medicines. Individuals can easily consult which medicines fall within the scope of the basic insurance by consulting this website: www.kiesbeter.nl. The Dutch government supports the use of generics by subsidizing the cheapest available medicines from a group with the similar active substance (mainly a generic pharmaceutical). This policy is also marked by the enactment of the increasing availability of generics. People with a lower incomes can, if they are in compliance with certain specified prerequisites, apply for state health insurance subsidies.

Sources

Legal instruments

- Grondwet voor het Koninkrijk der Nederlanden van 24 augustus 1815, Grondwetsherziening van 17 februari 1983 (Grondwet) Staatsblad 1983, 70 (Gw), *Constitution of the Kingdom of The Netherlands*.
- Wet van 14 december 1967, houdende algemene verzekering bijzondere ziektekosten (Algemene Wet Bijzondere Ziektekosten) Staatsblad 1967, 617 (AWBZ), *General Act on Special Medical Expenses*.
- Wet van 16 juni 2005, houdende regeling van een sociale verzekering voor geneeskundige zorg ten behoeve van de gehele bevolking (Zorgverzekeringswet) Staatsblad 2005, 358 (Zw), *Health Insurance Act*.
- Wet van 16 juni 2005, houdende regels inzake de aanspraak op een financiële tegemoetkoming in de premie van een zorgverzekering vanwege een laag inkomen (Wet op de zorgtoeslag) Staatsblad 2005, 369 (WZt), *Health Insurance Subsidy Act*.
- Besluit van 28 juni 2005, houdende vaststelling van een algemene maatregel van bestuur als bedoeld in de artikelen 11, 20, 22, 32, 34 en 89, van de Zorgverzekeringswet (Besluit zorgverzekering) Staatsblad 2005, 389 (Besluit Zv), *Health Insurance Decision*.
- Regeling van de Minister van Volksgezondheid, Welzijn en Sport van 1 september 2005, nr. Z/VV-2611957, houdende regels ter zake van de uitvoering van de Zorgverzekeringswet (Regeling zorgverzekering) Staatscourant 2005, 171 (Regeling Zv), *Health Insurance Regulation*.

Web links

- CIA World Fact book, *The Netherlands*. Available at: <https://www.cia.gov/library/publications/the-world-factbook/geos/nl.html>

Government Commitment

<p>Provision:</p> <p>Art 5 AWBZ</p> <p>1. Verzekerd overeenkomst de bepalingen van deze wet is degene, die;</p> <p>a. ingezetene is;</p> <p>b. geen ingezetene is, doch ter zake van in Nederland in dienstbetrekking verrichte arbeid aan de loonbelasting onderworpen.</p> <p>Art 2 Zv.</p> <p>1. Degene die ingevolge de Algemene Wet Bijzondere Ziektekosten en de daarop gebaseerde regelgeving van rechtswege verzekerd is, is verplicht zich krachtens een zorgverzekering te verzekeren of te laten verzekeren tegen het in artikel 10 bedoelde risico.</p> <p>Art 10 Zv.</p> <p>Het krachtens de zorgverzekering te verzekeren risico is de behoefte aan:</p> <p>c. farmaceutische zorg</p>
<p>Comments:</p> <p>The Dutch national legislation does not include a provision with mandatory language that commits the government to for see in health care services or procurement of medicines, though it does establish a framework that substantially initiates the same. All Dutch residents are insured under the AWBZ (General Act on Special Medical Expenses). This legislation establishes a government-paid insurance that covers excessive medical costs, such as hospital stays or stays at a nursing home. The Health Insurance Act, however, requires those who are insured under the AWBZ to purchase a basic health insurance that covers pharmaceuticals, among other things.</p>

