SIXTY-SECOND WORLD HEALTH ASSEMBLY **WHA62.15**

Agenda item 12.9 **22 May 2009**

Prevention and control of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis

The Sixty-second World Health Assembly,

Having considered the reports on the prevention and control of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis;[1]

Noting the progress made since 1991 towards achieving the international targets for 2005, the acceleration of efforts following the establishment of the Stop TB Partnership in response to resolution WHA51.13, and more recently following resolution WHA58.14 encouraging Member States to ensure availability of sufficient resources to achieve the internationally agreed goal relevant to tuberculosis contained in the United Nations Millennium Declaration by 2015;

Aware that the development of the Stop TB strategy as a holistic approach to tuberculosis prevention and control and represents a significant expansion in the scale and scope of tuberculosis-control activities as a part of strengthening health systems within the context of primary health care and addressing social determinants of health;

Noting that the Stop TB Partnership's Global Plan to Stop TB 2006–2015 sets out the activities oriented towards implementing the Stop TB strategy and achieving the international targets for tuberculosis control set by the Stop TB Partnership – in line with the target of the internationally agreed development goal relevant to tuberculosis contained in the United Nations Millennium Declaration to "have halted by 2015 and begun to reverse the incidence of major diseases" – of halving tuberculosis prevalence and death rates by 2015 compared with 1990 levels;

Noting that the care and control of tuberculosis have progressed significantly during the past decade and the incidence of new cases is estimated to have fallen slightly each year since 2003;

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[1] Documents A62/20 and A62/20 Add.1.

Aware that a significant proportion – an estimated 37% of tuberculosis cases worldwide remain un-notified and receive either no treatment or inappropriate treatment;

Recognizing that the rates of tuberculosis are disproportionately high in high-risk populations including indigenous populations;

Recognizing that emergence and spread of multidrug-resistant and extensively, drug-resistant tuberculosis is facilitated by not detecting sufficient cases of tuberculosis and not treating them appropriately by DOTS-based treatment;

Concerned that the highest levels of multidrug-resistance reported in WHO's fourth global report on anti-tuberculosis drug resistance[1] – an estimated half a million multidrug-resistant cases occurring globally, including 50 000 cases of extensively drug-resistant tuberculosis – pose a threat to global public health security;

Recognizing that there is an urgent need to invest in research for development of new diagnostics, medicines and vaccines and in operational research to prevent and manage tuberculosis, including multidrug-resistant and extensively drug-resistant tuberculosis; while exploring and, where appropriate, promoting a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products;

Noting that less than 3% of the estimated total number of multidrug-resistant and extensively drug-resistant cases of tuberculosis receive treatment according to WHO recommended standards;

Concerned that the disease transmission occurs mostly in communities where there is a lack of appropriate infection control;

Concerned that the insufficient demand from countries for internationally quality-assured anti-tuberculosis medicines resulting in an inadequate supply through the Green Light Committee mechanism has been a major bottleneck to treating multidrug-resistant and extensively drug-resistant tuberculosis and that quality-assured fixed-dose drug combinations, developed as a tool to prevent the emergence of resistance, are not widely used;

Aware that the delays in implementing the Global Plan to Stop TB 2006–2015 will result in increasing numbers of tuberculosis cases and deaths, including those due to multidrug-resistant and extensively multidrug-resistant tuberculosis and to the impact of HIV, and therefore in delays in achieving by 2015 the international targets for tuberculosis control and the internationally agreed development goal relevant to tuberculosis contained in the United Nations Millennium Declaration;

Recalling resolution WHA60.19 on tuberculosis control in which the Health Assembly urged Member States to develop and implement long-term plans for tuberculosis including multidrug-resistant and extensively drug-resistant tuberculosis prevention and control in line with the Global Plan to Stop TB 2006–2015, within the overall health development plans, and resolution WHA58.33 on achieving universal coverage;

Welcoming the Beijing Call for Action on tuberculosis control and patient care given jointly by representatives of 27 Member States carrying a high burden of multidrug-resistant and extensively

[1] Document WHO/HTM/TB/2008.394.

drug-resistant tuberculosis, civil society, the private sector and others to address the alarming threat of multidrug-resistant and extensively drug-resistant tuberculosis,[1]

1. URGES all Member States:

(1) to achieve universal access to diagnosis and treatment of multidrug-resistant and extensively drug-resistant tuberculosis as part of the transition to universal health coverage, thereby saving lives and protecting communities, by means of:

(a) developing a comprehensive framework for management and care of multidrug-resistant and extensively drug-resistant tuberculosis, that includes directly-observed treatment, community-based and patient-centered care, and which identifies and addresses the needs of persons living with HIV, the poor and other vulnerable groups, such as prisoners, mineworkers, migrants, drug users, and alcohol dependants, as well as the underlying social determinants of tuberculosis and multidrug-resistant and extensively drug-resistant tuberculosis;

