7. **Restricting the availability of anti-TB medicines**

The problem

1. Currently, only 62% of estimated drug-susceptible TB cases and less than 5% of the estimated MDR-TB cases are detected and treated within NTPs. The majority of them have previously been visiting one or several health providers outside NTP. For example, studies have shown that the proportion of patients that had turned first to a private provider was 50% in Viet Nam, 75% in India and 96% in Myanmar. Use of public sector providers that are not linked to NTP is also common.

2. In some settings, a considerable proportion of people with TB also receive TB treatment outside NTPs. For example, 75% of all TB patients were treated outside the NTP in a large city in Indonesia; a study from a metropolitan area in Viet Nam estimated that 40% of patients on TB treatment were treated by private providers not linked to the NTP; and among cases on TB treatment identified in the prevalence surveys in China in 2000 and Myanmar in 2006 (Yangon only), 88% and 48% respectively were treated outside the NTP. A recent estimate of the TB drug market in 10 countries found that about half of the total TB drug market was in the private sector. In some of the major high-TB-burden countries the share is even higher: 90% in the Philippines, 74% in India, 67% in Indonesia and 56% in China.

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3. Unfortunately, private physicians, as well as public sector providers outside NTP, rarely follow recommended TB treatment regimens. Treatment outcomes are poor in private and public facilities that operate outside NTP, often with a treatment success rate of less than 50%.

4. Many patients thus receive TB treatment of questionable quality at private and public facilities. Therefore, prevention of drug-resistance development and amplification needs to include efforts to minimize irrational use of anti-TB medicines across the whole health system.

5. Both FLDs and SLDs are widely available over-the-counter (OTC) in retail pharmacies. This encourages self-treatment and the purchase of inadequate quantities of medications - a recipe for encouraging the emergence of drug resistance. Even when anti-TB medicines are sold against a prescription, prescribers outside national programmes may not use recommended regimens, and patients may fill only part of the prescription due to financial constraints.

6. Prescription and dispensing of medicines in general, and antibiotics (including anti-TB medicines) in particular, is poorly monitored and regulated in most countries. When regulation exists, there is often not enough capacity to enforce it. Misuse of antibiotics is a huge problem world-wide, which is fuelling the rapidly increasing occurrence of antimicrobial resistance. The misuse of anti-TB medicines therefore need to be addressed as part of broader health systems strengthening efforts to limit misuse of antibiotics.

The solution

An essential step to prevent further development of MDR-TB is to continue to scale up public-private mix (PPM) approaches for TB care and control, which promotes rational use of anti-TB medicines among all health-care providers (see background paper on "Prevention of M/XDR-TB: Gaps in basic TB control"). PPM approaches have been successfully piloted in several countries and scaled up in a few. However, no country has been able to engage all relevant health-care providers, and most countries with PPM initiatives have still only engaged a fraction of the private providers. This is partly due to reluctance among some providers to engage in activities that may not have any clear financial benefit for them. The PPM approach builds on voluntary collaboration and has rarely been supported by regulatory interventions to restrict availability of anti-TB medicines and/or prescription rights to quality-assured facilities. Complementary efforts

to improve rational use of anti-TB medicines across the whole system may therefore involve:

1. **Enforced prohibition of OTC dispensing of anti-TB medicines**: Many countries have regulations in place, but they are rarely enforced, and penalties for violations are normally benign. Strengthened capacity for enforcing such regulation is needed. Similarly, dispensing of anti-TB medicines by prescribing physicians should be prohibited, as the direct financial incentive from drug sales may negatively affect prescribing behaviour. Obviously, such efforts need be done in collaboration with drug regulatory bodies and other relevant stakeholders.

2. **Explore regulatory approaches to restrict prescription and dispensing rights to accredited facilities**: One strategy to further limit misuse of anti-TB medicines is to restrict prescribing and dispensing rights to facilities where rational prescribing and dispensing can be assured and essential information on the patient and the provider can be monitored. A possible model is to completely ban TB drug sales and dispensing outside facilities that are directly affiliated with the NTP. Several countries (e.g. Brazil, Syrian Arab Republic, United Republic of Tanzania, and Zambia) have regulations that completely prohibit sales of FLDs in retail pharmacies, and give the NTP a monopoly for drug procurement and distribution. In at least some of these countries, this regulation seems to work in that anti-TB medicines are not available outside quality assured facilities designated to treat TB (public or private). Further documentation is needed to validate this and analyse how such regulation can effectively be put in place.

Restricting availability to SLDs may be more challenging than restricting sale of 1st line medicines since many of them are used for other indications than TB. However, it is in principle possible to restrict access to at least some of them (the ones most specific for TB, and the ones that are suitable only for treatment in special institutions) to accredited providers. Restricting prescription and/or dispensing rights would require classification of anti-TB medicines into a category of “controlled substances” (such as narcotics and psychotropic medicines or medicines that are made available on special license for specific projects or cases). This is easier for medicines that are being registered for the first time in a country. For example, the Philippines has managed to restrict the availability of all SLDs, except amikacin and fluoroquinolones, to GLC-approved projects in selected facilities. They are not available in retail pharmacies. There is very little experience of this approach globally, and it should be explored further, piloted, and evaluated.

3. **Develop guidelines and recommended practice**: An alternative, “softer”, approach is to recommend (but not prohibit) pharmacies not to stock anti-TB medicines and refer

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all clients requesting anti-TB medicines to NTP-affiliated facilities. This has been tried in Cambodia, where the NTP in collaboration with the national pharmacy association, has instructed all pharmacies in selected areas not to stock anti-TB medicines, but refer TB suspects to the NTP. Simultaneously they requested all private providers to refer all TB suspects to the NTP. Preliminary investigations indicate that this approach has led to non-availability of anti-TB medicines in these pharmacies. Similar approaches have been reported from Viet Nam. In theory, such an approach could be considerably strengthened if both professional associations and pharmaceutical companies are engaged in efforts to make medicines available only at quality assured facilities as well as in the dissemination of information about the need to refer TB cases to these facilities.

**Urgent actions needed**

- Put in place and enforce regulation that prohibits the dispensing of anti-TB medicines without a prescription, and which prohibits physicians to sell such medicines directly to patients.
- In conjunction with PPM scale-up and the development of formal accreditation mechanisms, explore regulatory approaches that restrict prescription and dispensing rights to quality-assured facilities only.
- Regardless of existing regulation, develop recommendations and guidelines for all health-care providers, including pharmacies, stating that anti-TB medicines should be prescribed and dispensed only in facilities of assured quality.

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14 Travel report by Monica Diaz Yesudian, January 2009.