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COST-CONTAINMENT MECHANISMS FOR ESSENTIAL MEDICINES, INCLUDING ANTIRETROVIRALS, IN CHINA

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Cost-containment mechanisms for essential medicines, including antiretrovirals, in China

Mission report

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Contents

Terms of reference

Following meetings between the Chinese Ministry of Health (MOH) and the World Health Organization Representative in China, the MOH requested WHO to provide technical assistance on cost-containment mechanisms for antiretrovirals (ARVs) and other essential medicines in China.

The MOH requested information in the following areas:

1. The range of cost-containment options for ARVs and other essential medicines that China might consider.

2. Lessons from other countries' experience in negotiating price discounts and voluntary licensing arrangements for ARVs and other essential medicines.

3. China's World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Agreement (TRIPS) compatible options to undertake compulsory licensing; and the modalities of how a compulsory licence might be issued in China.

Germán Velásquez, Coordinator of the Drug Action Programme within WHO's Department of Essential Drugs & Medicines Policy, headed a three-person delegation that went to China, from 11 to 13 December 2002, for meetings with the MOH and other Chinese agencies. He was accompanied by Professor Carlos Correa of the University of Buenos Aires and Robert Weissman, an attorney practicing in Washington, D.C., who served as expert consultants on licensing and intellectual property issues.

This report contains a short summary of issues discussed during the mission in the area of cost-containment mechanisms and policies for access to essential medicines.

Introduction

Cost-containment mechanisms should be used for any essential medicine not affordable to the people or the health insurance systems. Various measures can be taken in China to increase value for money and to contain costs in the pharmaceutical sector.

Cost-effective medicine selection

Selection of cost-effective medicines at the primary health care, hospital or national level should be a major, and probably the first, component of cost-containment of medicines in China. Selective medicines lists for public health systems or private insurance include:

- Positive lists (essential medicines) setting criteria for new medicines to qualify for reimbursement;
- Negative lists, as in some industrialized countries, which exclude medicines from coverage under the health insurance system for therapeutic or financial reasons.

From a macro-economic perspective, access to HIV-related medicines should be seen in the context of a consistent selection of medicines supplied to patients by the public sector or by health insurance schemes (see also page 9, Government price controls).

Price information

As a mechanism for cost-containment of medicines, information on prices of medicines is crucial. Transparent pricing information enables rational decision-making about medicines selection, from the national level to individual prescriptions, and is a vital element in making use of other cost-containment mechanisms. As indicated in the box hereafter, WHO offers numerous medicines price information resources, as well as a methodology for sampling prices and comparing local prices with international reference prices (draft manual and worksheet currently being finalized).

WHO medicines price information services[1]

WHO works with several partners to make price information easily accessible to governments, nongovernmental organizations, donor agencies and any institution involved in medicines procurement. WHO medicines price information services are accessible at :<http://www.who.int/medicines/organization/par/ipc/drugpriceinfo.shtml>.

Particular resources include: *International Drug Price Indicator Guide:* Details 252 active ingredients in 448 dosage forms. Indicative prices of generic products on the international market and selected tender prices. Produced by Management Sciences for Health and WHO.

Sources and Prices of Selected Drugs and Diagnostics for People Living With HIV/AIDS: Details 73 active ingredients in 110 dosage forms. Issued by UNICEF, UNAIDS, Médecins Sans Frontières and WHO. Covers antiretroviral (ARV) medicines, HIV/AIDS test kits for diagnosis and ongoing monitoring, and medicines for treating opportunistic infections, for pain relief, for use in palliative care, for the treatment of HIV/AIDS-related cancers, and for managing drug dependence.

Pharmaceutical Starting Materials/Essential Drugs Report: Details over 262 active ingredients. Issued by WHO and the International Trade Centre, a joint WTO-UNCTAD publication.

AFRO Essential Drugs Price Indicator: Nearly 300 essential medicines and dosage forms listed - details provided by 24 Member States and 2 international low-cost essential drugs suppliers. Published by the Regional Office for Africa and the WHO Collaborating Centre for the Quality Assurance of Medicines, University of Potchefstroom, South Africa.