(b) strengthening health information and surveillance systems to ensure detection and monitoring of the epidemiological profile of multidrug-resistant and extensively drug-resistant tuberculosis and monitor achievement in its prevention and control;

(c) aiming to ensure the removal of financial barriers to allow all tuberculosis patients equitable access to tuberculosis care, that their rights are protected, and that they are treated with respect and dignity in accordance with the local legislation;

(d) making available sufficiently trained and motivated staff in order to enable diagnosis, treatment and care of tuberculosis including multidrug-resistant and extensively drug-resistant tuberculosis, as an integral part of efforts to address the overall health workforce crisis;

(e) strengthening laboratory systems, through increasing capacity and adequate human resources, and accelerating access to faster and quality-assured diagnostic tests;

(f) engaging all relevant public and private health-care providers in managing tuberculosis including multidrug-resistant and extensively drug-resistant tuberculosis and tuberculosis-HIV coinfection according to national policies, and strengthening primary health care in early detection, effective treatment and support to patients;

(g) ensuring that national airborne infection-control policies are developed (as part of general infection prevention and control programmes) and implemented in every health-care facility and other high-risk settings and that there is sufficient awareness of tuberculosis infection control in the community;

[1] Document A62/20 Add.1, Annex.

(h) ensuring uninterrupted supply of first-, and second-line medicines for tuberculosis treatment, which meet WHO prequalification standards or strict national regulatory authority standards, and that quality-assured fixed-dose combination medicines of proven bioavailability are prioritized within a system that promotes treatment adherence;

(i) strengthening mechanisms to ensure that tuberculosis medicines are sold on prescription only and that they are prescribed and dispensed by accredited public and private providers;

(j) undertaking effective advocacy, communication and social mobilization**,** avoiding stigmatization and discrimination, and spreading community awareness about policies and plans for prevention and control of tuberculosis including multidrug-resistant and extensively drug-resistant tuberculosis;

(k) establishing national targets in order to accelerate access to treatment according to WHO guidelines, for multidrug-resistant and extremely drug-resistant tuberculosis patients;

(2) to enhance quality and coverage of DOTS in achieving 70% detection rate and 85% success rate of tuberculosis treatment, thereby preventing secondary multi-drug resistant tuberculosis;

(3) to use all possible financing mechanisms in order to fulfil the commitments made in resolutions WHA58.14 and WHA60.19, including the commitment to ensure sustainable domestic and external financing, thereby filling the funding gaps identified in the Global Plan to Stop TB 2006–2015;

(4) to increase investment by countries and all partners substantially in operational research and research and development for new diagnostics, medicines and vaccines to prevent and manage tuberculosis including multidrug-resistant and extensively drug-resistant tuberculosis;

2. REQUESTS the Director-General:

(1) to provide technical support to Member States in order to develop and implement response plans, based on a comprehensive framework for management of care, for the prevention and control of tuberculosis including multidrug-resistant and extensively drug-resistant tuberculosis;

(2) to provide support to Member States in developing and implementing strategies to engage all relevant public, voluntary, corporate and private health-care providers in the training for and scaling up of prevention and control of tuberculosis including multidrug-resistant and extensively drug-resistant tuberculosis and all aspects of tuberculosis-HIV coinfection;

(3) to advise and support Member States to bring the standards of national drug regulatory agencies in line with international standards, thus enabling national pharmaceutical manufacturers to produce material of assured quality to be sold in the local and international markets;

(4) to provide support to Member States for upgrading laboratory networks to be able to undertake diagnosis and monitoring of multidrug-resistant and extensively drug-resistant tuberculosis and facilitate systematic evaluations of newer and faster diagnostic technology;

(5) to strengthen the Green Light Committee mechanism to help to expand access to concessionally-priced and quality-assured first- and second-line medicines, to encourage and assist the local pharmaceuticals in high-burden countries to get qualification within the Green Light Committee mechanism;

(6) to explore and, where appropriate, promote a range of of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products;

(7) to work with countries to develop country indicators and to support monitoring and evaluation of the implementation of the measures outlined in this resolution;

(8) to report through the Executive Board to the Sixty-third and Sixty-fifth World Health Assemblies on overall progress made.

