

Update on the Global Use of Bedaquiline  
and Delamanid  
for Programmatic Management of Drug-  
Resistant Tuberculosis

DR-TB Scale-Up Treatment Action Team  
(DR-TB STAT)

October 2017



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# DR-TB STAT Task Force

- Formed in April 2015 in response to a “Call to Action” to accelerate access to newer drugs for DR-TB\*
- Officially adopted as a Global DR-TB Initiative (GDI) Task Force in July 2015
- Multiagency participation
- Collects information from National TB Programs and partners each month on the number of individuals who have received either BDQ or DLM under program conditions
- Monthly teleconferences and quarterly global data reports
- Provides technical assistance and support for countries to overcome barriers to newer drug introduction
- Data current to 1 July 2017
- See more at [www.drtb-stat.org](http://www.drtb-stat.org)

\*<http://www.msfaaccess.org/content/call-action-accelerate-access-dr-tb-drugs>

# Newer drugs for DR-TB treatment

- Bedaquiline
- Delamanid



	Bedaquiline (BDQ)	Delamanid (DLM)
Rx length, pills	6 months, 188 pills (100 mg tablet)	6 months, 672 pills (50 mg tablet)
Indication	MDR-TB (WHO Essential Medicines List)	MDR-TB (WHO Essential Medicines List)
WHO EML	Yes	Yes
Registration	Restricted use pre-XDR/XDR Conditional approval <b>Registered in 18 countries; under assessment in 16 (11/30 high DR-TB burden countries without submission yet)</b>	Broader recommendation for MDR-TB Conditional approval <b>Registered in 6 countries; under assessment in 4 (25/30 high DR-TB burden countries without submission yet)</b>
Patent Status	Intellectual property barriers (compound and multiple secondary patents) until 2029	Intellectual property barriers (compound and multiple secondary patents) until 2031
Voluntary licensing?	Not clear if engagement in bilateral or Medicines Patent Pool (MPP)-led voluntary license negotiations	No advance on potential voluntary licenses
Business partners	Pharmstandard in Commonwealth of Independent States (CIS) countries	R-Pharm in CIS countries; Mylan in India, South Africa and other countries where Otsuka does not operate