Average Prices of a One Year Treatment with Antiretrovirals in Countries of Latin America and the Caribbean: Survey by Pan American Health Organization of ARV therapy in Latin American countries.

Antiretrovirals in Latin America and the Caribbean: Details prices and uses of ARV treatments, and access policies for these medicines. Also covers prices by country and by groups of countries.

International open tendering

Open tender is a formal procedure by which quotations are invited from any manufacturer or manufacturer's representative on a local or worldwide basis, subject to the terms and conditions specified in the tender invitation. In medicines procurement, the use of competitive international tendering has indisputable economic advantages and is one of the classic cost-containment mechanisms. According to the experiences of many countries, international tendering reduces prices by 40 to 50 %[2].

[1] Annual Report 2001 – Essential Drugs and Medicines Policy: Extending the Evidence Base (WHO/EDM/2002.1).

[2] Quick et al. *Managing Drug Supply*. Kumarian Press, 1997.

However, the economic advantages of this mechanism apply mainly to multi-source products where competition exists and not for patented medicines. Open tendering is not an option for medicines, such as the majority of ARVs, that are protected by patents.

Voluntary discount agreements

Two categories can be distinguished of voluntary agreements between supplier firms and developing country governments to supply differentially priced products:

a) initiatives where prices are negotiated at a central level, such as the Global Alliance for Vaccines and Immunization (GAVI) and the Green Light Committee (GLC);

b) initiatives where prices are negotiated at a disaggregated level, between suppliers and countries[3].

Voluntary agreements in the second category include those between firms and countries to supply discounted ARVs through the Accelerating Access Initiative (a collaboration between 5 UN agencies and 6 research-based pharmaceutical companies); as well as agreements between countries and Indian, Brazilian or other countries' public or private pharmaceutical manufacturers. These agreements need to be assessed in terms of their price level, volume assured, duration of the deal and any other conditions which may be requested by the manufacturer.

Voluntary licensing

Voluntary licensing arrangements between a patent holder and another party in a country, or serving the country's market, may afford opportunities for significant cost-containment. As with negotiated discounts, the benefits of voluntary licensing arrangements depend crucially on the terms of the licence. For voluntary licences, the capacity of the licensee is also critical.

Patent holders may at their discretion, license to other parties, on an exclusive or nonexclusive basis, the right to manufacture, import, and/or distribute a pharmaceutical product. Depending on the terms of the licence, the licensee may act entirely or effectively as an agent of the patent holder; or the licensee may be free to set the terms of sale and distribution within a prescribed market or markets, contingent on payment of a royalty. Either option, or arrangements in between, may allow for substantial price reductions. However, terms in a voluntary licence may set price ranges, or include other terms, that maintain prices at or near the same level as those offered by the patent holder. Or terms may limit how many patients or which categories of patients are eligible to benefit from the lower prices provided by the licensee. Again, such matters turn on the terms of the licence contract. Voluntary licensing arrangements, at the discretion of the patent holder, are usually made for strategic reasons (e.g. market entry) rather than as price gestures and they may not entail any price reduction at all.

Compulsory licensing

When a product is patented, competitive bidding is not a viable option to reduce prices because, unless a patent is made ineffective, there is no competition. Compulsory licences may be an important cost-containment measure in that situation. The granting of such licences creates competition by one or more compulsory licensees, which in turn may force prices down. At the same time, the patent holder (and/or any voluntary licensees) can continue with commercial

[3] Unpublished paper commissioned by WHO to Cheri Grace, 2002.

exploitation of the patent, and will receive a compensation (generally in the form of a royalty) from the compulsory licensee/s.

Article 31 of the WTO TRIPS Agreement expressly allows the granting of compulsory licences. The Agreement contains no limits on the grounds under which such licences can be granted. Members' right to determine such grounds has been confirmed by the Doha Declaration on the TRIPS Agreement and Public Health (November 2001). Article 31 makes particular, but not exhaustive, reference to cases of national emergency or extreme urgency, dependency of patents, licences for governmental non-commercial use, and licences to remedy anti-competitive practices. National laws can, however, provide for the granting of such licences whenever the title holder refuses to grant a voluntary licence "on reasonable commercial terms" (Article 31 (b)) and for other reasons, such as public health or broad public interest considerations. The Agreement permits compulsory licences to authorize licensees to exercise any of the rights conferred by a patent, including production or importation.