Eighth plenary meeting, 22 May 2009
A62/VR/8

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SIXTY-SECOND WORLD HEALTH ASSEMBLY A62/20
Provisional agenda item 12.15 16 April 2009

Prevention and control of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis

Report by the Secretariat

1. In 2007, the Health Assembly in resolution WHA60.19 noted considerable progress made in tuberculosis control globally since 1991 and acknowledged the WHO Stop TB strategy, which incorporates the internationally recommended DOTS strategy, as a comprehensive approach to global control. Recognizing the alarming emergence and transmission of drug-resistant tuberculosis,[1] Member States were urged to develop and implement plans for prevention and control in line with the Stop TB Partnership's Global Plan to Stop TB 2006–2015 as part of their national health development plans. However, data suggest the problem of multidrug resistance is worsening: in 2008, WHO's fourth global report on anti-tuberculosis drug resistance[2] noted the highest levels of multidrug resistance ever recorded in a general population, with an estimated half a million cases occurring globally, including 50 000 cases of extensively drug-resistant tuberculosis. Recognizing its relevance for global security, the Executive Board agreed that an item on the prevention and control of multidrug and extensively drug-resistant tuberculosis should be added to the provisional agenda of the World Health Assembly.[3] Notwithstanding the achievements over the past decade, prevention and management of drug-resistant tuberculosis require much stronger control which, in turn, requires resolving of weaknesses of health systems. The challenges posed by drug-resistant tuberculosis offer important opportunities to strengthen health systems with the goal of achieving universal coverage for health care.

2. The care and control of tuberculosis have progressed significantly during the past decade and the incidence of new cases is estimated to have fallen slightly each year since 2003. In 2007, 9.3 million new cases are estimated to have occurred and 63% were treated under programmes using the Stop TB strategy, with over 85% treatment success. An estimated 37% of cases worldwide, however, remain un-notified, with patients receiving either no treatment or treatment that is unlikely to reach internationally recommended standards.

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[1] Multidrug-resistant tuberculosis is defined as resistance to at least rifampicin and isoniazid, the two most powerful anti-tuberculosis medicines. Extensively drug resistant-tuberculosis is defined as multidrug-resistant tuberculosis that is also resistant to any one of the fluoroquinolones and to at least one of three injectable second-line antibiotics (amikacin, capreomycin or kanamycin).

[2] Document WHO/HTM/TB/2008.394.

[3] Document EB124/2009/REC/2, summary record of the eleventh meeting, section 3, and the twelfth meeting, section 1.

3. Emergence and spread of multidrug- and extensively drug-resistant tuberculosis are facilitated by inadequate case detection and inappropriate treatment. While country-level data collection and reporting need further improvements, several countries have reported increasing levels of anti-tuberculosis drug resistance. Twenty-seven countries,[1] 15 of which are in eastern Europe and central Asia, account for 85% of the total burden of multidrug-resistant tuberculosis. China, India and the Russian Federation together constitute over half the burden but the problem of multidrug- and extensively drug-resistant tuberculosis is global and present in almost all countries surveyed. Fifty-five countries have, at the time of writing, reported at least one case of extensively drug-resistant tuberculosis, but in most low-income countries the magnitude of the problem is unknown.

4. Altogether countries, in their planning for 2008, expected a total of about only 25 000 patients with multidrug-resistant tuberculosis to be detected and treated, of which about half would have been treated according to internationally recommended standards, representing only about 3% of the 500 000 estimated new cases of multidrug-resistant tuberculosis. Yet treatment is feasible and cost-effective if WHO guidelines are followed, with cure rates of up to 80% among multidrug-resistant cases and up to 60% among extensively drug-resistant cases in low-resource settings. Inappropriate treatment that is not in line with the recommended guidelines runs the risk of raising mortality, increasing resistance and spreading resistance even further.

5. Well-functioning national control programmes with high cure and detection rates are detecting only low levels of multidrug-resistant tuberculosis. Conversely, multidrug-resistant tuberculosis emerges as a result of underinvestment in the Stop TB strategy.[2] The emphasis for action therefore needs to be both on strengthening basic control to prevent the emergence of drug resistance and on diagnosing and treating the cases of multidrug- and extensively drug-resistant tuberculosis effectively in order to prevent transmission. The frameworks for controlling both drug-susceptible and drug-resistant disease exist in the Stop TB strategy and in the WHO guidelines for the programmatic management of drug-resistant tuberculosis. Nevertheless, major obstacles persist, which include: weak general health systems, with consequent gaps in basic tuberculosis control; health workforce crisis; inadequate laboratory capacity; insufficient expansion of programmes to treat drug-resistant tuberculosis; non-engagement of private-care providers; inadequate collaboration between HIV and tuberculosis programmes; problems with production, supply and rational use of anti-tuberculosis medicines; inattention to infection control; insufficient funding for research and development; and inadequate financial resources.

6. Weak national health systems impede basic control and facilitate re-appearance and spread of drug-resistant tuberculosis. Effective control requires appropriate national policies, trained and motivated staff, and quality-assured laboratory- and medicine-supply systems supported by an adequately funded tuberculosis programme. All health-care facilities used by patients with symptoms of tuberculosis must be engaged with general and specialized hospitals, academic institutions and the array of diverse private-care providers need to be involved as a priority. A network of patient-friendly health clinics and staff is essential to ensure that treatment is supervised in a supportive manner and is quality-assured, free of cost, and easy to access. If patients discontinue their treatment, there must be

[1] These are the countries with 4000 or more cases of multidrug-resistant tuberculosis estimated to occur annually: Armenia, Azerbaijan, Bangladesh, Belarus, Bulgaria, China, Democratic Republic of the Congo, Estonia, Ethiopia, Georgia, India, Indonesia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Myanmar, Nigeria, Pakistan, Philippines, Republic of Moldova, Russian Federation, South Africa, Tajikistan, Ukraine, Uzbekistan, and Viet Nam.

