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HEALTH SYSTEMS REPORTER: focus on access to medicines 22 December 2006

produced by the [IDS Health and Development Information](#) team
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This is our monthly email bulletin, bringing together research to inform policy debates on health in developing countries.

The Health Systems Reporter aims to provide readers with a more in-depth look at a particular area of health policy. This month's theme is on [access to medicines](#). The bulletin also features summaries of new documents and other additions to the [Health Systems Resource Guide](#).

[Health Systems Reporter archive](#) - an archive is now available on the Health Systems Resource Guide. See previous issues of the Health Systems Reporter at www.eldis.org/healthsystems/archive.htm

All documents listed below are available free on the web. If you are unable to access any of these materials online and would like to receive a copy of a document as an email attachment, please contact r.wolfe@ids.ac.uk.

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Feature: access to medicines

Every year, over 10 million people die from preventable and treatable diseases because they cannot afford medicines. There are several factors that combine to prevent access including household poverty, poorly functioning public health systems and insufficient funding. More recently, it has been argued that international patent protection, introduced as part of the World Trade Organisation's (WTO) Trade-Related aspects of Intellectual Property rights (TRIPS) agreement, also poses a barrier to providing access to affordable medicines. The purpose of patent protection is to create incentives to develop new pharmaceutical products; however, in many developing countries which lack profitable markets to entice production of these products, the effect of the TRIPS agreement has been to push up the prices of imported medicines. It is estimated that price increases caused by the introduction of patent regimes have been as high as 200 per cent for many low income countries.

It is important for developing countries who are members of the WTO to balance their obligations under the TRIPS agreement with efforts to improve access to affordable medicines. One option is to take advantage of the public health safeguards available to them in the TRIPS agreement including compulsory licensing (authorisation given by a government to use a patented invention without the consent of the patent holder) and parallel importation (importation without the consent of the patent holder of a patented product marketed in another country). However, many countries have failed to implement these safeguards, partly because they lack the technical capacity to execute such complex processes.

Patent holders, such as universities, government agencies and non-profit organisations, can themselves cause significant price reductions by making intellectual property concessions. Initiatives include allowing open-access to information and the introduction of licensing which allows people engaged in research on "neglected diseases" to experiment on and with university technologies. The World Health Organization and other international organisations can also play a role in ensuring access by developing guidelines and case studies on different intellectual property approaches and monitoring the effects of the TRIPS agreement on access and innovation.

For more information see:

- Section on access to medicines and international issues
www.eldis.org/healthsystems/access/index.htm
- World Health Organization section on trade, intellectual property rights and access to medicines
www.who.int/medicines/areas/policy/globtrade/en/index.html
- Medecins Sans Frontieres campaign for access to essential medicines
www.accessmed-msf.org/
- DFID health resource centre section on access to medicines
www.dfidhealthrc.org/publications/access_medicines.html/

Recommended readings on access to medicines

Medicines for the developing world: promoting access and innovation in the post-TRIPS environment

Authors: Morgan, M.

Produced by: Faculty of Law, University of Toronto (2006)

This paper, published in the University of Toronto Faculty of Law Review, examines the challenges in providing access to effective, affordable pharmaceutical treatments for HIV and AIDS as well as diseases such as malaria and tuberculosis. It argues that the Trade-Related aspects of Intellectual Property Rights (TRIPS) Agreement, which mandates universal pharmaceutical patent protection by all World Trade Organisation members, poses a barrier in providing improved access to new medicines for those most in need. The paper discusses policy initiatives which have the potential to effectively address access to pharmaceutical treatments for HIV and "neglected" diseases which are widespread in many developing countries.

Recommendations include: exploiting flexibilities in the TRIPS agreement such as compulsory licences; addressing constraints other than patent protection including inadequate infrastructure, insufficient financing and high drug prices; inducing differential pricing across developed and developing markets; and bulk purchasing. The article also discusses strategies to induce innovation where treatments for neglected diseases are insufficient or lacking. Two broad approaches exist: "push mechanisms" which subsidise research inputs and "pull mechanisms" which reward innovators for research outputs. The author concludes that stronger financial and political commitments to pharmaceutical access are required from all countries, and that such a commitment is economically, morally and legally imperative.