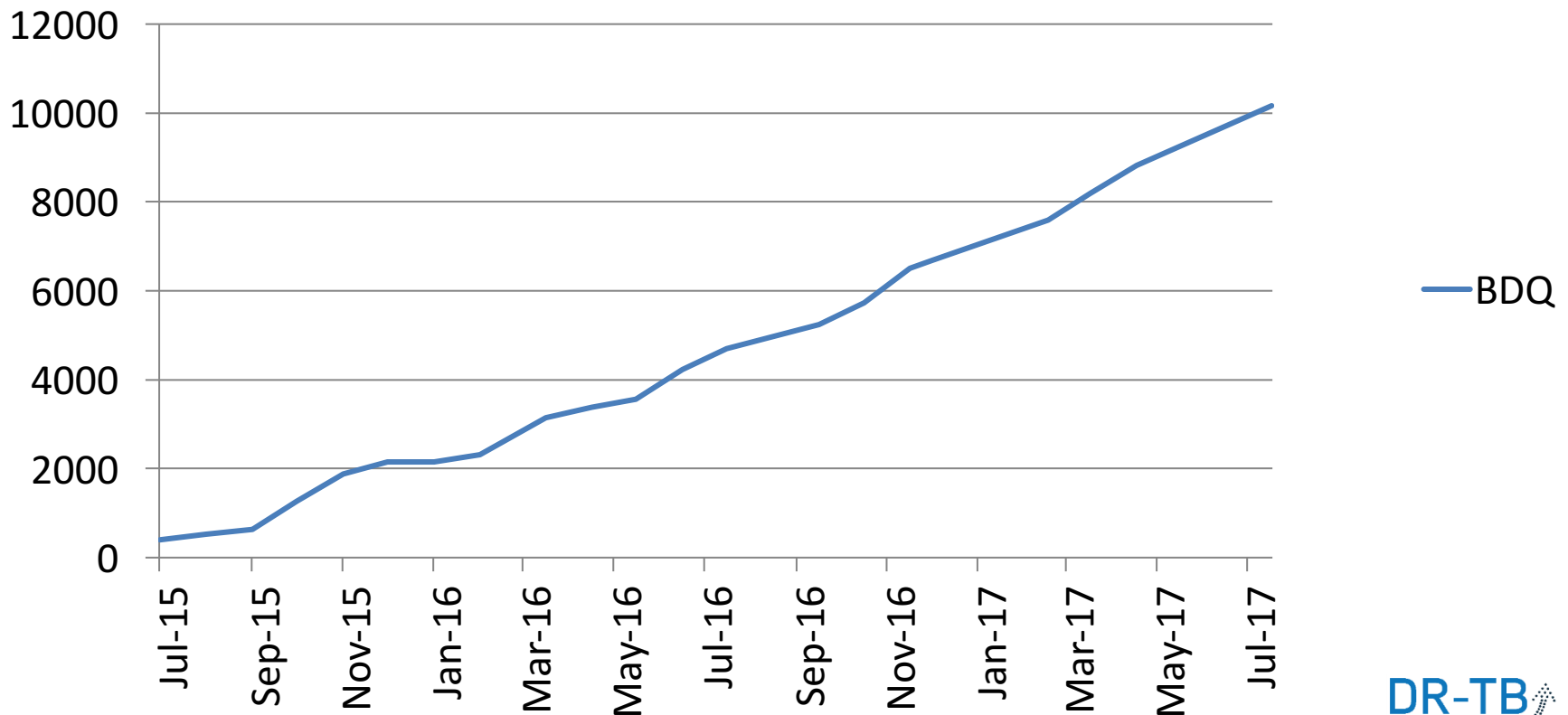
	<b>Bedaquiline (BDQ)</b>	<b>Delamanid (DLM)</b>
Competition	No	No
Stringent regulatory authority approved suppliers	1 (Janssen)	1 (Otsuka)
<b>GDF price</b>	<b>\$0 through GDF 6-month supply: \$900 lower income countries; \$3000 middle income countries; \$30,000 upper income countries</b>	<b>\$1,700 for 6-month supply</b>
Target price range (USD)	\$8.80 - \$16.40 / month	\$3.50 - \$8.60 / month
'Access policies'	Donation April 2015: 30,000 courses over 4 years for Global Fund-eligible countries; quota for CIS countries; compassionate use program phased out in 2015	Donation announced April 2015: 20% of MDR-TB patients by 2020; no information available

# Timeline: introduction of **bedaquiline** and delamanid

<b>December 2012</b>	FDA grants accelerated approval for bedaquiline
<b>June 2013</b>	WHO releases interim guidelines for use of bedaquiline to treat DR-TB
<b>March 2014</b>	EMA conditionally approves bedaquiline
<b>April 2014</b>	EMA conditionally approves delamanid
<b>October 2014</b>	WHO releases interim guidelines for use of delamanid to treat DR-TB
<b>May 2015</b>	WHO adds bedaquiline and delamanid to Essential Medicines List
<b>April 2015</b>	Janssen/USAID launch bedaquiline donation program
<b>April 2015</b>	Otsuka announces FighTBack Initiative delamanid donation program
<b>October 2015</b>	Georgia becomes first country to receive donated bedaquiline
<b>October 2016</b>	WHO guideline update on the use of shorter MDR-TB regimen
<b>October 2016</b>	WHO releases guidance on delamanid use for DR-TB in children
<b>March 2017</b>	WHO releases GDG meeting report on the use of bedaquiline for DR-TB
<b>September 2017</b>	WHO releases statement on off-label use of bedaquiline and delamanid
<b>December 2017</b>	Five years after bedaquiline approval

