Essential medicines and human rights: what can they learn from each other?

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Abstract Most countries have acceded to at least one global or regional covenant or treaty confirming the right to health. After years of international discussions on human rights, many governments are now moving towards practical implementation of their commitments. A practical example may be of help to those governments who aim to translate their international treaty obligations into practice. WHO's Essential Medicines Programme is an example of how this transition from legal principles to practical implementation may be achieved. This programme has been consistent with human rights principles since its inception in the early 1980s, through its focus on equitable access to essential medicines. This paper provides a brief overview of what the international human rights instruments mention about access to essential medicines, and proposes five assessment questions and practical recommendations for governments. These recommendations cover the selection of essential medicines, participation in programme development, mechanisms for transparency and accountability, equitable access by vulnerable groups, and redress mechanisms.

Bulletin of the World Health Organization 2006;84:371-375.

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Introduction

Essential medicines

Since the 1970s WHO has promoted equitable access to basic health services through the concepts of primary health care and essential medicines. The first *Model list of essential medicines* of 1977 preceded the famous 1978 Alma Ata Declaration on Health For All and is widely regarded as one of WHO's most influential public health achievements.

Essential medicines are those that satisfy the priority health-care needs of the population. They are selected with due regard to disease prevalence, evidence on efficacy, safety and comparative cost-effectiveness. Essential medicines are intended to be available at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.[1] Since 1977 the concept of essential medicines has become truly global. By the turn of the century over 150 countries had a national list of essential medicines, and over 100 countries had a national medicines policy. Although initially aimed at developing countries, the concept of essential medicines is increasingly seen as relevant for middle- and high-income countries as well.[2]

Human rights

Human rights concern the relationship between the state and the individual, generating individual rights and state obligations. The promotion of human rights is one of the principal purposes of the United Nations and, as such, affects WHO's work as anchored in its constitutions and the UN Charter.

Human rights are legally guaranteed by international, regional and national human rights law, protecting individuals and groups against actions that interfere with fundamental freedoms and human dignity. Most human rights are interdependent. For example, the right to health is closely associated with the right to life and indispensable for the exercise of most other human rights. Freedom from discrimination underpins all human rights.

Most countries have acceded to at least one global or regional covenant or treaty confirming the right to health. Over 150 countries have become States Parties to the International Covenant on Economic, Social and Cultural Rights, and over 100 countries have incorporated the right to health in their national constitution.[3] In addition, in September 2005 all WHO Member States decided to integrate the promotion and protection of human rights into national policies and to support the further mainstreaming of human rights throughout the United Nations system. After years of international discussions on human rights, many governments are now moving towards practical implementation of their commitments.

Essential medicines and human rights

The human rights debate, which has tended to be dominated by human rights lawyers focusing on points of principle, now has to move towards practical implementation. This has three main implications. Firstly, the discussion on strict legal principles must now move towards a political process which can only proceed on the basis of compromise. Secondly, as Amartya Sen put it, "the richness of practice is also critically relevant for understanding the concept and reach of human rights."[4] In this regard WHO's Essential Medicines Programme has much to offer. Its consistent focus on sustainable, universal access to essential medicines through the development of national medicines policies has always been in line with human rights principles of non-discrimination and care for the poor and disadvantaged. This also applies to its focus on good governance. For example, the careful

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Ref. No. **06-031153**

(*Submitted: 27 February 2006 – Final revised version received: 31 March 2006 – Accepted: 3 April 2006*)

selection of essential medicines, good quality assurance, procurement and supply management and rational use all serve to optimize the value of limited government funds, and thereby empower and support governments in making basic services available to all. Other aspects of good governance work towards the same goal, such as standardized procedures for monitoring inequities in the pharmaceutical situation, and management tools to assess and reduce vulnerability to corruption.

WHO also supports equitable access through its normative activities on pharmaceuticals. For example, the proactive early development of global quality standards, the international prequalification programme and the dissemination of information on sources and prices, regulation status and patent status of priority medicines for human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), tuberculosis and malaria have promoted good-quality manufacture in developing countries, increased availability and competition, and lowered prices. The WHO/Health Action International standardized medicine prices survey methodology[5] has empowered countless nongovernmental organizations in developing countries to measure the availability, out-of-pocket prices and affordability of essential medicines;[6] the ensuing national political discussions have often led to increased affordability and more equitable access.

Thirdly, all development programmes, including national essential medicines programmes, should ensure that all aspects of the rights-based approach are in place. Some practical information in this regard may help governments who wish to translate their international treaty obligations into rights-based health programmes to benefit their population. After a brief review of the available legal instruments, this paper focuses on the third aspect: in what sense is a rights-based programme more than just a good public health programme?