The Chinese Patent Law provides that compulsory licences may be issued in the case of patent holder refusal to grant voluntary licences on reasonable commercial terms (Article 48), or to address a national emergency, an extraordinary state of affairs or public interest needs (Article 49).

China, like any other WTO Member country, may address the current problems of access to antiretrovirals or other essential medicines by issuing one or more compulsory licences. The granting of such licences -- subject to the conditions set forth by Article 31 of the TRIPS Agreement and Chinese Patent Law -- would constitute a legitimate implementation of one of the safeguards allowed by the TRIPS Agreement in order to protect public health.

Compulsory licences and government use provisions have been extensively used in developed countries, such as Canada and the USA, to address various public interests through the creation of competitive sources of supply[4].

Local state production

Two recent experiences have shown the importance of the existence of a state medicines manufacturing capacity.

During the 1998 Asian financial crisis, the Indonesian Government was able to supply hospitals, health centres and other health facilities with essential medicines thanks to the existence of state-owned local pharmaceutical manufacturers. Privately-owned local and foreign companies practically halted production for several weeks as the collapse of the local currency and uncertainty in foreign exchange rates prevented them from importing necessary raw materials.

Another important example has been the success of the Brazilian policy to fight AIDS, which has relied crucially on state pharmaceutical manufacturing capacity. Brazil produces most of the ARVs required for the local market, at prices significantly below those charged by brand-name companies. In addition, the existence of a significant local capacity to manufacture medicines increased Brazil's negotiating power in discussions with brand-name companies over price discounts.

[4] Correa C. *Integrating Public Health Concerns into Patent Legislation in Developing Countries*. Geneva, South Centre, 2000, p. 93-94.

The existence of a state pharmaceutical manufacturing capacity may also play an important role regarding prices in the international market. If states act as competitors in the global market, that will reduce worldwide prices.

Government price controls

Price regulation and negotiations
A competitive marketplace is the best way to ensure low prices for medicines. Proper organization of the market and application of anti-trust (monopoly) laws should facilitate price competition. However, if pharmaceutical markets do not become competitive, governments may choose to institute price controls.

Control or regulation of medicines prices may be based on:

a) actual costs (cost-plus pricing based on manufacturer's or importer's cost plus a fixed mark-up),
b) controlling companies' profit margins, or
c) comparison with prices in other countries or prices of other medicines in the same therapeutic category (yardstick, benchmark, or reference pricing). Once initial prices are established, decisions must then be made about price increases.

Reimbursement controls
A further means of controlling costs to the government is to establish different levels of reimbursement and to increase the proportion of the cost paid by the consumer for certain products (those not included in the national essential medicines list, for example).

Economic evaluation
Medicines selection decisions and the establishment of standard treatments involve judgements about relative therapeutic value. The economic evaluation of medicines is a systematic method to identify which of a series of alternative therapies will achieve medical objectives most cost-effectively. It forms part of a newly-emerging discipline called pharmacoeconomics.

Economic evaluation is being used in some industrialized countries to determine whether the magnitude of the benefit of a new medicine justifies the cost and then to subsidize those medicines that produce the greatest output in improved health in return for the lowest cost.

Policy-makers are faced with a lack of unbiased and accurate information on the trade-offs between competing product options. Economic evaluation is useful because it offers a logical framework for considering a new medicine for subsidy, for drug formulary management, or for price-setting. Yet it is not a proven means of budgetary control. It is a complex, time-consuming and resource-intensive process. Nevertheless, it would be a way to ensure that the medicines budget represents value for money. Frequent reassessment of decisions is necessary as more information becomes available.