[2] Document WHO/HTM/TB/2006.368.

mechanisms to trace them and re-establish treatment. Moreover, informed, motivated and resourced communities can contribute to case finding and adherence support especially in resource-poor settings.

7. WHO estimates that 57 countries, including 36 in sub-Saharan Africa, 15 of them with a high tuberculosis-burden, are facing a serious shortage of health-service providers.[1] Cases of detection and treatment success rates in these countries are generally low. Insufficient workforce, uneven distribution, weak capacity, high workload, frequent transfers, low motivation, and weak supervision are among the important deficiencies. There is no standard solution to resolve these problems, but effective strategies should focus on improving recruitment, helping the existing workforce to perform better, and slowing the rate at which health workers leave the workforce, all in line with a comprehensive strategic plan for human resources for health.

8. Presently, less than 5% of the estimated cases of multidrug-resistant tuberculosis are being diagnosed. Many countries, especially in Africa, lack laboratory capacity to culture *Mycobacterium tuberculosis* and do drug-susceptibility tests. Laboratory capacity, neglected for a long time, needs rapid expansion under international norms and standards, as part of the strengthening of a broader national public health laboratory system; the Global Laboratory Initiative of WHO and partners is helping to enhance coordination of the response. New technologies that can accelerate the diagnosis of drug-resistant tuberculosis are available, but not yet widely implemented, the main obstacle being lack of an adequate, safe laboratory infrastructure and appropriately trained staff.

9. National programmes need policies on where and how to treat drug-resistant tuberculosis cases. In some countries, patients are admitted to hospital for long periods of time, which is labour-intensive and costly, raises important ethical and social issues, and increases the risk of nosocomial transmission if infection control is weak. New models of care enabling safe and effective treatment supplemented by community-based support have proven to be feasible and effective in low-resource settings. To expand treatment services effectively and rapidly, countries will need centres of excellence to ensure adequate capacity building of health-care providers for tuberculosis management.

10. A large proportion of tuberculosis patients are diagnosed and treated in the private sector in many countries and the quality of management is uneven: the patients detected are not notified and their treatment outcomes are unknown. Models of collaboration with the private sector for care and control including management of multidrug-resistant tuberculosis, in which patients do not have to pay for costs of care, have proved effective in resource-poor settings and are necessary for rapid expansion of multidrug-resistant tuberculosis management. Health ministries should involve the private-care sector in ensuring provision of quality treatment through public–private mix approaches linked with the national tuberculosis programme.

11. People living with HIV are more susceptible to developing tuberculosis, including drug-resistant tuberculosis. Also, HIV infection greatly increases the fatality rate among multidrug- and extensively drug-resistant tuberculosis. Improved and strengthened collaboration between tuberculosis and HIV programmes is required to prevent rapid transmission of drug-resistant tuberculosis and resulting high mortality among communities heavily affected by HIV. To this end, WHO recommended that collaborative tuberculosis/HIV activities should be expanded.[2]

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[1] *The world health report 2006: working together for health.* Geneva, World Health Organization, 2006.

[2] Documents WHO/HTM/TB/2004.330 and WHO/HTM/HIV/2004.1.

12. Quality-assured medicines are essential for successful treatment of tuberculosis. Manufacturing processes must meet international standards and the quality of the finished product must be assured. WHO standards for quality medicines are not always observed. Quality-assured fixed-dose combinations, developed as a tool to prevent the emergence of resistance, are not widely used. Inadequate supply of quality-assured second-line medicines has been a major issue. Since 2000, the Green Light Committee, established by WHO and partners, has provided access to medicines that are quality assured to WHO standards, and concessionally priced, for projects worldwide that apply WHO guidelines.[1] Concerted action on the part of governments, drug-regulatory authorities, the pharmaceutical industry, and WHO is required to ensure that adequate and uninterrupted supply of quality-assured anti-tuberculosis medicines are available and accessible to all those in need.

13. Availability of over-the-counter anti-tuberculosis medicines in retail pharmacies and irrational prescriptions by care providers in many countries have facilitated emergence of drug resistance. Some countries have successfully restricted prescribing and dispensing of anti-tuberculosis medicines to accredited facilities where full adherence to internationally recommended standards of treatment can be ensured. Such practices should be encouraged and supported. Countries should also undertake active promotion of rational use of medicines through comprehensive approaches involving drug regulatory authorities, national tuberculosis programmes, health-care providers, the pharmaceutical industry, pharmacists and consumers.