Human rights instruments and health

The WHO Constitution (1946) states: "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition." (Box 1). Article 25.1 of the Universal Declaration of Human Rights (1948) reads: "Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services". The fundamental right to the enjoyment of the highest attainable standard of health (hereafter: "the right to health") was reiterated in the 1978 Declaration of Alma Ata and is widely recognized in many other international[7,8,9] and regional[10,11,12] human rights instruments.

After the Universal Declaration of Human Rights, two subsequent international treaties of 1966 provide more detail on the practical implications of human rights: the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR). The latter provides the main foundation for legal obligations in the field of health. In the ICESCR States Parties "recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health". In Article 12.2 it lists a number of steps to be taken by States Parties to achieve the full realization of this right, including the right to: maternal, child and reproductive health; healthy natural and workplace environments; prevention, treatment and control of disease; and "the creation of conditions which would assure to all medical service and medical attention in the event of sickness."

Access to essential medicines as part of the fulfilment of the right to health

The implementation of the ICESCR, which is binding to its over 150 States Parties, is monitored by the Committee on Economic, Social and Cultural Rights which regularly issues authoritative but non-binding comments to clarify the nature and content of individual rights and state obligations. For example, in General Comment No.14 of May 2000[13] the Committee stated that the medical service in Article 12.2.(d) of the ICESCR includes the provision of essential drugs "as defined by the WHO Action Programme on Essential Drugs".

Progressive realization and immediate obligations

It is important to note that the right to health cannot be fulfilled overnight, as resource constraints may prevent States Parties from immediate implementation. The principle of "progressive realization" therefore acknowledges the limits of available resources (Box 2). However, the Covenant also imposes on States Parties two *immediate obligations*. Firstly, States Parties have to guarantee that the right to health will be exercised without discrimination of any kind (Article 2.2) and, secondly, to take deliberate, concrete and targeted steps (Article 2.1) towards the full realization of Article 12. There is a strong presumption that retrogressive measures are not permissible, which means that once states have taken steps towards the fulfilment of the right to health, these cannot be withdrawn.[14]

Practical implications for essential medicines programmes

For many countries the body of international human rights treaties and national constitutional provisions has created a binding legal framework to promote access to essential medicines. Although the essential medicines concept was already in line with human rights principles, the following practical recommendations may help committed governments and health policy-makers to translate legal text into pragmatic action.

Box 1. **Opening text of the Constitution of WHO (1946)**

"The States Parties to this Constitution declare, in conformity with the Charter of the United Nations, that the following principles are basic to the happiness, harmonious relations and security of all peoples.

Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity… . The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition. Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures."

The rights-based approach to development cooperation

The first general principle of the rights-based approach is that the general development process must be consistent with human rights. This implies that the norms, standards and principles of the international human rights system be integrated into the plans, policies and processes of development. The basic principles of what is now called the "rights-based approach" (Box 3) include participation, accountability, non-discrimination, attention to vulnerable groups, and explicit linkage to human rights instruments.

The rights-based approach in medicines programmes

The second general principle is that specific medicines policies and programmes must be consistent with the rights-based approach. The human rights implications of any new medicines policy, legislation or programme must therefore be assessed in advance.

There are also some specific ways in which the rights-based approach can strengthen national essential medicines programmes. They are presented here as five simple questions which can be used to assess the situation in a specific country or programme.

1. Which essential medicines are covered by the right to health?

General Comment No.14 to the ICESCR refers to the right to essential medicines "as defined by the WHO Action Programme on Essential Drugs" and in paragraph 12a it refers to the *WHO model list of essential medicines*.[1] In line with this definition, exactly which medicines are regarded as essential remains a national responsibility and within countries the national list of essential medicines should therefore be used to define the minimum needs. If no such national list exists, the first step is to develop one. For situations outside the scope of national governments, such as ships and refugee camps, specific lists of essential medicines have been developed by WHO and relevant stakeholders.[15]

Suggested assessment questions: Does the national constitution, or any other national law, recognize the right of everyone to the enjoyment of the highest attainable standard of health? Are there laws which specify the government's responsibility in ensuring equitable access to essential medicines? Is there a national list of essential medicines, updated within the last two years?

2. Have all beneficiaries of the medicine programme been consulted?

True participation means that the beneficiaries of national medicines policies and programmes are consulted in decisions that affect them. Besides the usual discussion partners, such as the central government, universities and professional associations, other important beneficiaries to be consulted are rural communities, nongovernmental organizations, patients and consumer groups, and representatives of the vulnerable groups listed in 4. below.

Suggested assessment questions: Is there a national medicines policy updated within the last 10 years? Were patients' organizations and rural communities consulted when the national medicines policy and programme were developed?