Reduction of import and other taxes for essential medicines, and rational dispensing practices

Reducing import and other taxes on pharmaceuticals may serve to lower final prices to consumers. Where there is competition, such taxes will clearly add to the final price of a product, an add-on to the wholesale price. Where patent protections are in place, patent holders have much more pricing discretion, and may set wholesale prices with an eye to the final retail price. Thus tax reductions may not translate into reduced retail prices, or price

reductions equivalent to the tax reduction. Whether tax reductions thus benefit consumers will turn in significant part on the particularities of specific markets: whether products are patented, whether price controls are in place, how patent holders choose to act and pricing discretion available to pharmacies and dispensing agencies.

Pharmaceutical dispensaries may engage in significant price mark-ups, or unscientific dispensing practices that favour use of brand-name and higher-cost products at the expense of generics and lower-cost alternatives. As is the case in many countries, China may consider regulations to require or prefer generic substitution, where safe and effective generics exist. Many price-increasing and unscientific dispensing practices relate to the percentage mark-up by dispensaries. To realign dispensary incentives, China may consider regulations stipulating that pharmacies charge a flat fee per sale, as opposed to a percentage of sales.

Public investment in R & D for new medicines: A mid- to long-term strategy

An option that developing countries with a large scientific base, such as China, should explore more systematically is the strengthening and expansion of the R & D needed to address the diseases prevalent in those countries, including HIV/AIDS. China may have significant cost advantages to undertake R & D in complex fields (including genomics, proteomics and other new fields) and become an important player in the discovery of new medicines and treatment. This could be done on the basis of public investment at the national level, or through partnerships with other countries, for the public good, that is, in order to make available new therapeutic

options for non-profit purposes. Of course, several modalities may also be envisaged to recoup investments in R & D as well as to establish partnerships with the private sector.

Background and experiences with voluntary agreements

The most prominent of the formal arrangements to facilitate voluntary price reductions for pharmaceutical products for developing countries is the Accelerating Access Initiative (AAI).

The AAI was launched by UNAIDS in a partnership with several UN agencies and five pharmaceutical companies (Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Merck & Co and Hoffman-La Roche[5]). Responsibility for this initiative was transferred to WHO at the end of 2001. The main AAI goal is to provide developing countries with access to ARV medicines at reduced prices.

The launch in 1997 of the UNAIDS Drug Access Initiative, which antedated the AAI, resulted in participating research-based firms dropping their prices for triple ARV therapy from US$ 12 000/year to US$ 7 000/year. With the launch of the AAI in May 2000, the cost of triple drug combination regimens sourced from the participating companies quickly fell to about US$ 1 200/year. After the Indian Generics industry entered the scene, prices for first line regimens decreased further. Currently, four Indian generic companies offer first line triple combination regimens at less than half the price offered by the lowest priced companies participating in the AAI. A recent check of offers found the following prices: Cipla at US$ 350, Hetero at US$ 347, Aurobindo at US$ 289, and Ranbaxy at US$ 295[6]. These prices (not only those of the generic ARVs, but also those of the R & D industry) continue to drop and increasingly the quality of generic ARVs is being documented: both CIPLA and Ranbaxy obtained WHO prequalification of their first line ARVs[7].

[5] Abbott has now joined, so there are now 6 participating companies.

[6] *Untangling the WEB of price reductions – a Pricing Guide for the Purchase of ARVs for Developing Countries*, MSF, June 2002.

[7] Pilot Procurement Quality and Sourcing Project: Access to Antimalarial, Anti-tuberculosis and HIV/AIDS Drugs and HIV/AIDS Diagnostics of Acceptable Quality (http://www.who.int/medicines/organization/qsm/activities/pilotproc/pilotprocmain.shtml).

Since the launch of the AAI, 80 countries have expressed their interest in the Initiative. In 39 of these 80 countries, national plans to improve access to care have been or are being developed. These plans have been used as a framework for dialogue with the pharmaceutical companies. Nineteen countries[8] have concluded agreements with individual companies participating in the Initiative[9].

Despite the broad country interest, the actual number of patients receiving ARVs through AAI remains disappointingly low - less than 1% of the HIV population currently needing ARV treatment. As of December 2001, about 27,000 people had gained access to ARV therapy in the 19 participating countries. That number has now increased, but not by an order of magnitude.