Sustainable Financing

<p>Provision:</p> <p>Art 2.2 Besluit Zv.</p> <p>1. De vergoeding van kosten, bedoeld in artikel 11, eerste lid, onderdeel b, van de wet omvat de kosten die de verzekerde heeft gemaakt voor zorg of overige diensten die naar inhoud en omvang zijn omschreven in de artikelen 2.4 tot en met 2.15.</p> <p>2. Bij het bepalen van de vergoeding worden in mindering gebracht:</p> <p>a) hetgeen de verzekerde als eigen bijdrage had moeten betalen indien hij krachtens de zorgverzekering recht zou hebben op prestaties bestaande uit zorg of overige diensten;</p> <p>b) de kosten die hoger zijn in de Nederlandse marktomstandigheden in redelijkheid passend is te achten.</p> <p>Art 2.8 Besluit Zv.</p> <p>1. Farmaceutische zorg omvat terhandstelling van:</p> <p>a) de bij ministeriële regeling aangewezen geregistreerde geneesmiddelen voor zover deze zijn aangewezen door de zorgverzekeraar;...</p> <p>6. De verzekerde betaalt een eigen bijdrage voor een geneesmiddel dat is ingedeeld in een groep van onderling vervangbare geneesmiddelen, indien de inkoopprijs hoger is dan de vergoedingslimiet. Een eigen bijdrage wordt ook betaald voor zover een geneesmiddel is bereid uit een geneesmiddel waarvoor een eigen bijdrage is verschuldigd. Bij ministeriële regeling wordt geregeld hoe de eigen bijdrage wordt berekend.</p> <p>Art 2 WZt.</p> <p>1. Indien de normpremie voor een verzekerde in het berekeningsjaar minder bedraagt dan de standaardpremie in dat jaar, heeft de verzekerde aanspraak op een zorgtoeslag ter grootte van dat verschil. Voor een verzekerde met een partner wordt daarbij tweemaal de standaardpremie in aanmerking genomen; in dat geval worden de verzekerde en zijn partner voor de toepassing van deze wet geacht gezamenlijk één aanspraak te hebben.</p> <p>2. De normpremie bedraagt een percentage van het drempelinkomen in het berekeningsjaar, vermeerderd met een percentage van het toetsingsinkomen van de verzekerde in dat jaar voorzover dat toetsingsinkomen het drempelinkomen te boven gaat. Voor een verzekerde met een partner wordt daarbij het gezamenlijke toetsingsinkomen in aanmerking genomen.</p> <p>3. De percentages worden voor verzekerden met een partner vastgesteld op 5% van het drempelinkomen uitgaat voor een verzekerde zonder partner op 2.7% van het drempelinkomen, vermeerderd met 5% van het toetsingsinkomen voor zover dat boven het drempelinkomen uitgaat. Deze percentages kunnen bij algemene maatregel van bestuur worden gewijzigd.</p> <p>4. In afwijking van het eerste lid bedraagt de aanspraak op een zorgtoeslag voor een verzekerde met een partner die geen verzekerde is, vijftig procent van het op grond van het eerste lid berekende bedrag.</p> <p>5. In afwijking van het eerste lid heeft een verzekerde met een partner die niet heeft voldaan aan de voor hem op grond van artikel 2 van de Zorgverzekeringswet geldende verplichting zicht krachtens een zorgverzekering te verzekeren, geen aanspraak op zorgtoeslag.</p> <p>6. De aanspraak op een zorgtoeslag wordt voor iedere kalendermaand afzonderlijk bepaald.</p> <p>7. Bij regeling van Onze Minister kunnen omtrent het bepaalde in het zesde lid nadere regels worden</p>

gesteld.

...

Comments:

The Dutch private health insurers are required to cover all pharmaceutical costs, with the exemption of a determined amount that the individual has to pay out of pocket. After this individual coverage has been exhausted, the private insurer covers the costs of pharmaceuticals. Furthermore, the Dutch government has created a detailed scheme for state subsidy eligibility. Under certain prerequisites one can receive a monthly fee (health insurance fee) from the government to pay the monthly health insurance. This fee is based on the national average income and the personal income of an individual. This provision also set outs who may not receive this subsidy (e.g. persons who do not meet the requirement of purchasing a basic health insurance. See annex 2.2.2.)

