Round Table

A human rights approach to the WHO Model List of Essential Medicines

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Abstract Since the first WHO Model List of Essential Medicines was adopted in 1977, it has become a popular tool among health professionals and Member States. WHO's joint effort with the United Nations Committee on Economic, Social and Cultural Rights has resulted in the inclusion of access to essential medicines in the core content of the right to health. The Committee states that the right to health contains a series of elements, such as availability, accessibility, acceptability and quality of health goods, services and programmes, which are in line with the WHO statement that essential medicines are intended to be available within the context of health systems in adequate amounts at all times, in the appropriate dosage forms, with assured quality and information, and at a price that the individual and the community can afford. The author considers another perspective by looking at the obligations to respect, protect and fulfil the right to health undertaken by the states adhering to the International Covenant of Economic, Social and Cultural Rights (ICESCR) and explores the relationship between access to medicines, the protection of intellectual property, and human rights.

Bulletin of the World Health Organization 2006;84:405-411.

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يمكن الاطلاع على الملخص بالعربية في صفحة 407.

Essential medicines are those that satisfy the priority health-care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. The first WHO Model List of Essential Medicines was adopted in 1977. Since then, the number of medicines listed has increased remarkably and, because of its usefulness, the WHO Model List has become a popular tool among health professionals and Member States. An emerging perspective considers access to the essential medicines as a fundamental element when assessing compliance with the right to health. This position has been adopted by WHO, being the result of setting its work within the context of international human rights law. Currently, WHO mentions the recognition of access to essential medicines as a human right at the state level among the priorities in the framework of implementation of pharmaceutical policies in the period 2004–2007,[1] and WHO's joint effort with the United Nations Committee on Economic, Social and Cultural Rights, the body in charge of the surveillance of the International Covenant of Economic, Social and Cultural Rights (ICESCR), has resulted in the inclusion of access to essential medicines in the *core content* of the right to health.

The ICESCR is the text of reference among those international treaties recognizing the right to health. Its article 12 recognizes "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health", mandating "the creation of conditions which would assure to all medical service and medical attention in the event of sickness", among which the Committee has mentioned the supply of essential medicines. The Committee states that the right to health contains a series of interrelated and minimum elements, such as *availability, accessibility, acceptability* and *quality of health goods, services and programmes*.[2] In this framework, medicines must be available in sufficient quantity, without discrimination, overcoming physical and economical constrictions and respecting medical ethics, provided that they are scientifically and medically appropriated. These four elements are in line with the WHO statement that essential medicines are intended to be available within the context of health systems in adequate amounts at all times, in the appropriate dosage forms, with assured quality and information, and at a price that the individual and the community can afford.

Another perspective in the analysis of the relationship between the right to health and access to medicines can be adopted by looking at the obligations to respect, protect and fulfil the right to health undertaken by the states adhering to the ICESCR. The *obligation to respect* urges states not to violate the right to health with their acts. It imposes, therefore, obligations of a negative nature, which are translated, in the field of access to medicines, as not to impede the supply of drugs or introduce arbitrary discriminatory criteria in the supply of them. In pursuance of the *obligation to protect*, states must prevent infringements of the right committed by third parties — and react against them. The practical applications of this second obligation are those related to medicines' pre-qualification and pharmacovigilance activities. Lastly, the *obligation to fulfil*

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Ref No. **04-019133**

refers to the adoption of positive measures, be they legislative, budgetary or promotional, needed for the fulfilment of the right to health and, more specifically, access to essential medicines.

The Committee has remarked that states adhering to the Covenant take on obligations having immediate effect, such as the prohibition of discrimination and the obligation to ensure that the core content of the rights is complied with. Especially relevant in this regard is the Committee's identification of the supply of essential medicines as part of the core and inviolable content of the said right. Furthermore, states also assume international obligations, as section 2.1 of ICESCR provides that each Member State "undertakes to take steps, individually and through international assistance and cooperation" with a view to achieving the realization of the rights recognized in the Covenant. When dealing with the relationship between this aspect and the right to health, the Committee has pronounced that states must ensure that the right to health is given due attention in international agreements.

As far as the relationship between the protection of intellectual property and access to essential drugs is concerned, it is often said that medicines included in the WHO Model List are not protected by patent but, even if they were, various international treaties would also protect property rights. The first statement is clearly wrong, as there are patented medicines in the list. Moreover, an increase in the number of patented medicines included in the list is foreseen resulting from the gradual adoption of selection criteria based on need and not on cost, to which can be added a renewed objectivity commitment in the selection process by WHO.[3] With regard to whether property rights should prevail over the right to health, the United Nations Sub-Commission on the Promotion and Protection of Human Rights has pointed out that the right to the protection of moral and economic interests resulting from scientific research is a human right "subject to public interest limitations".[4] In this sense, within the framework of the World Trade Organization (WTO) Dispute Settlement Understanding, the *right* to access to essential medicines provides powerful arguments to states reported to be infringing intellectual property rights. In such a case, states could argue that by taking action to guarantee a minimum access to essential medicines, they are just complying with another international obligation.