[8] Barbados, Benin, Burkina Faso, Burundi, Cameroon, Chile, Cote d'Ivoire, Gabon, Honduras, Jamaica, Mali, Morocco, Republic of Congo, Romania, Rwanda, Senegal, Trinidad and Tobago, Uganda, and Ukraine.

[9] *UNAIDS, Accelerating Access Initiative, Widening access to care and support for people living with HIV/AIDS.* Progress report. June 2002.

Country rights to be protected in voluntary agreements for reduction of prices of medicines

Countries entering negotiations with patent holders of ARVs and other essential medicines for price reductions will enhance their effectiveness by considering negotiations in the context of other mechanisms for cost-containment. On the one hand, the benefits of negotiated price reductions will be enhanced by combining negotiations with other tools, such as eliminating import taxes (a measure already taken by China) and rational national dispensing practices. On the other hand, countries can strengthen their bargaining power by fully informing themselves of the potential benefits of other tools. For example, an awareness of the price reductions available from compulsory licensing or local state production will provide important information for countries entering into negotiations. Negotiations conducted against the backdrop of considerable efforts to introduce generic competition will also improve the government's bargaining power.

A negotiation will inevitably involve trade-offs, and, in most circumstances, a government is not likely to achieve everything it desires. Although it may offer major benefits, a negotiated resolution is also likely to include price or other conditions that to some extent frustrate the government. It is therefore particularly important for governments to be aware of certain limitations that patent holders may seek in a price reduction agreement, and to be aware of the relative risks of such provisions before agreeing to them.

Such conditions and limitations include:

- Limitations on re-export of discounted products. There is a legitimate patent holder interest in seeing products specially discounted for one market not leak into other markets. However, governments should recognize the potential difficulties in preventing their re-export. Overly burdensome requirements for governments to track, monitor, oversee and report on pharmaceutical distribution and consumption may strain government resources, and add significantly to the cost of providing essential medicines. At the same time, governments should be cognizant of the other tools available to deter cross-border re-sale. For example, most rich country markets maintain legal restrictions on unauthorized re-importation of pharmaceuticals from developing countries, as well as well-resourced and effective enforcement systems to ensure these restrictions are respected. Where these are inadequate, pharmaceutical companies are well positioned to urge those countries to improve enforcement. Pharmaceutical patent holders also retain significant ability to restrain re-export, including by changing the presentation of products (so pills are a different colour) or through labelling (labelling in Chinese characters would deter export to non-Chinese-speaking markets).

- Duration of the discount. Discount terms may only be available for a limited time. Where the need giving rise to the discount arrangement is not likely to recede, limited-term discount arrangements may only postpone the day of reckoning. For products such as ARVs, which must be taken for the life of the patient, limited-term solutions are particularly problematic. Of course, discounts need only be afforded during the period of effective patent protection, if an effective generics market is operational.

- Static price discount. The negotiated discount is likely to provide a set price over an extended period. By contrast, competition offers dynamic benefits and ongoing price

reductions as competitors improve manufacturing technique and gain economies of scale. Thus, as government officials negotiate a set price, keeping in mind what price benefits they might obtain from compulsory licensing or state production, they should also be mindful that the cost savings from these approaches would grow over time. A discount price should be negotiated against a backdrop of awareness of the dynamic benefits of competition and local production.

- Secrecy. Patent holders may request that the terms of a final negotiation -- price, ancillary conditions, or both -- remain confidential. Confidentiality does not directly weaken the government's negotiating hand; obviously, the government knows what it negotiated. But a practice of confidentiality among multiple government beneficiaries of price reductions weakens them all. Each operating individually, they deprive themselves through secrecy of the collective knowledge of other discount deals, and the leverage afforded by knowledge of what others were able to negotiate. Similarly, secrecy protects the patent holder from international public pressure in support of more generous terms.

- Policy conditions. Patent holders may request that governments agree to certain TRIPS-plus legal or regulatory changes in exchange for discount products. They may also request that governments agree not to undertake compulsory licensing of other products. Such agreements may severely limit the government's flexibility, and have long-term impacts on the overall national pharmaceutical bill.