Rational Selection

Provision:

[Art 2.5 Regeling Zv.](#)

1. De aangewezen geregistreerde geneesmiddelen zijn de geneesmiddelen, genoemd in bijlage 1 bij deze regeling.
2. Indien een geneesmiddel, genoemd in bijlage 1 bij deze regeling, behoort tot een van de in bijlage 2 bij deze regeling genoemde categorieën van geneesmiddelen, omvat de farmaceutische zorg slechts aflevering van dat geneesmiddel indien voldaan is aan de bij die categorieën vermelde criteria.
3. Polymere, oligomere, monomere en modulaire diëetpreparaten behoren slechts tot de farmaceutische zorg indien voldaan is aan onderdeel 1 van bijlage 2 van deze regeling.

Comments:

Medicines listed in the first appendix of the regulation on the Health Insurance Act are covered under the basic health insurance. Medicines listed in the second appendix of this regulation are only covered by the basic insurance if they meet certain prerequisites. Medicines listed in the first appendix are considered to be the most essential medicines. The Dutch government has not explicitly established an essential medicines list, though it for see in an essential medicines framework that arrives at substantially similar results.

Affordable Prices

Provision:

[Art 2.8.3 Regeling Zv.](#)

De aanwijzing door de zorgverzekeraar geschiedt zodanig dat van alle werkzame stoffen die voorkomen in de bij ministeriële regeling aangewezen geneesmiddelen ten minste een geneesmiddel voor de verzekerde beschikbaar is.

[Art 2.8.6 Regeling Zv.](#)

De verzekerde betaalt een eigen bijdrage voor een geneesmiddel dat is ingedeeld in een groep van onderling vervangbare geneesmiddelen, indien de inkoopprijs hoger is dan de vergoedingslimiet. Een eigen bijdrage wordt ook betaald voor zover een geneesmiddel is bereid uit een geneesmiddel waarvoor een eigen bijdrage is verschuldigd. Bij ministeriële regeling wordt geregeld hoe de eigen bijdrage wordt berekend.

Comments:

The Dutch government supports and promotes the use of generics. Individuals should always have access to one pharmaceutical out a group with the similar active substance. The insured must pay an additional fee out-of-pocket for a certain registered medicines if there is a less expensive pharmaceutical with a similar active substance available. Generics, generally less expensive than brand name medicines, are promoted over brand name drugs because of the total coverage of the cheapest drug compared to the additional fee that has to be paid out of pocket for more expensive pharmaceuticals.

Annex 5: South Africa

This annex reflects the situation in 2010.

Legal System

South Africa's constitutional democracy is based on both a Roman-Dutch Law system and an English common-law system. The system is also influenced by an indigenous law system. For a condensed overview of the Dutch legal system consult Annex 2.1.1. Country Profile (NL).

Health Care System

South Africa provides in a free-of-charge Health Care Delivery System, subject to certain prerequisites. The national government mandates provinces and local authorities to foresee in the carrying out of this delivery system. This system results in different standards throughout the country. The government pays approximately 40% of all the health care costs. The remainder of the health care expenses are covered by private initiatives, fundraising etc. South Africa has multiple state hospitals, though the number of private establishments is steadily increasing.

Constitution

Constitution of the Republic of South Africa, 108 of 1996, Art 27(1-3): 1) Everyone has the right to have access to a. health care services, including reproductive health care; b. sufficient food and water; and c. social security, including, if they are unable to support themselves and their dependents, appropriate social assistance. 2) The State must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights. 3) No one may be refused emergency medical treatment.

Overview of Relevant Provisions

Indicator	National Legislation	National Bill	National Regulation
Government Commitment Mandatory language	The Minister of Health must protect, promote, fulfill and maintain within the limits of available resources the health of the population. This should at least include primary health care service. The departments on national, provincial and municipal level must provide in those health services. NHA 2003 art 3.	The scope of essential health services is determined by the Minister of Health after consultation of the Health Council. The scope of primary health care services is determined in a similar way. NHB 2003 B32A cls 1.2, 1.8.	
Sustainable Financing State reimbursement scheme			
Sustainable Financing State subsidy	The Minister of Health may, after consulting the Minister of Finance, determine who is an <i>eligible person</i> that may rely on free health care service. The Minister is bound by several aspects which he must take in consideration prior to this determination. NHA 2003 art 4.		
Rational Selection Essential medicines framework	The Minister of Health may make regulations on developing an essential medicines list. NHA 2003 art 90(D).		
Affordable Prices Availability of generics	Pharmacists must inform people on the availability of interchangeable multi-source medicines. The pharmacist has to note the brand name if he procures interchangeable multi-source medicines (<i>Section 1 (b)</i>)		Manufacturers or importers have to provide specific information on generics. RTPS 2004 art 3.