14. Infection control in health-care and institutional settings, essential to prevent disease transmission, has yet to receive adequate attention in the policy and practice of control of communicable diseases such as tuberculosis in resource-poor countries. Recent outbreaks of extensively drug-resistant tuberculosis with high mortality have stimulated activities to institute infection control in some settings. To better protect health-care workers and decrease the risk of tuberculosis transmission in institutional settings, such as correctional facilities and within households, infection control requires engagement with a wide range of stakeholders across the health system including hospital administrators, architects, engineers, as well as doctors, nurses and laboratory staff.

15. Research in tuberculosis has only recently been established on a reasonable scale, although research funding in 2007 showed little increase over 2006. Global control of multidrug-resistant tuberculosis will depend, ultimately, on wide availability of new, rapid diagnostic tests capable of providing results within hours without complex equipment or laboratory biosafety requirements; new medicines to shorten treatment and treat multidrug- and extensively drug-resistant tuberculosis within months rather than years; and a vaccine to prevent tuberculosis, be it drug-susceptible or resistant. Greater attention to and resources for, tuberculosis research are essential.

16. To achieve the target set out in the Global Plan to Stop TB 2006–2015, 1.5 million cases of multidrug- and extensively drug-resistant tuberculosis will need to be treated in the 27 countries with the highest burden in the seven years from 2009 to 2015. The projected number of treated cases increases from 70 000 in 2009 to 382 000 cases in 2015. Combined with a cost per patient treated that is usually in the range US$ 3000–10 000,[2] the total cost of treating 1.5 million cases amounts to US$ 11 500 million over seven years, rising from US$ 500 million in 2009 to US$ 3100 million in

[1] By end 2008, the Green Light Committee had approved 60 countries for multidrug-resistant tuberculosis management and treatment for a total of 49 858 multidrug-resistant tuberculosis patients since 2000. Of the 27 priority multidrug-resistant tuberculosis countries, all have Green Light Committee approval, except Nigeria and South Africa.

[2] Costs vary according to the drug regimen, the model of care that is used, and prices of inputs (for example, higher costs for staff are expected in countries with higher incomes).

2015; the latter figure is 43 times the funding available in 2009 and 53% of the total funding required for tuberculosis control. Most funding is required in the European Region (US$ 7800 million), followed by Asia (US$ 2800 million). In order to mobilize the required funding for improved management of multidrug- and extensively drug-resistant tuberculosis, preparation of country-specific budgets as part of national strategic plans is the first step that needs to be taken. WHO has prepared a planning and budgeting tool for this purpose. Domestic resources need to be accessed especially in middle-income countries. If sufficient domestic funding cannot be mobilized, countries should make full use of resources available from the Global Fund to Fight AIDS, Tuberculosis and Malaria, the International Drug Purchase Facility (UNITAID), and other donor agencies and funding mechanisms.

ACTION BY THE HEALTH ASSEMBLY

17. The Health Assembly is invited to note the report and provide guidance.

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World Health Organization

SIXTY-SECOND WORLD HEALTH ASSEMBLY
Agenda item 12.15

A62/20 Add.1
19 May 2009

Prevention and control of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis

Ministerial meeting of countries with a high burden of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis and Beijing "Call for Action" on tuberculosis control and patient care

Report by the Secretariat

1. Health ministers from countries most affected by multidrug-resistant tuberculosis[1] and extensively drug-resistant tuberculosis and others with relevant experience[2] met in Beijing from 1 to 3 April, 2009, at a meeting organized by WHO, the Ministry of Health of China and the Bill & Melinda Gates Foundation. The aims were to build consensus and political commitment globally and in countries with a high burden of multidrug-resistant and extensively drug-resistant tuberculosis, with countries with emerging economies taking the lead; and to stimulate immediate action to expand the prevention and management of those diseases and start developing five-year national strategic plans to control them within national tuberculosis and health-sector plans.

2. The Member States represented at the meeting issued the Beijing "Call for Action" on tuberculosis control and patient care (at Annex).

3. Particularly relevant was the acknowledgement by all the governments represented that full control and care of multidrug-resistant and extensively drug-resistant tuberculosis do not depend solely on the actions of national tuberculosis programmes, but on policies that span the health sector and engage other sectors as well and which require action at the ministerial level.

4. The first such policy is commitment to moving towards universal access to high-quality care that ensures removal of financial barriers. Other necessary elements of ministerial-level policy featured in the Call for Action include:

- redressing the lack of appropriately trained health workers

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[1] Armenia, *Azerbaijan*, *Bangladesh*, *Belarus*, *Bulgaria*, *China*, *Democratic Republic of the Congo*, Estonia, *Ethiopia*, Georgia, India, Indonesia, *Kazakhstan*, *Kyrgyzstan*, Latvia, Lithuania, Myanmar, Nigeria, Pakistan, *Philippines*, Republic of Moldova, Russian Federation, *South Africa*, *Tajikistan*, Ukraine, Uzbekistan, *Viet Nam* (the use of italics denotes that the minister or vice/deputy minister was present).