Available online at: <http://www.law.utoronto.ca/accesstodrugs/documents/TRIPS%20executive%20summaries.doc>

Processes and issues for improving access to medicines: willingness and ability to utilise TRIPS flexibilities in non-producing countries

Authors: Baker, B.

Produced by: Department for International Development Health Systems Resource Centre (DFID HSRC) (2004)

This HSRC paper examines ways in which a non-producing country (NPD) can utilise TRIPS flexibilities, primarily focusing on importation. It also examines how to promote local production through pharmaceutical capacity building and through both compulsory and voluntary licensing. It then describes the advantages and disadvantages of these alternatives, in terms of developing countries' sustainable access to more affordable medicines, and highlights the differing legal interpretations, political realities and administrative and economic constraints. The paper concludes with options for policy-makers in the UK to adopt additional measures designed to aid non-producing countries' access to medicines.

The author concludes that parallel importation, compulsory licenses and government use orders, limited exceptions and the new Paragraph 6 system all have a role to play. However, most NPDs are ill prepared and lack the resources to make use of these flexibilities. Many of these flexibilities impose burdensome conditions and procedures that could complicate and delay access to more affordable medicines. Suggested options for UK policy makers include: providing high-level technical assistance to NPD countries and regions; encouraging the development of a competitive generic industry; encouraging widespread licensing and technology transfer for the production of essential medicines; and consider life-saving medicines to be international public goods. [adapted from author]

Available online at: www.dfidhealthrc.org/publications/atm/Baker.pdf

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Managing the effect of TRIPS on availability of priority vaccines

Authors: Milstien, J.; Kaddar, M.

Produced by: Bulletin of the World Health Organization (WHO): the International Journal of Public Health (2006)

This article in the Bulletin of the World Health Organization (WHO) assesses the effect of implementing the Trade-Related Aspects of Intellectual Property rights (TRIPS) agreement on access to vaccines in developing countries. It considers factors in stimulating research and development (R&D) for priority vaccines and examines how global implementation of an intellectual property protection system might affect access to priority vaccines. The article also analyses approaches to managing the effects of TRIPS on developing countries. These include licensing and technology transfer agreements and developing new technologies in developing countries.

The paper discusses the potential role of the WHO and other international partners in ensuring innovation in and access to vaccines in developing countries. It recommends that organisations can help ensure equitable access by: developing guidelines and best practice standards; developing and disseminating case studies on different intellectual property approaches; and monitoring the impact of TRIPS on innovation and access. The authors conclude that in order to ensure access to vaccines, it is necessary to manage the effects of the TRIPS agreement at regulatory and strategic levels. At the regulatory level countries can use the protections guaranteed by the TRIPS agreement to maintain access to new priority vaccines. At the strategic level, licensing and technology transfer agreements can help ensure access. [adapted from authors]

Available online at: <http://www.who.int/bulletin/volumes/84/5/360.pdf>

TRIPS, the Doha Declaration and increasing access to medicines: policy options for Ghana

Authors: Cohen, J. C.; Gyansa-Lutterodt, M.; Torpey, K.; et al

Produced by: BioMed Central (2005)

This paper, published in *Globalization and Health*, analyses the impact of the Trade Related Intellectual Property Rights (TRIPS) agreement in Ghana. It examines Ghana's patent law changes, and assesses how these changes impact on access to medicines. The paper discusses new and existing barriers, as well as possible solutions available to governments that may lead to improved access to medicines. These include: compulsory licensing which allows governments to pursue local production of medicines; parallel importing (the import and resale of a patented product in a state without the consent of a patent holder); technology transfer; and pharmaceutical firms voluntarily offering drugs at lower prices than they would in developed countries.

The paper recommends that local production can be an effective option for increasing access to medicines if human and technological capacity is scaled up. It also encourages the use of compulsory licensing and suggests that in Ghana, effective implementation requires support from developed countries or international organisations. It concludes that the opportunities for addressing access to medicines can only be effective if other existing barriers are simultaneously addressed. Most importantly, an effective exemption policy for poor people needs to be developed and implemented.