- Restrictions on number of patient beneficiaries. Patent holders may agree to provide discounted treatment only to a limited number of patients, leaving others in need of medicines to purchase them at the market rate, or to go without.

- Restrictions on type of patient beneficiaries. Patent holders may agree to provide discounted treatment only to a certain category of patients. Price discounts may only be available to those classified as impoverished, for example, with others required to purchase products at the market rate. The patent holder goal in this circumstance would be to bifurcate the market, and maintain a viable market for less poor consumers who may be able to afford to pay more. However, many of those consumers denied discounts may be unable to afford any medicine at the market rate.

- Restrictions on type of distributing institution. Patent holders may provide discounts only to public hospitals, thus restricting the number of people who benefit from price reductions. Or they may provide discounts confined to certain lower-income geographical areas. Again, the patent holder goal may be to maintain a market for better-off consumers, even though many in this category may not be able to pay, or their insurance providers may refuse to pay, the higher rates. Patent holders may also require the dispensing institution to demonstrate its capacity to properly handle patient treatment and care related to the discount product. While governments must ensure the safe and efficacious provision of medicines, demonstrations of such capacity may be onerous or administratively complicated such that relatively few institutions are able to meet externally imposed tests.

Compulsory licensing - practical aspects and procedures

The granting of a compulsory licence under China's existing legislation (and in conformity with the TRIPS Agreement) would require a number of steps which are described below.

Identify relevant patents

In most cases, pharmaceutical products are protected by a patent on the active ingredient (the main patent) and by a number of patents on formulations, manufacturing processes, new indications, etc. (secondary patents). All these patents should be identified and be included in the compulsory licence, as necessary, to allow freedom to operate with the needed product. Otherwise, the use of the invention under the compulsory licence may be perturbed or blocked on the basis of allegations of infringement of secondary patents (as illustrated by the well- documented case of ddI in Thailand).

Explore possible sources of supply based on local production

The analysis to be undertaken should include:

- the availability of technical resources for reverse engineering;
- the cost and duration of developing manufacturing processes and formulations;
- the need for technology transfer;
- GMP and quality of final products made by local producers; and
- estimates of the investment required and of the marginal cost of production.

Identify possible sources of importation of the required medicine

The analysis to be undertaken should include:

- compliance with GMP and product quality assurance by potential suppliers;
- prices of supply over time; and
- the sustainability of the exporter's supply.

Marketing approval

Registration requirements may pose obstacles to the speedy distribution of needed medicines. While considering the issuance of a compulsory licence, steps should be taken to ensure that such obstacles do not exist or are overcome.

China has recently introduced an exclusivity period of protection for test data (Article 35 of the Implementing regulations of the Drug Administration Law) which would only apply to products containing new chemical entities.

Request for a compulsory licence

Compulsory licences can be granted in China on the basis of Article 48 or 49 of the Chinese Patent Law. The applicable conditions will vary depending on the alternative to be followed.

Article 48

A request to the patent holder on reasonable commercial terms should be made, including:

- information about the requesting party;
- the expected volume of production;
- the royalty to be paid;
- the form of payment;
- the intended mode of use of the invention;
- quality controls;
- trademark to be used, if any;
- the duration of the licence;
- the licensee's right to control sales for determination of royalties due;
- the applicable law and jurisdiction in case of disputes.

The "reasonable period of time" for the patent holder to accept or reject the offer is undefined in the Chinese Law and Regulations. One to three months may be a reasonable period.

Article 49

Under Article 49, there is no need for prior negotiation (provided that Article 51 of the Law is understood to apply to Article 48 only). "Public interest" is a legitimate ground for issuance of a compulsory licence under Article 49.

Declaring a "national emergency" is not a pre-condition for granting a compulsory licence under Article 49. If this option is followed, it should be borne in mind that an "emergency" may be a long-lasting situation, as in the case of the HIV/AIDS epidemic, not just a short-term problem.

An Article 49 compulsory licence is preferable to a licence grounded on Article 48, because there is no requirement for prior negotiation, and because an Article 49 licence would make clear from the outset that public health reasons are the key governmental consideration in granting a compulsory licence. This will make it politically more difficult for patent holders, their business associations and respective governments to challenge the compulsory licence.