[2] Lesotho, Peru, Thailand (in all cases the minister or vice/deputy minister was present).

- establishing an adequate laboratory network with modern diagnostics for care and surveillance, using technologies that can be extended to other priority conditions

- assuring quality of all anti-tuberculosis medicines, including all first-line and second-line anti-tuberculosis medicines

- ensuring rational use of all anti-tuberculosis medicines, particularly the second-line, last-resort medicines for multidrug-resistant disease, making them available on prescription only and limiting their prescription to accredited providers

- elaborating and implementing policies for airborne infection control in all health-care facilities and high-risk settings.

5. Failure to address these and other policy reforms properly will simply allow multidrug-resistant and extensively drug-resistant tuberculosis to continue to spread.

ACTION BY THE HEALTH ASSEMBLY

6. The Health Assembly is invited to note this report.

ANNEX[1]

THE BEIJING CALL FOR ACTION ON TUBERCULOSIS CONTROL AND PATIENT CARE: TOGETHER ADDRESSING THE GLOBAL M/XDR-TB EPIDEMIC

1. We, Member States of the World Health Organization (WHO) and others represented here today, and especially those affected by M/XDR-TB*, are meeting in Beijing, China, on 1–3 April 2009, to address the alarming threat of M/XDR-TB. While there have been major achievements over the past decade in TB control, we **note with grave concern** that M/XDR-TB poses a threat to global public health security and severely undermines our efforts to implement the Stop TB Strategy and dramatically reduce the global burden of TB.

(a) More than half a million new MDR-TB cases are estimated to emerge annually as a result of inadequate treatment and subsequent transmission. The 37% of incident cases who are not reached globally by the Stop TB Strategy are especially affected. XDR-TB, a sub-set of MDR-TB caused by highly drug-resistant strains, with significantly worse outcomes, is now reported by more than 50 countries. Yet only some 3% of cases of MDR-TB are being treated according to WHO standards. Furthermore, people living with HIV/AIDS are at particular risk of dying if affected by M/XDR-TB.

(b) M/XDR-TB represents a tragedy for patients, their families and communities, compounded by stigma, and by the catastrophic expenditures often required today for effective diagnosis and treatment.

(c) The global threat of M/XDR-TB can be halted if we respond urgently, reconfirming a system-based approach, involving partners across the health system and beyond. If we fail to do so, we are aware our countries will face the prospect of a bigger M/XDR-TB epidemic requiring significantly heavier investment.

2. **We recognize that countries have not yet fully addressed the possible causes of M/XDR-TB:**

Causes related to inadequate treatment: too few trained and motivated health-care providers to offer proper treatment and support for patients; insufficient coordination among ministries involved in provision of care; public and private facilities which do not follow national policies; unregulated sale and use of first and second-line anti-TB medicines; manufacturers not complying with stringent standards applied by drug regulatory authorities and by the WHO Prequalification Programme; insufficient use of fixed-dose combination medicines, or co-blistered drugs in single doses under direct observation; and insufficient attention to advocacy, communication and social mobilization around TB issues.

[1] M/XDR-TB: multidrug-resistant and extensively drug-resistant tuberculosis.

* Armenia, Azerbaijan, Bangladesh, Belarus, Bulgaria, China, Democratic Republic of the Congo, Estonia, Ethiopia, Georgia, India, Indonesia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Myanmar, Nigeria, Pakistan, Philippines, Republic of Moldova, Russian Federation, South Africa, Tajikistan, Ukraine, Uzbekistan, and Viet Nam.

Causes related to transmission: insufficient and late case detection; insufficient infection control in health facilities and other high-risk settings.

Causes related to the underlying social determinants, which influence the risk of drug-resistance. Poverty, poor living conditions, and social vulnerability put people at higher risk of infection, developing active disease, having poor access to quality care and difficulties to adhere to treatment.

3. **We recognize the key barriers to effective management of M/XDR-TB lie throughout the health system and beyond:** not all countries have comprehensive, adequately funded, and M/XDR-TB control policies and plans that respect human rights; access to diagnosis and treatment remains difficult and costly for patients; community-based M/XDR-TB treatment is not sufficiently emphasized; health workers often lack the necessary training and resources to diagnose and treat patients with M/XDR-TB; many national laboratory networks have insufficient capacity and unsafe infrastructure with no access to the new rapid tests to detect M/XDR-TB; people living with HIV/AIDS too often pick up the infection in health facilities, while the diagnosis of M/XDR-TB arrives too late; and other vulnerable groups, such as migrant workers and prisoners, often do not benefit from adequate preventive measures and care.