Approaching access to essential medicines as a right not only opens a subjective dimension that refers to individual enforceability of the right to health, but modifies issues such as the relationship between access to medicines and intellectual property rights, strengthening the patient's position. Likewise, it allows a merely ethical valorization to be overcome in favour of the analysis of actions adopted in the framework of public health in a context of legal enforceability. Finally, the perspective emerging from the right of access to essential medicines provides simultaneously the tools to report violations and a useful framework to guide states' pharmaceutical policies in a positive direction. ■

Competing interests: none declared.

Résumé

Liste modèle OMS des médicaments essentiels : une approche fondée sur les droits de l'homme

Depuis l'adoption de la première liste modèle OMS des médicaments essentiels en 1977, celle-ci est devenue un outil très populaire parmi les professionnels de santé et les Etats Membres. Les efforts conjoints de l'OMS et du Comité des Droits économiques, sociaux et culturels de l'ONU ont abouti à ce que l'accès aux médicaments essentiels fasse partie intégrante du droit à la santé. Le Comité stipule que le droit à la santé recouvre une série d'éléments comme la disponibilité, l'accessibilité, l'acceptabilité et la qualité des biens, services et programmes de santé. Ces éléments sont conformes à la position de l'OMS selon laquelle des médicaments essentiels de qualité vérifiée doivent être disponibles à tout moment dans le cadre des systèmes de santé, en quantités suffisantes, sous des formes pharmaceutiques appropriées, avec une qualité garantie et accompagnés des informations nécessaires et à un prix abordable pour l'individu et pour la communauté. L'auteur aborde un autre point de vue en examinant l'obligation de respecter, de protéger et de faire appliquer le droit à la santé à laquelle ont souscrit des Etats Membres en adhérant au Pacte international relatif aux droits économiques, sociaux et culturels et étudie les relations entre l'accès aux médicaments, la protection de la propriété intellectuelle et les droits de l'homme.

Resumen

Derechos humanos y Lista Modelo OMS de Medicamentos Esenciales

Desde su adopción en 1977, la Lista Modelo OMS de Medicamentos Esenciales se ha convertido en un instrumento popular entre los profesionales de la salud y los Estados Miembros. El esfuerzo conjunto realizado por la OMS y el Comité de Derechos Económicos, Sociales y Culturales de las Naciones Unidas ha desembocado en la inclusión del acceso a los medicamentos esenciales entre los componentes centrales del derecho a la salud. El Comité señala que el derecho a la salud abarca una serie de elementos, como la disponibilidad, accesibilidad, aceptabilidad y calidad de los productos, servicios y programas de salud, que están en consonancia con la declaración de la OMS de que los medicamentos esenciales deben estar disponibles en todo momento en las cantidades adecuadas y en las formas farmacéuticas que se requieran en el ámbito de los sistemas de salud, con la calidad e información necesarias, y a un precio asequible para los individuos y la comunidad. Desde otra perspectiva, el autor considera las obligaciones de respetar, proteger y cumplir el derecho a la salud asumidas por los Estados que se han adherido al Pacto Internacional de Derechos Económicos, Sociales y Culturales (ICESCR), y analiza la relación entre el acceso a los medicamentos, la protección de la propiedad intelectual y los derechos humanos.

ملخص

الأسلوب الذي يراعي حقوق الإنسان تجاه
القائمة النموذجية للأدوية الأساسية لمنظمة الصحة العالمية

لدى اعتماد أول قائمة نموذجية للأدوية الأساسية لمنظمة الصحة العالمية في عام 1977، شاع استخدام هذه القائمة بين أرباب المهن الصحية وفي الدول الأعضاء. وقد أسفرت الجهود المشتركة بين المنظمة وبين لجنة الأمم المتحدة للحقوق الاقتصادية والاجتماعية والثقافية، عن تضمين حق الحصول على الأدوية الأساسية في صميم الحق في الصحة. وتنص اللّجنة على أن الحق في الصحة يشمل سلسلة من العناصر، مثل إتاحة السلع والخدمات والبرامج الصحية، وسهولة الحصول عليها، ومقبوليتها، وجودتها وهو ما يتفق مع بيان منظمة الصحة العالمية الذي ينص على ضرورة إتاحة الأدوية الأساسية في إطار النظم الصحية بالكميات المناسبة وفي جميع الأوقات، وبالتوليفة والجرعة المناسبة، وبالجودة المضمونة والمعلومات اللازمة، وبأسعار في متناول الأفراد والمجتمعات. ويتناول الباحث أيضاً في هذه الورقة منظوراً آخر، حيث يبحث الالتزام الذي اضطلعت به الدول الموقعة على العهد الدولي الخاص بالحقوق الاقتصادية والاجتماعية والثقافية، باحترام الحق في الصحة وحمايته وتحقيقه؛ كما يستطلع الباحث في هذه الورقة العلاقة بين الحصول على الأدوية، وحماية حقوق الملكية الفكرية، وحقوق الإنسان.

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