Available online at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1334179>

Addressing global health inequities: an open licensing approach for university innovations

Authors: Kapczynski, A.; Chaifetz, S.; Katz, Z.; Benkler, Y.

Produced by: Berkeley Technology Law Journal (BTLJ), University of California, Berkeley (2005)

This article, published in the Berkeley Technology Law Journal, demonstrates the potential of public sector institutions, particularly universities, to eliminate the barriers that patents pose on access to medicines and research in developing countries. It analyses the role that patents play in contributing to the access and research and development (R&D) gaps, and reviews existing proposals to eliminate the burdens that patents can impose on poor people. These include: top-down change by governments such as changes to international trade agreements and alterations in national patent laws; and private sector voluntary concessions.

The article finds that neither governments nor the private sector will act spontaneously and systematically to close the R&D gap or eliminate costs created by the global intellectual property rights regime. The authors propose alternative initiatives where participants, such as universities and other public sector institutions, change their practices to reduce barriers posed by patents and copyrights. These proposals are "Equitable Access" licensing - where intellectual property rights are used to secure freedom for an open class of potential users; and "Neglected Disease" licensing - designed to provide those engaged in neglected disease research, the freedom to experiment on and with proprietary university technologies.

Available online at: <http://www.benkler.org/EALFinalBTLJ.pdf>

Other documents from the health systems resource guide

Gender and equity in access to health care services in the Middle East and North Africa

Authors: Roudi-Fahimi, F.

Produced by: Population Reference Bureau (PRB) (2006)

This article, published by the Population Reference Bureau, investigates differences in access to health care services between men and women in the Middle East and North Africa. It suggests that significant inequalities in access to health care services and overall health status persist for the region's women, especially in the area of reproductive health. Socially assigned gender roles and cultural norms determine their "health-seeking behaviours" -- whether and where they look for health services. The article argues that gender inequities are so powerful among the region's low-literacy rural populations, that women in these populations are often not able to recognise a reproductive problem when it exists.

The article makes several recommendations for improving women's access to reproductive health services: Programme planners and policy makers in the regions should address the cultural constraints to women's reproductive health access. In particular, more investment should be made in interventions that raise women's health awareness and in outreach to encourage women's involvement. It suggests that developing community-based health promotion programmes can be an effective way to increase the health awareness of women in communities and encourage them to seek health care earlier.

Available online at: <http://www.prb.org>

Developing new technologies to address neglected diseases: the role of product development partnerships and advanced market commitments

Authors: Grace, C.

Produced by: Department for International Development (DFID) Health Resource Centre (HRC) (2006)

This paper, published by the DFID Health Resource Centre, focuses on the complementary roles of Product Development Partnerships (PDPs) and Advanced Market Commitments (AMCs) as ways of giving incentives to industry to develop new health technologies for neglected diseases. In PDPs, research partners from academia and the private sector are brought together with public sector funding. In AMCs, donors commit themselves to supporting a market for a new product which would otherwise not be profitable. The paper highlights some examples of similar mechanisms for funding research that have been used in the past. Firms appear to respond well to "push" incentives (such as PDPs), but only respond to "pull" incentives (such as AMCs) when they are accompanied by push incentives.

The paper concludes that in the neglected disease sector, push funding appears to be both effective and efficient. Push funding will likely be needed in this sector when new products are introduced, although it is difficult to generalise because costs of entering the market, distribution of expertise and development challenges differ across disease and technology. The paper also concludes that AMCs will not be enough by themselves. It recommends that using PDPs for full-scale clinical trials should not be ruled out if highly promising candidates appear and no private entity is willing to take up the challenge.

Available online at: http://www.dfidhealthrc.org/publications/atm/push_pull_06.pdf

Theory and practice: a case study of coordination and ownership in the Bangladesh health SWAp

Authors: Sundewall, J.; Forsberg, B. C.; Tomson, G.