4. We there **commit ourselves** to accelerate efforts to prevent M/XDR-TB through effective TB care and control, and to scale-up the diagnosis and treatment of M/XDR-TB. This will be done by developing and implementing strategic M/XDR-TB policies and plans that respect human rights, as part of national TB control plans, in line with the Millennium Development Goals relevant to TB control**, the Global Plan to Stop TB, 2006–2015, and overall health system strengthening efforts, and must include the following actions:

(a) Moving urgently towards universal access to diagnosis and treatment of M/XDR-TB by 2015 as part of the transition to universal health coverage[1] and supporting the global target of enrolling 1.6 million M/XDR-TB patients on treatment by 2015, thereby saving lives and protecting communities;

(b) Ensuring the removal of financial barriers to allow all TB patients equitable access to TB care,[2] that their rights are protected, and that they are treated with respect and dignity;

(c) Ensuring a comprehensive framework for management and care of M/XDR-TB is developed, including community-based care, and identifying the groups most vulnerable to, and at risk of, drug-resistant TB and its impact, including people living with HIV, prisoners, mine workers, mobile populations, drug users, alcohol dependents, the poor and other vulnerable groups; and ensuring that services to prevent and treat drug-resistant TB are targeted to their needs;

(d) Ensuring sufficiently trained and motivated staff are available to implement both TB and M/XDR-TB diagnosis, treatment and care, as part of overall health workforce development efforts;

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[1] Resolution WHA58.33 on Sustainable health financing, universal coverage and social health insurance.

[2] WHO Stop TB Strategy endorsed by the Health Assembly in resolution WHA60.19 and WHO Expert Committee on Tuberculosis – Ninth Report 1974.

** Millennium Development Goals
Goal 6: Combat HIV/AIDS malaria and other diseases.

(e) Strengthening laboratory systems, through increasing capacity and adequate human resources, and accelerating access to faster and quality-assured diagnostic tests;

(f) Ensuring that all ministries involved in provision of TB care collaborate, and ensure that public and private health-care providers are properly managing TB and M/XDR-TB patients according to national policies, and the primary health-care network is effective in supporting patients;

(g) Ensuring that national airborne infection control policies are developed (as part of general infection prevention and control programmes) and implemented in every health-care facility and other high-risk settings[1] and that there is sufficient TB infection control awareness in the community;

(h) Ensuring a sufficient supply of first- and second-line medicines for TB treatment, which meet WHO prequalification or strict regulatory authority standards, and fixed-dose combination medicines are used within a system that promotes treatment adherence,[2] or that co-blistered medicines in single doses are used under direct observation by a DOT provider;

(i) For achieving the Millennium Development Goals, supporting developing countries to establish manufacturing plants to produce combined preparations of anti-TB medicines to the standards of the WHO Prequalification Programme to ensure adequate drug supply for the prevention and control of M/XDR-TB;

(j) Strengthening mechanisms to ensure that TB medicines are made available on prescription only[3] and that they are prescribed and dispensed by public and accredited private providers;

(k) Strengthening harmonized surveillance, monitoring and evaluation systems to ensure cases of M/XDR-TB are identified and notified to the fullest extent possible;

(l) Identifying and addressing the underlying social determinants of TB and M/XDR-TB. This needs action both within and outside the health system, and should linked to broader national initiatives to ensure "health in all policies"; and

(m) Ensuring effective advocacy, communication, and social mobilization initiatives are an essential component of M/XDR-TB policies and plans.

5. As part of our efforts to promote sustained financing for health in this time of economic crisis, and to protect the most vulnerable, we **further commit** to help mobilize the estimated US$ 2 billion needed over the next two years to adequately finance TB and M/XDR-TB control and care, using all available financing mechanisms and specially the Global Fund and UNITAID, harmonized with national health strategies and budgets. We call upon funding agencies to help implement the necessary actions to stop TB and M/XDR-TB, reflecting the needs of each country.

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[1] Resolution WHA60.19 – referring to prompt implementation of infection control precautions.

[2] WHO Stop TB Strategy endorsed by the Health Assembly in resolution WHA60.19.

[3] Resolution WHA51.44 – referring to prohibiting the dispensing of antimicrobials without the prescription of a qualified health-care professional.

6. We **call** for substantially increased investment by Governments and all partners in research and development of new diagnostics, medicines and vaccines to prevent and manage TB and M/XDR-TB. This requires coordinated action at the global level.

7. We **urge WHO**, together with technical agencies in the Stop TB Partnership, to:

- provide technical support for the development and implementation of M/XDR-TB response plans;
- assist national regulatory agencies in adopting international standards and enabling pharmaceutical manufacturers to produce products of sufficiently high quality to be sold in international markets;
- systematically evaluate newer and faster diagnostic technology and made the results widely available;
- strengthen the Green Light Committee mechanism to help expand access to concessionally-priced and quality assured second-line medicines; and
- monitor and evaluate the implementation of the measures outlined in this Call for Action by governments, civil society, communities and the private sector, among others.