3. Are there mechanisms for transparency and accountability?

The objectives of the medicines policy and programme should be clear, and government obligations to respect, protect and fulfil the right to health should be articulated, in line with any binding obligations of the applicable international treaties (Box 2). Indicators and targets should be identified and used to monitor the progressive realization of universal access to essential medicines. The national medicines policy should specify the roles and responsibilities of all stakeholders, with mechanisms in place to hold all accountable.

Suggested assessment questions: Does the national medicines policy describe the obligations of the various stakeholders? Are there baseline and target data on access to essential medicines against which progress can be measured?

4. Do all vulnerable groups have equal access to essential medicines? How do you know?

The main vulnerable groups to be considered are children (especially girls), women, people living in poverty, rural communities, indigenous populations, national (ethnic, religious, linguistic) minorities, internally displaced persons, the elderly, people with disabilities and prisoners. Ensuring equality and freedom from discrimination starts with collecting disaggregated access statistics for each of these groups. Such statistics are essential to create awareness among policy-makers, to identify vulnerable groups that need special attention and to monitor progress towards universal access. The absolute minimum in this regard consists of gender-disaggregated statistics and incidental surveys specifically aimed at vulnerable groups.

Box 3. **Justice as a right, not as charity**

A rights-based approach to development describes situations not simply in terms of human needs, or of developmental requirements, but in terms of society's obligations to respond to the inalienable rights of individuals; empowers people to demand justice as a right, not as charity; and gives communities a moral basis from which to claim international assistance when needed.

Kofi Annan, United Nations Secretary-General

Box 2. **Promoting and protecting the right to health in South Africa**

The Constitution of South Africa[16] is notable for its simplicity and clarity on the right to health. In Section 27 it states that everyone has the right to have access to health-care services and social security; and that the State must take reasonable legislative and other measures, *within its available resources*, to achieve the progressive realization of each of these rights. In 1998 the government issued a national action plan for the protection and promotion of human rights[17] in recognition of the fact that the realization of socioeconomic rights requires public expenditure to meet basic needs, develop infrastructure, promote growth and stimulate job creation. In its foreword, President Nelson Mandela wrote: "As the beneficiaries of the international insistence that human rights are the rights of all people everywhere, the people of South Africa are proud to be participating, through this Plan, in an international effort to promote and protect human rights."

Suggested assessment questions: Are disaggregated access statistics available for girls, boys, women and men, and for urban and rural populations? Are essential medicines available in prisons? Are training materials and drug information leaflets available in all common ethnic languages?

5. Are there safeguards and redress mechanisms in case human rights are violated?

Access to essential medicines is best ensured by the development and implementation of rights-based medicines policies and programmes, as described above. However, in cases of unjustifiably slow progress, possibilities for redress and appeal are also needed as a last resort. A recent WHO study has shown that careful litigation has been one additional mechanism to encourage governments to fulfil their constitutional and international treaty obligations with respect to the right to health and access to essential medicines (Box 4).

Suggested assessment question: Are legal mechanisms available and have they been used to file complaints about lack of access to essential medicines?

Box 4. **Court cases in 12 low- and middle-income countries**

An analysis was made of court cases from 12 low- and middle-income countries in which access to essential medicines was claimed with reference to the right to health. Half of these cases related to life-saving treatment of HIV/AIDS. In many cases access to essential medicines as part of the fulfilment of the right to health could indeed be enforced through the courts, with most experience to date coming from Central and Latin America. Success was mainly linked to constitutional provisions on the right to health, supported by the human rights treaties. Other success factors were a link between the right to health and the right to life, and support by public-interest nongovernmental organizations. Individual cases have generated entitlements across a population group, the right to health was not restricted by limitations in social security coverage, and government policies have successfully been challenged in court. The study concluded that skillful litigation can help to ensure that governments fulfil their constitutional and international treaty obligations. This is especially valuable in countries in which social security systems are still being developed. In some countries with more mature social security systems, such as Costa Rica, Colombia and Brazil, constitutional obligations related to the right to health have sometimes been misused to claim access to medicines which where especially excluded from reimbursement by the respective expert committees on the basis of their safety or cost-effectiveness profile. The recent case of a nurse fighting to receive an anti-cancer medicine not yet approved for reimbursement in the United Kingdom proves that this question is also relevant in developed countries. Redress mechanisms through the courts serve an essential function, but should be used as a last resort. Rather, policy-makers should ensure that human rights standards guide their health policies and programmes from the outset.[18]

Conclusion

Many essential medicines' policies and programmes are based on human rights principles and can contribute valuable experience to the international human rights community in its task of practical implementation. National medicine programmes can be used to promote access to essential medicines as part of the progressive fulfilment of the right to health. Governments and policy-makers can maximize the extent of this promotion by taking the following steps:

- ensure that constitutional and other legal provisions on the fundamental right to the enjoyment of the highest attainable standard of health, on the right to life and on the right to non-discrimination are in place;
- specify the obligations of the government and other stakeholders with regard to social welfare, the provision of health-care services and access to essential medicines, with emphasis on vulnerable groups;
- develop and implement a national medicines policy to fulfil these obligations, and collect disaggregated statistics to monitor access by gender and vulnerable groups;
- create the necessary legal instruments for enforcement and redress;
- report regularly (e.g. every five years) on the progressive realization of the right to health, with, for example, disaggregated statistics on access to essential medicines.

