



**Patients and TB: Improving treatment outcomes  
through a patient centred approach and  
access to new treatments**

**5<sup>th</sup> TB Symposium – Eastern Europe and Central Asia  
Ministry of Labour, Health and Social Affairs of Georgia  
and Médecins Sans Frontières**

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**New Drugs: Progress across the Region**

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# Thanks

- MSF TB Advisors - Cathy Hewison, Krzysztof Herboczek, Alex Telnov, Grania Brigden, Dmytro Donchuk, Philipp Du Cros
- MSF programmes in region (Russia, Belarus, Kyrgyzstan, Uzbekistan, Tajikistan, Ukraine, Georgia, Armenia)

# Objectives

- Present MSF regional data on use of new drugs
- Highlight access and implementation challenges
- Consider the future impact of ongoing studies

# MSF Regional Data

	Bdq/Dlm	Date of Bdq	Date of Dlm	Cfz available	Lzd available	Imp available
Armenia	Both	April '13	Nov '15	Yes	MSF only	MSF only
Belarus	Both	June '15	Aug '15	MSF only	Yes	Yes
Georgia	Both	2011	Jan '15	Yes	Yes	Yes
Kyrgyzstan						
Russia	Both	June '14	Sept '15	MSF only	MSF only	MSF only
Tajikistan	Bdq	May '15		Yes	No	No
Ukraine						
Uzbekistan	Bdq	Jul '15		Yes	Yes*	Yes*

\* Limited availability

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# MSF Regional Data

	Started Bdq	Started DIm	6-m cult conv (Bdq)	6-m cult conv (DIm)	National guideline	Off label indications
Armenia	82	8	30/35		No - planned	>24w, children (DIm)
Belarus	15	6			Yes - both	Children (MSF)
Georgia	160	12	36/43	2/2	Bdq only	Children (DIm)
Kyrgyzstan						
Russia	87	9	38/45		Bdq only	Children (MSF)
Tajikistan	5	0	5/5		Bdq only	Children
Ukraine						
Uzbekistan	12	0	3/4		Bdq only	Children, >24w

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# MSF Regional Data

	Regulatory status - Bdq	Regulatory status - Dlm	Ongoing challenges
Armenia	Unregistered	Unregistered	
Belarus	Unregistered, import waiver	Unregistered, import waiver	Logistics of importation
Georgia	Unregistered, import waiver	Unregistered, import waiver	Discussing off-label use - >24w, Bdq & Dlm together
Kyrgyzstan			
Russia	Registered	CU only	Logistics of importation
Tajikistan	Unregistered, import waiver		
Ukraine			
Uzbekistan	Unregistered, import waiver	Registered (2016)	

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# Delamanid

- Fewer than 200 pts treated
- Recent inclusion in Global Drug Facility
- Removal of exclusion of pregnant women
- CU allows combination with Bdq and children down to 6y
- \$1700 per 6m course
- Limited registration (EU, Japan, S Korea) – more pending



# Implementation hurdles

- Limited accessibility for children
  - Recent dosing recommendations for DIm
  - Bdq experience with adolescents
  - Dosing uncertainty for Lzd
- Pharmacovigilance
  - WHO aDSM
  - Included in Bdq and DIm interim guidelines





# Implementation hurdles

- Availability of companion drugs
  - Lzd, Imp, Cfz
- Challenges
  - Imp and need for infusions
  - Off label uses – children, >24 weeks
  - Sequential introduction of companion drugs → resistance



# Future with Delamanid

- Will the indications for Dlm expand in the future?
  - Phase 3 study for MDR-TB with OBR fully enrolled
- How to increase access and where should NTPs prioritise?

# Key further steps

- Bring national protocols in line with WHO guidelines and consider next steps beyond current recommendations
- Increase accessibility to companion drugs
- Implement waivers and work on registration of new and companion drugs
- Share experiences of using new drugs in literature