Produced by: Health Research Policy and Systems (2006)

This paper, published in the Health Research Policy and Systems journal, examines how partners involved in health Sector Wide Approaches (SWAps) in Bangladesh define ownership and coordination in their daily work. Ownership and coordination are integral parts of SWAps, yet how they are defined is not particularly clear. It finds that partners in the Bangladesh health SWAp define coordination and ownership differently. This is because SWAps are translated into local context and have only been in effect for a few years. The paper analyses the possible implications of this, and finds that different definitions become an obstacle only when disagreements arise between partners.

The paper concludes that in Bangladesh, the notions of ownership and coordination have been accepted, but they have neither been discussed nor formalised. Thus, whilst the partners involved are supportive of the notions of ownership and coordination, they have different views on what the terms actually mean. The authors recommend that coordination can be improved if partners in development devote more attention to managing their working relationships. They also advise that roles and responsibilities within a sector-wide approach should be clearly delineated and that there should be appropriate mechanisms in place to handle potential disagreements between key stakeholders.

Available online at: <http://www.health-policy-systems.com/content/4/1/5>

Paying out-of-pocket for health care in Asia: catastrophic and poverty impact

Authors: van Doorslaer, E.; O'Donnell, O.; Somanathan, A.; et al

Produced by: Equitap (Equity in Asia-Pacific Health Systems) (2005)

This Equitap paper analyses the extent of out-of-pocket (OOP) payments for healthcare in 14 countries in Asia, and the impact of these payments on household's income and resources and vulnerability to poverty. It finds that the heavy reliance on OOP financing for healthcare has important consequences for living standards: in Bangladesh, China, India, Nepal and Vietnam, OOP payments absorb more than a quarter of household resources in at least one in ten households. OOP payments push a lot of families further into poverty: in 11 low/middle income countries, 2.7 per cent of the total population are pushed below the threshold of \$1 per day due to payments for health care.

The paper concludes that the extent of the negative impacts from OOP payments depends on three factors: the degree of reliance on OOP financing; the nature and distribution of OOP payments; and the public sector user-charging policy and the effectiveness with which the poor are exempted from charges. The authors provide examples where targeted exemptions, implemented through a health card, have some success in shielding poor families from high payments for health care.

Available online at: <http://www.equitap.org/publications/wps/EquitapWP2.pdf>

Priority setting in developing countries health care institutions: the case of a Ugandan hospital

Authors: Kafiriri, L.; Martin, D. K.

Produced by: Health Services Research (HSR) [journal] (2006)

This article, published by Health Services Research in BioMed Central, describes how priorities are set in a teaching hospital in Uganda and uses an ethical framework to evaluate whether this process is a fair one. In particular, it asks whether the process is accountable and reasonable. The article finds that priority is given to several factors including need, emergencies and the number of patients. Decisions are made by senior managers. These are publicised through general meetings and circulars, but this information does not always reach the front line practitioners. There are no formal mechanisms for challenging the reason of these decisions or mechanisms to ensure adherence to the conditions of a fair process.

The article concludes that priority setting at this hospital does not satisfy the conditions of fairness. The authors make some recommendations to improve priority setting in the hospital and other similar contexts. The hospital should engage front line practitioners, publicise the reasons for decisions both within the hospital and to the general public, and develop formal mechanisms for challenging the reasoning. In addition, capacity strengthening is required for senior managers who must accept responsibility for ensuring that these conditions are met. [adapted from authors]

Available online at: <http://www.biomedcentral.com/1472-6963/6/127>

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- Health Resource Guide - www.eldis.org/health
- Health Systems Resource Guide - www.eldis.org/healthsystems
- HIV and AIDS Resource Guide - www.eldis.org/hivaids

The HRC provides access to technical assistance and information for the Department for International Development (DFID UK), and its partners, in support of pro-poor health policies as well as health systems, service delivery and public health topics and programmes.

Eldis currently includes descriptions and links to over 4,500 organisations and over 16,000 full-text online documents covering development and environmental issues. It can be searched or browsed free over the Internet.

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