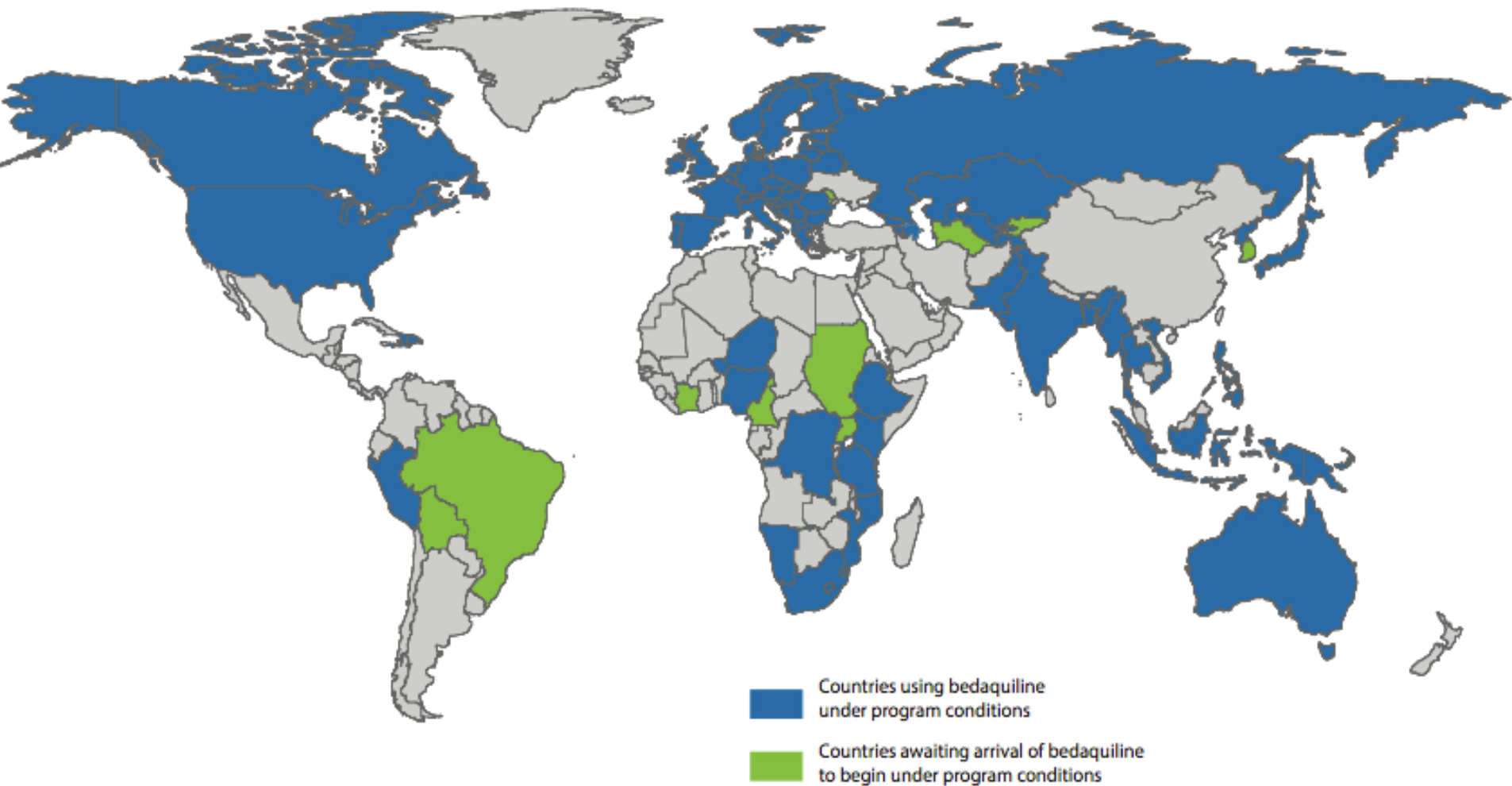
# Progress of global BDQ introduction

- **10,164** patients have received BDQ as of 1 July 2017 (67% in South Africa, 15% in Russia)
- 13,825 orders from the Global Drug Facility