The WHO Essential Medicines Programme is ready to assist all Member States and nongovernmental organizations in making such an assessment and in strengthening their national essential medicines programmes on this basis. ■

Competing interests: none declared.

Résumé

Médicaments essentiels et droits de l'homme : quels peuvent être les apports mutuels de ces deux concepts

La plupart des pays ont accédé à au moins un accord ou un traité mondial ou régional affirmant le droit à la santé. Après des années de discussions au niveau international sur les droits de l'homme, nombre d'États s'apprêtent maintenant à mettre en pratique leurs engagements. Un exemple de réalisation dans ce domaine peut aider ces États à transposer sous forme pratique leurs obligations au titre d'un traité international. Ainsi, le Programme d'action OMS pour les médicaments essentiels illustre la transition entre principes juridiques et application pratique. Depuis son lancement au début des années 80, ce programme s'inscrit dans le droit fil des principes des droits de l'homme à travers son objectif principal qu'est l'accès équitable aux médicaments essentiels. L'article donne un bref aperçu de ce que prévoient les instruments internationaux favorables aux droits de l'homme à propos de l'accès aux médicaments essentiels et propose cinq critères d'évaluation et des recommandations pratiques à l'intention des États. Ces recommandations couvrent la sélection des médicaments essentiels, la participation au développement de programmes, l'aménagement d'un accès équitable pour les groupes vulnérables et des mécanismes correctifs.

Resumen

Medicamentos esenciales y derechos humanos: enseñanzas mutuas

La mayor parte de los países han accedido al menos a un pacto o tratado regional o mundial que confirma el derecho a la salud. Después de varios años de debates internacionales sobre los derechos humanos, muchos gobiernos están avanzando en la aplicación práctica de sus compromisos. Cualquier ejemplo extraído de la realidad puede ser de ayuda para los gobiernos que intentan materializar las obligaciones contraídas en virtud de esos tratados internacionales. El programa de Medicamentos Esenciales de la OMS es una muestra de la manera de lograr esa transición de los principios jurídicos a la ejecución práctica. Este programa ha sido coherente con los principios de los derechos humanos desde sus comienzos a principios de los años ochenta, haciendo hincapié en el acceso equitativo a los medicamentos esenciales. En este artículo se resumen las referencias que se hacen en los instrumentos internacionales de derechos humanos al acceso a los medicamentos esenciales, y se proponen cinco preguntas de evaluación y recomendaciones prácticas para los gobiernos. Estas recomendaciones abarcan la selección de medicamentos esenciales, la participación en la elaboración de programas, los mecanismos de transparencia y responsabilización, el acceso equitativo por los grupos vulnerables y los mecanismos correctivos.

ملخص

الأدوية الأساسية وحقوق الإنسان: ما الذي يمكننا أن نتعلمه من بعضنا البعض؟

إن لدى معظم البلدان اتفاقية أو معاهدة أو أكثر تؤكِّد على الحق في الصحة على الصعيد العالمي أو الإقليمي. وبعد سنوات من المناقشات على الصعيد الدولي حول حقوق الإنسان، فإن معظم الحكومات تتحرك الآن نحو التطبيق العملي لالتزاماتها. وقد تساعد الأمثلة التطبيقية الحكومات التي ترغب في ترجمة التزاماتها الدولية في هذه المعاهدات إلى حقيقة واقعة. ويعد برنامج منظمة الصحة العالمية حول الأدوية الأساسية من الأمثلة على كيفية تحقيق التحول من المبادئ القانونية إلى التنفيذ العملي. فقد كان هذا البرنامج متماشياً مع مبادئ حقوق الإنسان منذ ظهوره في بداية الثمانينيات، وذلك من خلال تركيز هذا البرنامج على الإتاحة العادلة للأدوية الأساسية. وتستعرض هذه الورقة بإيجاز ما تضمنته الوثائق الدولية لحقوق الإنسان حول إتاحة الأدوية الأساسية، وتقترح خمسة أسئلة تقيـيمية وتوصيات عملية للحكومات. وتغطي هذه التوصيات اختيار الأدوية الأساسية، والمساهمة في إعداد البرامج، وآليات الشفافية والمحاسبة، والإتاحة العادلة للمجموعات الأكثر تعرضاً وآليات التعويض.

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