	<p>MRSCA defines the term interchangeable multi-source medicine as equal to generic). Though he or she cannot sell those substitutes if the prescription explicitly states: "no substitution." <i>MRSCA 1965 s 22F.</i></p>		
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Comments

South Africa's Constitution requires the State to provide health care services. However, the right to essential medicines or pharmaceuticals is not explicitly stated. The National Health Act is South Africa's controlling legislation regarding access to health care. It contains explicit mandatory language regarding the provision of health services ("The State 'must provide'..."); however, there is no specific language on access to essential medicines. The Minister of Health must consider certain characteristics (e.g. minorities, gender perspectives, children,) to determine who is an *eligible person* that may receive free health care services. The law does not state who is an eligible person and does not state whether health care services contain access to pharmaceuticals. However, the Department of Health does establish a rather extensive national list of essential medicines (Essential Drug Programme South Africa, 2008). Since this is a national policy document without legal force, it is not included in the Table of Relevant Legal Provisions. Generics are available and the law requires pharmacy holders to inform individuals of the existence of a specific relevant generic if the prescription prescribes a brand-name drug. If the term "no substitution" is explicitly written on the prescription it prohibits the pharmacy holder from fulfilling that prescription with a generic drug.

Sources

Legal instruments

- Medicines and Related Substances Control Act, 101 of 1965 (MRSCA).
- Regulations Relating to a Transparent Pricing System of Medicines and Scheduled Substances Made in Terms of Section 22G of the Medicines and Related Substances Act, 101 of 1965, 2004 (RTPS).Constitution of the Republic of South Africa, 108 of 1996.
- National Health Act, 61 of 2003 (NHA).
- National Health Bill, 2003 B32A (NHB).

Web links

- CIA World Factbook, *South Africa*. Available at: <https://www.cia.gov/library/publications/the-world-factbook/geos/sf.html>
- Department of Health. Available at: <http://www.doh.gov.za/>
- South Africa, *Health*. Available at: <http://www.southafrica.info/about/health/health.htm>.
- South Africa, *Social*. Available at: <http://www.southafrica.info/about/social/govthealth.htm>.

Other

- Essential Drug Programme South Africa, Standard Treatment Guidelines and Essential Medicines List 2008.

Appendix South Africa

Government Commitment

Provision:[NHA 2003 art 3.](#)

1. The minister must, within the limits of available resources:
 - a. endeavor to protect, promote, improve and maintain the health of the population,
 - b. promote the inclusion of health services in the socio-economic development plan of the Republic;
 - c. determine the policies and measures necessary to protect, promote, improve and maintain the health and well-being of the population;
 - d. ensure the provision of such essential health services, which must at least include primary health care services, to the population of the Republic as may be prescribed after consultation with the National Health Council; and
 - e. equitably prioritize the health services that the State can provide.
2. The national department, every provincial department and every municipality must establish such health services as are required in terms of this Act, and all health establishments and health care providers in the public sector must equitably provide health services within the limits of available resources.

Comments:

South Africa appears to have a system that directly commits the government to provide health care delivery services. The government is responsible for subsidizing health costs for those citizens who are not able to fully support themselves. However, only essential health services are contemplated in the provision requiring South Africa's governmental commitment. There is no special mention of access to essential medicines

Sustainable Financing

Provision:[NHA 2003 art 4.](#)

The Minister, after consultation with the Minister of Finance, may prescribe conditions subject to which categories of persons are eligible for such free health services at public health establishments as may be prescribed.