Granting of the compulsory licence by the Patent Administration Department

The competent department will have to define the *scope* of the licence and its *duration*. It would be advisable for the scope to include all commercial and non-commercial uses of the relevant invention, and for the licence to last until the patents' expiry.

Negotiation with patent holder about fee

After the granting of the compulsory licence, *bona fide* negotiations should be undertaken with the patent holder to establish the fee for the exploitation of the patent. Generally, fees are determined as a percentage of the net sales price of the product made under the licence (and not the patentee's own product), but other modalities can be adopted, for instance, a fixed sum per unit sold.

The TRIPS Agreement requires that the compensation reflect the economic value of the licence.

Commercial practice in voluntary licensing is to use royalties ranging between 2% and 5%, though they may be higher in certain cases. There is some evidence available on the royalties determined by national authorities in Canada, the USA and other countries for the granting of compulsory licences[10].

Factors that may be considered to negotiate the fee include: launch date of the product, possible substitutes, coverage and possible invalidity (total or partial) of the patent/s, pending challenges to the patent/s, if any, accumulated sales and recovery of R & D investment made by the patent holder, global and Chinese market for the product (units and value), expected volume of production and price under the compulsory licence, royalties agreed upon in voluntary licences on the same or similar products.

Of course, gathering this information will require considerable preparation and work by an inter-disciplinary team.

Determination of fee by the Patent Administration Department

If the fee negotiations fail, the fee will be determined by the Patent Administration Department. For the purposes of transparency and consistency, it would be advisable to make explicit the criteria used for the determination (such criteria are not defined in Chinese legislation), and to establish guidelines that will apply to all such fee determinations.

Appeal

Chinese law establishes that patent holders may appeal a decision to grant a compulsory licence to a court, but that the appeal does not suspend the execution of the compulsory licence.

Other considerations

Patent holders (or their governments) may attempt to use legal measures, such as injunctions, to delay or prevent the execution of a compulsory licence. It would also be useful to check the possible application of other instruments, such as bilateral

[10] Niess, P. Technology evaluation and pricing. TECH MONITOR, November-December 1999, p. 16-17.

agreements on investment (which often consider intellectual property as an “asset” subject to their rules).

Concluding comments

1. In seeking to contain costs for ARVs and other essential medicines, China should consider the full panopoly of available policy tools, and examine closely how the various tools may complement one another.

2. In making policy choices related to cost-containment, including use of TRIPS flexibilities and safeguards, China should prioritize public health considerations. Affordability of essential medicines is a public health priority.

3. Voluntary negotiations can lead to substantial price reductions for on-patent medicines in developing countries. China will be strongest in negotiating for voluntary discounts if it has reviewed its options for compulsory licensing and domestic production, and can credibly present these approaches as an alternative to deep discounts.

4. Voluntarily offered price reductions may be accompanied by limiting conditions. These may limit the number or type of beneficiaries of the price reduction, impose significant burdens on the government, or limit the government's ability to deploy varying policy tools. The government may or may not decide that these limitations are an acceptable trade-off for the benefits of price discounts; but it should be aware both of the costs, and its options.

5. WHO supports measures which improve access to essential medicines, including application of TRIPS safeguards.

6. By introducing competition, compulsory licensing may significantly reduce the price of ARVs and other essential medicines.

7. Compulsory licensing is widely used in some industrialized countries, and is an integral part of the intellectual property system. If China chooses to proceed with the issuance of compulsory licences for some essential medicines, it will be showing its commitment to the patent system. That is, rather than ignoring patents or engaging in underground counterfeiting, the government would be addressing access concerns from within the patent system. The government would be indicating its respect for the patent system, even where crucial public health matters are at stake.

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Further reading

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- *Globalization and Access to Drugs – Perspectives on the WTO/TRIPS Agreement (Revised)*, Geneva, World Health Organization, 1999 (WHO/DAP/98.9) – available in Chinese.

- *Globalization, TRIPS and Access to Pharmaceuticals*, WHO Policy Perspectives on Medicines N° 3, Geneva, World Health Organization, March 2001 – available in Chinese.