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Dear Minister of Health and Commissioner Andriukaitis

On behalf of the medical humanitarian organisation Médecins Sans Frontières (MSF), I would like to congratulate Latvia for its leadership in convening the **1st Eastern Partnership Ministerial Conference on Tuberculosis and Multidrug Resistant Tuberculosis** to be held in Riga (30-31 March). This conference is a welcome event and an opportune time to raise much-needed European political commitments towards substantially improving tuberculosis (TB) and drug-resistant (DR-TB) treatment and care.

MSF has been involved in TB care for 30 years, often working alongside national health authorities to treat patients in a wide variety of settings, including chronic conflict zones, urban slums, prisons, refugee camps and rural areas. MSF's first programmes to treat multidrug-resistant TB (MDR-TB) opened in 1999, and the organisation is now one of the largest NGO treatment providers for drug-resistant TB. Today, MSF provides treatment for TB in 18 countries, including seven in the WHO European (EMRO) region.

Our latest report, *Out of Step: Deadly Implementation Gaps in the TB Response*ⁱ, is based on a survey of TB and DR-TB diagnostic and treatment policies in eight countries.ⁱⁱ We found that despite countries' openness to adopt TB policies reflecting best standards of care, significant and deadly gaps between policy and practice persist. Many of these policies contribute towards the amplification and spread of resistant forms of the disease, ultimately causing unnecessary deaths. In order to break this status quo, which results in DR-TB going undiagnosed and untreated, MSF requests a political commitment to improve these policies and narrow the implementation gap, as well as a

concerted effort to significantly enhance research and development (R&D) efforts for improved treatment regimens.

DR-TB is increasingly recognised as a public health crisis. Globally, more than one in five people previously treated for TB are thought to have multidrug-resistant TB (MDR-TB). But less than a third of MDR-TB patients worldwide are diagnosed, and only one in five receive proper treatment. Countries in Eastern Europe have among the highest proportion of MDR-TB cases, including 35% of new cases and 75% of previously treated cases in some contexts.ⁱⁱⁱ

MDR-TB is particularly difficult to treat; the treatment is both expensive and long - two years, including eight months of daily injections and a total of more than 14,600 pills to swallow. Additionally, many of the medicines used have toxic side effects such as deafness, psychosis and severe nausea. Moreover, the success rate is unacceptably low with less than half of patients being cured. For the one in ten MDR-TB cases with extensively drug-resistant TB (XDR-TB), treatment is even longer and more expensive, with the success rate at a dismal 13%.

MSF has highlighted many areas in which the current TB response is not adequately addressing drug resistant forms of TB:

- **Patients are not being tested for drug resistance:** drug susceptibility testing (DST) for first- and second-line TB drugs is not available for many patients.
- **New treatments are not reaching patients:** two new drugs were approved by the European Medicines Agency (EMA) last year but with the exception of one country, the drugs are not available in any of the countries MSF surveyed outside of compassionate use programmes. In some countries compassionate use (or equivalent) programmes are not even in place.
- **Centralised and expensive models of care being used:** Compulsory hospitalisation is still in place for some period of MDR-TB care, despite more cost-effective, patient-centred, decentralised, and community-based care models achieving similar outcomes. An MSF study found that decentralised tuberculosis care is 42% cheaper than a centralised, hospital-based model.^{iv}
- **The current pipeline for TB medicines cannot deliver the necessary treatment regimens** to improve treatment outcomes and substantially decrease the incidence of drug-resistant and multi-drug resistant TB. With no drugs in phase one development and TB R&D funding from pharmaceutical companies decreasing^v, European countries need to consider new and innovative R&D models to address this looming crisis. Existing EU programmes and initiatives for TB research and development have not introduced an incentive framework that can deliver the necessary treatment regimens.^{vi}

Given the need for continued improvement of TB and DR-TB management, MSF proposes the following be considered as actionable items for member states attending the high level ministerial conference in Riga:

Conference participants should state their commitment to develop a high-level EU Action Plan for TB, which should include:

1. **A commitment to improving TB/DR-TB management in the region by upgrading national policies and protocols to meet international recommendations within three years.** Governments can break the status quo by committing to have zero countries in the region with suboptimal and outmoded policies in place by the end of three years, including practices such as: compulsory hospitalisation for TB and DR-TB, charging out of pocket fees for TB diagnostics and treatment, and selling TB drugs over the counter.
2. **A commitment by all countries to ensure access to new and repurposed DR-TB drugs for patients who are without treatment options.** This includes through fast-tracking registration and establishing 'compassionate use' programs as an interim measure.
3. **A commitment to work with others to put the right incentive framework in place to rapidly speed up the development of a robust TB drug development pipeline and ultimately deliver a new pan-TB regimen to treat all forms of TB.** This requires a commitment to:
 - Increase financial support for TB drug R&D and innovative incentive models, including grants and financial prizes to be awarded upon achievement of specific R&D objectives, such as early-stage and clinical development milestones.
 - Make this funding conditional on a commitment on the part of the recipient research organisation to work through an open collaborative research platform in which the intellectual property and scientific data on promising compounds are licensed and shared to maximise collaborative efforts and ensure complete regimens rather than single drug compounds are the ultimate result of R&D efforts. MSF has worked with others to develop an innovative '3P: Push, Pull, Pool' model^{vii} that would provide the necessary framework for this regimen-based innovation.

The Riga conference is a critical opportunity to strengthen the response against TB and its drug-resistant forms in Europe and Eastern Europe. We sincerely hope it will be followed by development of a high-level EU Action Plan as well as mechanisms for coordinating and mobilising financial resources to ensure its successful implementation.

We would appreciate an opportunity to discuss MSF's experience, our findings from the policy research, and our recommendations for the Ministerial conference in Latvia.

Yours sincerely



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CC:

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Dr. Charles Daley, Chair, Global Drug-Resistant TB Initiative (GDI);

Dr. Masoud Dara, Programme Manager Tuberculosis and M/XDR-TB control programme, WHO;

Ms. Lucica Ditiu, Executive Secretary, Stop TB Partnership;

Dr. Mark Dybul, Executive Director, Global Fund to Fight AIDS, TB and Malaria;

Dr. Eric Goosby, UN Secretary-General's Special Envoy for TB;

Ms. Zsuzsanna Jakab, Regional Director for Europe, WHO;

Dr. Michel Kazatchkine, UN Secretary-General's Special Envoy for AIDS in Eastern Europe and Central Asia;

Dr. Joel Keravec, Manager, Global Drug Facility;

Dr. Hans Kluge, Director of the Division of Health Systems and Public Health and Special Representative of the Regional Director to prevent and combat MDR-TB in the WHO European Region;

Dr. Line Matthiessen, Head of Unit for Infectious Diseases and Public Health, Directorate General for Research and Innovation;

Dr. Mario Raviglione, Director, Global TB Program, WHO;

Mr. John F. Ryan, Director General for Public Health, Directorate General SANTE;

Dr. Thomas Shinnick, Chair, Global Laboratory Initiative;

Dr. Marc Sprenger, Director, ECDC;

Mr. David Wilson, Global AIDS Program Director, World Bank.

ⁱ Médecins Sans Frontières. Out of Step: Deadly implementation gaps in the TB response [Internet]. 2014 Oct 30 [cited 2014 Oct 27]. Available from: http://www.msfaccess.org/sites/default/files/MSF_Out-of-Step_Final_for_printOct17_0.pdf

ⁱⁱ The findings in Brazil, India, Kenya, Myanmar, Russian Federation, South Africa, Uzbekistan and Zimbabwe represent a wide range of epidemiological, economic, geographic and demographic profiles, and are indicative of the challenges faced by TB programmes worldwide.

ⁱⁱⁱ World Health Organization. Supplement to the Global tuberculosis report (2014) [Online] 2014. [cited 2014 February 9]; Available http://apps.who.int/iris/bitstream/10665/137095/1/WHO_HQ_TB_2014.12_eng.pdf?ua=1

^{iv} Médecins Sans Frontières. Out of Step: Deadly implementation gaps in the TB response [Internet]. 2014 Oct 30 [cited 2014 Oct 27]. Available from: http://www.msfaccess.org/sites/default/files/MSF_Out-of-Step_Final_for_printOct17_0.pdf

^v Treatment Action Group. 2014 Report on Tuberculosis Research Funding Trends, 2005–2013 [Internet]. 2014 Oct 22 [cited 2014 Oct 27]. Available from:

http://www.treatmentactiongroup.org/sites/g/files/g450272/f/201410/TAG_2014_TB_Funding_Report.FINAL_.pdf

^{vi} The European and Developing countries Clinical Trial Partnership (EDCTP), Horizon 2020 annual Work Programme and the Innovative Medicines Initiative (IMI)

^{vii} <http://www.msfaccess.org/push-pull-pool>