1. In prescribing any condition contemplated in subsection (1), the Minister must have regard to-
 - a) the range of free health services currently available;
 - b) the categories of persons already receiving free health services;
 - c) the impact of any such condition on access to health services; and
 - d) the needs of vulnerable groups such as women, children, older persons and persons with disabilities.
2. Subject to any condition prescribed by the Minister, the State and clinics and community health centres funded by the State must provide-
 - a) pregnant and lactating women and children below the age of six years, who are not members or beneficiaries of medical aid schemes, with free health services;
 - b) all persons, except members of medical aid schemes and their dependents and persons receiving compensation for compensable occupational diseases, with free primary health care services; and
 - c) women, subject to the Choice on Termination of Pregnancy Act, 1996 (Act 92 of 1996), free termination of pregnancy services.

Comments:

South Africa has a system that grants the Minister of Health the discretion to determine (after consultation with the Minister of Finance) who is eligible to enjoy free health care services, though it does not specifically allow for state subsidy. The mandatory consultation of the Minister of Health demonstrates an interesting correlation with the applicable government commitment provisions in Annex 2.3.2. "Within its available resources" is further elaborated by including the mandatory consultation instead of the mere discretion of the Minister of Health.

Rational Selection

Provision:[NHA 2003 ch 11, reg\(s90\).](#)

1. The minister, after consultation with the National Health Council, may make regulations regarding -
 - d. the development of an essential drugs list and medical and other assistive devices list;

Comments:

The National Health act leaves the Minister of Health the discretion to make regulations and establish a national essential medicines list. South Africa's legal doctrine does not include a regulation on the establishment of an essential medicines list. Though their latest version of this list, updated in 2008, is available as a policy document (Essential Drug Programme South Africa, 2008). However, as a policy document, this list has no legal force.

Affordable Prices

Provision:

MRSCA 1965 s 22F.

Generic Substitution

- 1) Subject to subsections (2),(3) and (4), a pharmacist shall:
 - a. inform all members of the public who visit his or her pharmacy with a prescription for dispensing, of the benefits of the substitution for a branded medicine of an interchangeable multi-source medicine; and
 - b. dispense an interchangeable multi-source medicine instead of the medicine prescribed by a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, unless expressly forbidden by the patient to do so.
- 2) If a pharmacist is forbidden as contemplated in subsection (1)(b), that fact shall be noted by the pharmacist on the prescription.
- 3) When an interchangeable multi-source medicine is dispensed by a pharmacist he or she shall note the brand name or where no such brand name exists, the name of the manufacturer of that interchangeable multi-source medicine in the prescription book.
- 4) A pharmacist shall not sell an interchangeable multi-source medicine -
 - a. if the person prescribing the medicine has written in his or her own hand on the prescription the words 'no substitution' next to the item prescribed;
 - b. if the retail price of the interchangeable multi-source medicine is higher than that of the prescribed medicine; or
 - c. where the product has been declared not substitutable by the council.

Comments:

National legislation requires pharmacies to inform individuals of the availability of generics (interchangeable multi-source medicine). However, pharmacists are not allowed to sell a generic drug if the prescription explicitly states "no substitution." While there is no governmental duty to predominantly procure generics, there is a strong commitment on promoting their use. The patient holds the right to make the final decision to decide whether or not to use a generic or brand-name drug (unless the prescriber specifically forbids substitutions on the prescription itself).

Annex 6: Tonga

This annex reflects the situation in 2010.

Legal System

Tonga has a constitutional monarchy based on English common law. The legal system derives from the Constitution of 1875. Statutes created by the Legislative Assembly must be approved by the King. English common law and statutes of general application may still apply in Tonga, providing no Tongan statute applies to the particular situation and the people and laws of Tonga permit application of the English law/statute. The national government of Tonga consists of an executive branch (the Monarch, Prime Minister and Cabinet), a unicameral legislative assembly and a judicial branch (the Privy Council and Judiciary). There is no state or provincial subdivision; local and district authorities report to the central government.

Health Care System

In general, health care in Tonga is provided by the government free of charge. Health care is primarily delivered in hospitals and health centres. In practice, funding by the government covers the majority of health care costs, resulting in low out-of-pocket payments (the government established a system of user fees in 2005). The Minister of Health is given broad discretion, under the legislation mentioned below, to direct the provision of health care services. The Ministry of Health, Pharmacy Section of the Medical Ward, states its objective as "to provide good quality, safe, effectively and affordable essential drugs and standard medical supplies at all times to all the people of Tonga and ensure its rational use."