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World Health Organization

SIXTY-SECOND WORLD HEALTH ASSEMBLY
Agenda item 12.9

A62/A/Conf.Paper No.3 Add.1
21 May 2009

Report on financial and administrative implications for the Secretariat of resolutions proposed for adoption by the Executive Board or Health Assembly

1. Resolution Prevention and control of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis	
2. Linkage to programme budget	
Strategic objective:	Organization-wide expected result:
2. To combat HIV/AIDS, tuberculosis and malaria	2.1 Guidelines, policy, strategy and other tools developed for prevention of, and treatment and care for patients with, HIV/AIDS, tuberculosis and malaria, including innovative approaches for increasing coverage of the interventions among poor people, and hard-to-reach and vulnerable populations. 2.2 Policy and technical support provided to countries towards expanded gender-sensitive delivery of prevention, treatment and care interventions for HIV/AIDS, tuberculosis and malaria, including integrated training and service delivery; wider service-provider networks; and strengthened laboratory capacities and better linkages with other health services, such as those for sexual and reproductive health, maternal, newborn and child health, sexually transmitted infections, nutrition, drug-dependence treatment services, respiratory care, neglected diseases and environmental health. 2.3 Global guidance and technical support provided on policies and programmes in order to promote equitable access to essential medicines, diagnostic tools and health technologies of assured quality for the prevention and treatment of HIV/AIDS, tuberculosis and malaria, and their rational use by prescribers and consumers, and, in order to ensure uninterrupted supplies of diagnostics, safe blood and blood products, injections and other essential health technologies and commodities. 2.4 Global, regional and national systems for surveillance, evaluation and monitoring strengthened and expanded to keep track of progress towards targets and allocation of resources for HIV/AIDS, tuberculosis

and malaria control and to determine the impact of control efforts and the evolution of drug resistance.

2.5 Political commitment sustained and mobilization of resources ensured through advocacy and nurturing of partnerships on HIV/AIDS, tuberculosis and malaria at country, regional and global levels; support provided to countries as appropriate to develop or strengthen and implement mechanisms for resource mobilization and utilization and increase the absorption capacity of available resources; and engagement of communities and affected persons increased to maximize the reach and performance of HIV/AIDS, tuberculosis and malaria control programmes.

(Briefly indicate the linkage with expected results, indicators, targets, baseline)

The resolution builds on the Stop TB strategy, the Stop TB Partnership's Global Plan to Stop TB, 2006–2015, resolutions WHA58.14 and WHA60.19, and the Beijing "Call for Action" on tuberculosis control and patient care. It provides a framework for achieving the array of expected results, targets and baseline figures in respect of tuberculosis control outlined in strategic objective 2 for the Medium-term Strategic Plan 2008–2013. Furthermore, it is aligned with the expected results and indicators included in the workplan for tuberculosis for the biennium 2008–2009.

3. Financial implications

(a) Total estimated cost for implementation over the life-cycle of the resolution (estimated to the nearest US$ 10 000, including staff and activities)

The life-cycle of the resolution covers the period 2009–2015. The estimated cost for the Secretariat's implementation responsibilities – including actions at WHO headquarters, in all regional offices and in relevant country offices – is US$ 175 million.

(b) Estimated cost for the biennium 2008–2009 (estimated to the nearest US$ 10 000 including staff and activities, and indicating at which levels of the Organization the costs will be incurred, identifying specific regions where relevant)

For the remainder of the biennium, a total of US$ 11.5 million is needed, of which US$ 6 million is for the regional offices and relevant country offices. In order to fulfil WHO's responsibilities as outlined in the resolution, US$ 50 million will be required for the biennium 2010–2011 at headquarters and regional offices and in country offices in all countries with a high burden of multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis.

(c) Of the estimated cost noted in (b), what can be subsumed under existing programmed activities for the biennium 2008–2009?

Of the total of US$ 11.5 million, US$ 5.2 million can be subsumed under existing programmed activities in this biennium.

(d) For the amount that cannot be subsumed under existing programmed activities, how will the additional costs be financed? (indicate potential sources of funds)

Additional funding from a range of partners will be sought through active resource mobilization, building on strong existing partnerships, including those with the Global Fund to Fight AIDS, Tuberculosis and Malaria, the International Drug Purchase Facility (UNITAID), and several bilateral agencies and foundations.

4. Administrative implications

(a) Implementation locales (indicate the levels of the Organization at which the work will be undertaken, identifying specific regions where relevant)

Multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis pose a major threat in all regions; intensifying the response will require action at headquarters, the regional offices and in country offices in at least the 27 countries on which multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis place the heaviest burden.

(b) Additional staffing requirements (indicate additional required staff – full-time equivalents – by levels of the Organization, identifying specific regions where relevant and noting necessary skills profile)

Additional positions will need to be established in the regional offices for Africa, the Americas, South-East Asia, the Eastern Mediterranean and the Western Pacific.

(c) Time frames (indicate broad time frames for implementation)

The period 2009–2015, with interim annual and biennial reports on progress.

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