Constitution

Act of the Constitution of Tonga 1875, as amended 1988. The Constitution contains no mention of a right to health, health care, health insurance, pharmaceuticals, medicines, drugs or any other government provided benefit.

Overview of Relevant Provisions

Indicators	National Legislation	National Regulation
Government Commitment Mandatory language	"It shall be the duty of the Minister to provide such hospitals, health centres, clinics and other establishments as are necessary to meet the needs of public health." <i>HSA 1991 s 9(1)</i> . "The Minister is empowered... to provide personal health services including... pharmaceutical provision... within the limits of available finance and resources and according to the needs of the people of Tonga." <i>HSA 1991 s 10(b)</i> .	
Sustainable Financing State reimbursement scheme		"The duties of each medical officer within his district shall be... to afford free medical and surgical aid to all Tongan subjects in his district." <i>MSR 1991 s 2(a)</i> . ("Dispensing Fee per prescription \$5.00 plus selling costs of drugs." <i>HSR 2000 s 23</i> . This provision sets the general cost of pharmaceuticals for Non-Tongan subjects.)
Sustainable Financing State subsidy	"The Minister is empowered... to make such charges for services as may be reasonable, provided that no person be denied adequate care by reason of inability to meet the costs." <i>HSA 1991 s 10(l)</i> .	"The Minister of Health may, by notice published in the Gazette, exempt any person or class of persons from the payment of any fees or charges listed in the schedule and such exemptions may be made subject to such conditions as the Minister may specify." <i>HSR 2000 Preamble s 4</i> .
Rational Selection Essential medicines framework	-" (1) There shall be... a Committee to be called the National Drugs and Medical Supplies Committee. (2) The functions of the Committee shall be... (c) to maintain, annually revise and amend a List of Essential Drugs for the Kingdom which shall be the basis for	

	public sector medicinal drug procurement." <i>TGA 2001 s 4(2)(c)</i> .	
	-The TGA also sets out basic criteria for inclusion of a drug on Tonga's registered list. <i>TGA 2001 s 7</i> .	
Affordable Prices Availability of generics	"Except in cases of emergency, a registered pharmacist or assistant pharmacist shall not dispense any prescription for the supply of medicinal drugs unless the prescription... states the generic name of the medicinal drug" <i>TGA 2001 s 21(1)(f)</i> .	

Comments

The mandatory language in the HSA does not include mention of pharmaceuticals. However, the very next provision, as quoted above, gives the Minister of Health the discretionary power to provide pharmaceutical benefits. Section 4 of the TGA also gives the National Drugs and Medical Supplies Committee power to determine the medicinal products to be purchased by the Ministry of Health, and to initiate and maintain a program for rational use of medicinal drugs. The HSR sets the co-payment rate for pharmaceuticals for non-Tongan peoples, but makes no mention of the price for citizens of Tonga.

Overall, the government provides "free" health care, but such provision is limited to the government's ability to pay. The legislative provisions set out a system of complete coverage for health care services, but is vague as to what constitutes a "reasonable charge" for individual contribution. In practice, medicines are not completely free. The legislation is also vague about who may or may not qualify for government assistance when they cannot otherwise afford medicines. Also worth noting is the fact that only national regulations, not national laws, contain any provision about state financing of pharmaceuticals.

Sources

Legal instruments

- Act of the Constitution of Tonga 1875, as amended 1988.
- Health Services Act, 15 of 1991 (HSA).
- Medical Services Regulations, CAP 76A of 1991 (MSR).
- Health Services (Fees and Charges) Regulations 2000, GS 8D of 2000 (HSR).
- Therapeutic Goods Act, 3 of 2001 (TGA).

Web links

- CIA World Fact book, *Tonga*. Available at: <https://www.cia.gov/library/publications/the-world-factbook/geos/tn.html>
- Government of Tonga, *Facts about Tonga*. Available at: <http://www.thekingdomoftonga.com/discover/tonga-today/>
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- United States Department of State, *Background Note*, 28 June 2010. Available at: <http://www.state.gov/outofdate/bgn/tonga/153971.htm>
- World Health Organisation Western Pacific Region, tonga country profile: <http://www.wpro.who.int/countries/ton/en/>

Government Commitment

Provision:

HSA 1991 pt-III arts 9-10.

Part III - Aspects of Health Service

Article 9. Duty to provide services

1. It shall be the duty of the Minister to provide such hospitals, health centres, clinics and other establishments as are necessary to meet the needs of public health.
2. It shall be the duty of the Minister to provide such specialist or medical, dental, nursing, midwifery, paramedical and technical staff as are necessary to meet the needs of public health.
3. It shall be the duty of the Minister to provide for the registration and supervision of any hospitals, health centres, clinics, and other establishments used for private health service purposes and any person working as a private practitioner in a health profession.

Article 10. Powers of the Minister

The Minister is empowered -

- b. to provide personal health services including maternal and child health and welfare, family planning, school health, dental care, ophthalmic care, pharmaceutical provision, immunization, community nursing, care of the mentally and physically handicapped, ambulance service, nutrition guidance and health education, within the limits of available finance and resources and according to the needs of the people of Tonga.

Comments:

It appears that Tonga has no specific provision that outlines the governmental commitment to allow access to essential medicines. Though it does for see in a framework that requires, by mandatory language, the government to provide health care services (hospitals, centres, etc.) The right to access essential medication is not specifically included.

Sustainable Financing

Provision:

HSA 1991 s 10(I).

10. Powers of the Minister

The Minister is empowered —

- (a) to provide pathology including laboratory, blood transfusion, radiological, and pharmaceutical facilities including facilities for the laboratory study of air, water, milk and other food-stuffs.
- (b) to provide personal health services including maternal and child health and welfare, family planning, school health, dental care, ophthalmic care, pharmaceutical provision, immunization, community nursing, care of the mentally and physically handicapped, ambulance service, nutrition guidance and health education, within the limits of available finance and resources and according to the needs of the people of Tonga.
- (c) to provide facilities for the purchase, storage, supply and maintenance of equipment including transport and materials required in the provision of a comprehensive health service.
- (d) to provide such training facilities as may be required to maintain the personnel of the health services at the highest possible level of professional and technical expertise and performance.
- (e) to request, conduct, or assist research in health matters by employees of the Ministry or by such other persons or bodies as he may decide.
- (f) to establish a statistics, epidemiological and health information service.
- (g) to establish an occupational health service.
- (h) to provide a public health service of the Ministry charged with implementing the Public Health Act and other relevant legislation, and having specific responsibilities with respect to potable water, food hygiene, building standards, disease control, prevention of pollution, waste disposal, health and safety at work and such other matters as the Minister shall decide.
- (i) to require the registration of any person working as a private practitioner in a health profession and also the separate registration of any premises used for private health service purposes.
- (j) to prepare, maintain and periodically test a health emergency plan to meet any national or local disaster affecting the health and welfare of the populace.
- (k) to collaborate with national, international, voluntary health organizations, and non-governmental organizations.
- (l) to make such charges for services as may be reasonable, provided that no person be denied adequate care by reason of inability to meet the costs."**

HSR 2000 preamble s 4.

IN EXERCISE of the powers conferred by section 11 of the Health Services Act 1991 on the Minister of Health with the consent of Cabinet, makes the following Regulations: ...

2. The medical fees and charges set out in the Schedule hereto shall be the authorized fees and charges for services rendered by or on behalf of medical and dental officers of the government.
3. All fees and charges are to be paid to general revenue.
4. The Minister of Health may, by notice published in the Gazette, exempt any person or class of persons from the payment of any fees or charges listed in the schedule and such exemptions may be made subject to such conditions as the Minister may specify."

Comments:

National legislation determines that pharmaceuticals should be included within the government provided health care. The Minister of Health, however, is also empowered to establish a system of “co-payments” for medical services. The only limitation on this power is that no person can be denied “adequate care” because of inability to pay. In the regulations promulgated for this national act, the Minister also has the power to exempt some individuals from the system of co-payments to make health care more affordable. Neither the national legislation nor the regulations, however, specifically define 1) the amount of co-payment for pharmaceuticals; 2) what is included in “adequate care,” or 3) exactly who is or is not a person or class of persons exempt from co-payments. The regulations refer to the Government Gazette of Tonga; however, due to research limitations the provisions of this Gazette could not be located. At this point, it can only be determined that Tonga does establish a system for further subsidized pharmaceuticals for individuals who are unable to afford them within the established system of partial subsidy for all citizens. The exact specifics of this additional subsidy may only become known upon access to the Government Gazette.

Rational Selection**Provision:****TGA 2001 s 4(2)(c).***4. Establishment, functions and constitution of committee*

- (1) There shall be established for the purposes of this Act a Committee to be called the National Drugs and Medical Supplies Committee.
- (2) The functions of the Committee shall be—
- (a) to establish, maintain and annually revise and amend the list of medicinal drugs registered for import into the Kingdom;
 - (b) to determine the class in the registered list to which any medicinal drug will be allocated;
 - (c) to maintain, annually revise and amend a **List of Essential Drugs** for the Kingdom which shall be the basis for public sector medicinal drug procurement;
 - (d) to consider the product range and determine the therapeutic goods to be purchased by the Ministry of Health based on the list of essential drugs for the Kingdom;
 - (e) to confirm or reject decisions of the Principal Pharmacist regarding the award of tenders for the supply of therapeutic goods;
 - (f) to control procedures for the procurement, storage, distribution and administration of therapeutic goods;
 - (g) to receive from the Central Pharmacy and Medical Store, collate, review and, if necessary, suggest action, upon reports of adverse drug reactions within the Kingdom;
 - (h) to initiate, maintain and supervise a national programme on rational use of medicinal drugs;
 - (i) to advise the National Health Development Committee on any matter relating to the National Drug Policy; and
 - (j) to propose to the National Health Development Committee any changes or modifications to this Act, any Schedule hereto, or the National Drug Policy as may be deemed appropriate.

TGA 2001 s 7.*7. Criteria for inclusion in the Registered List*

A medicinal drug may be included in the registered list only if the Committee is satisfied that the medicinal drug—

- (a) is of acceptable quality;
- (b) meets an acceptable safety profile;
- (c) is of demonstrated efficacy;
- (d) is of United States Pharmacopoeia or British Pharmacopoeia standard or proven equivalent standard;
- (e) has been proven by the manufacturer to be registered in one of the countries listed in the Schedule or following assessment of a detailed submission by the manufacturer, and payment of the prescribed fee, is found to meet the requirements of subsections (1) to (4); and
- (f) would be appropriate for use in Tonga.

Comments:

Both of these provisions are found within National Legislation for Tonga. A Committee, rather than a Minister of Health, is responsible for determining the list of essential medicines. Furthermore, the legislative act seems more “involved” in the selection of pharmaceuticals to be included on the list of essential medicines in that it creates minimum requirements (as opposed to giving complete discretion to a Minister of Health or a Committee). Also, Tonga uses the United States Pharmacopoeia and the British Pharmacopoeia as a mechanism to ensure quality and safety of medicinal products (a legislative provision that could be used by Member States who do not have the resources to independently verify and test all medicinal products). Finally, Tonga specifically uses the term “List of Essential Drugs” (compared to some States who simply have a schedule of reimbursement that is assumed to contain all essential medicines).

Affordable Prices**Provision:****TGA 2001 s 21(1)(f).***21. Requirements for prescriptions*

- (1) Except in cases of emergency, a registered pharmacist or assistant pharmacist shall not dispense any prescription for the supply of medicinal drugs unless the prescription...

(f) is written in terms and symbols such as are used in ordinary professional practice, and states the generic name of the medicinal drug;

Comments:

The legislative provision in Tonga addressing availability of generics seems very sparse. Neither the Health Services Act, the Health Services (Fees and Charges) Regulations, nor the Therapeutic Goods Act contain specific provisions setting the requirements for classification of a pharmaceutical as brand name or generic or setting a policy to encourage the use of generics over brand name pharmaceuticals. The provision listed here requires pharmacists to list a generic name on all prescriptions. This can be interpreted in two ways: 1) that the government will then provide the generic item to reduce costs; or 2) the generic name is required to ensure disbursement of the correct pharmaceutical.

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