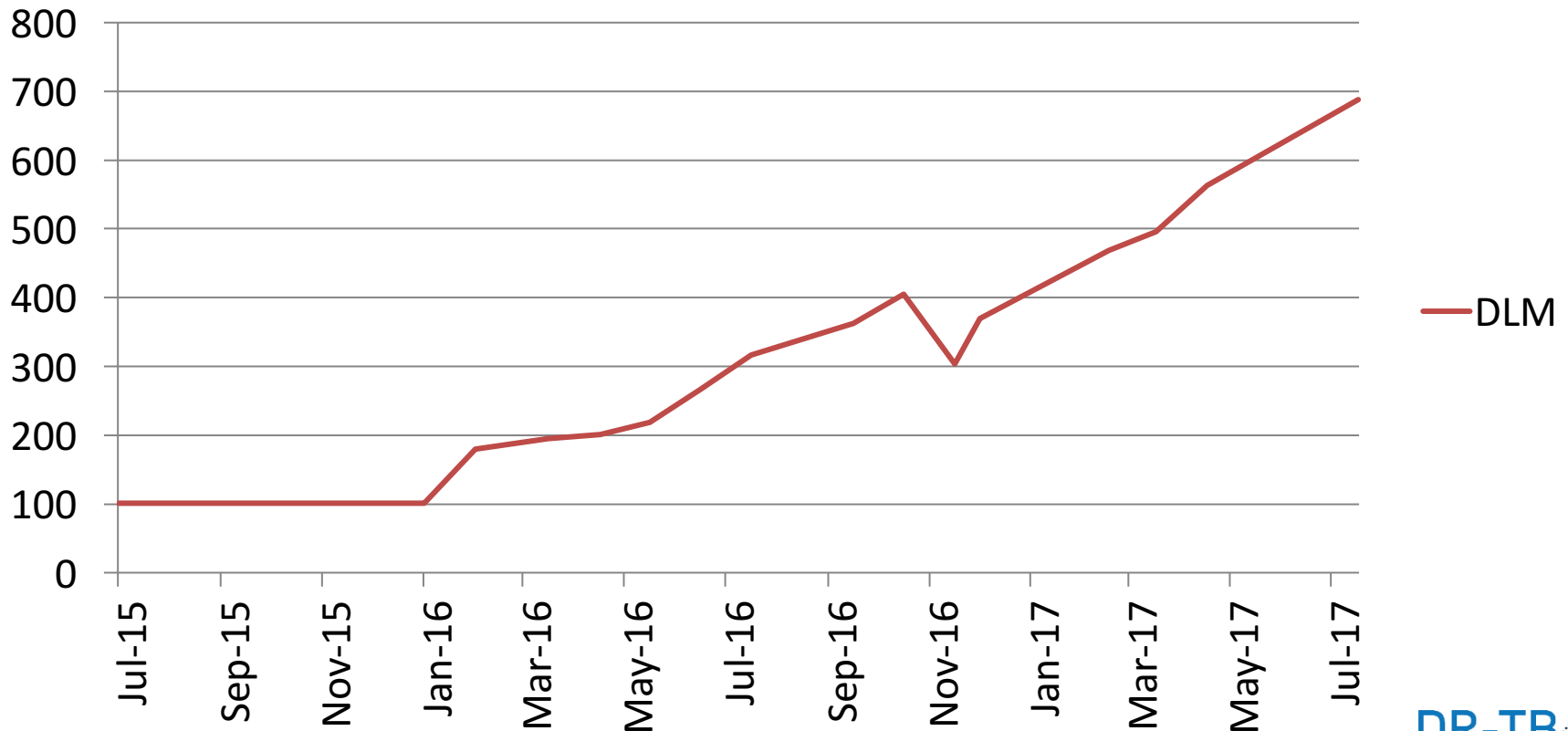
# Global BDQ implementation\*



*\*As of 1 July 2017*

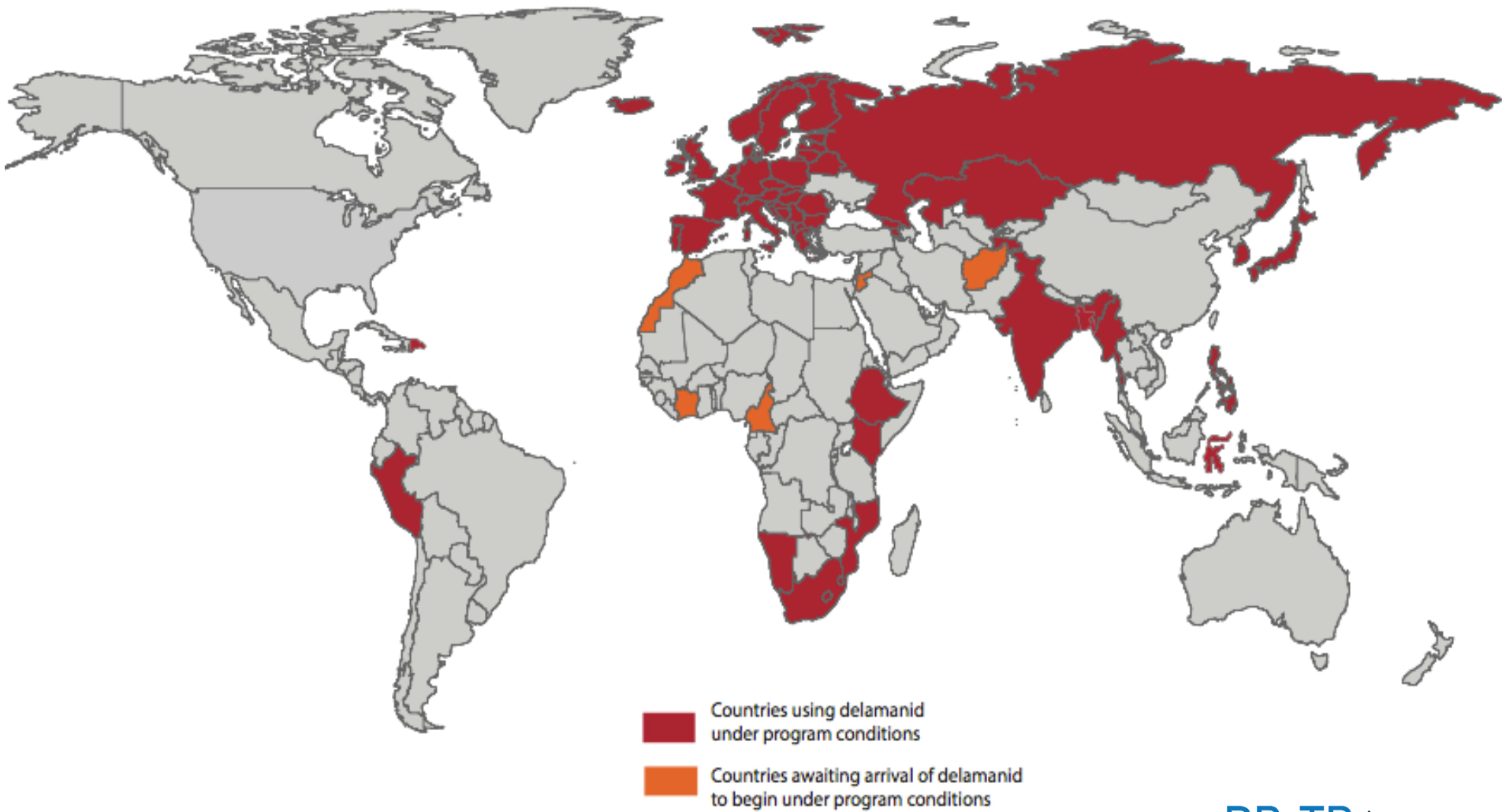
# Progress of global DLM introduction

- **688** patients have received DLM as of 1 July 2017, mostly in MSF, IRD and PIH sites (endTB project)
- **3,238** orders from the Global Drug Facility



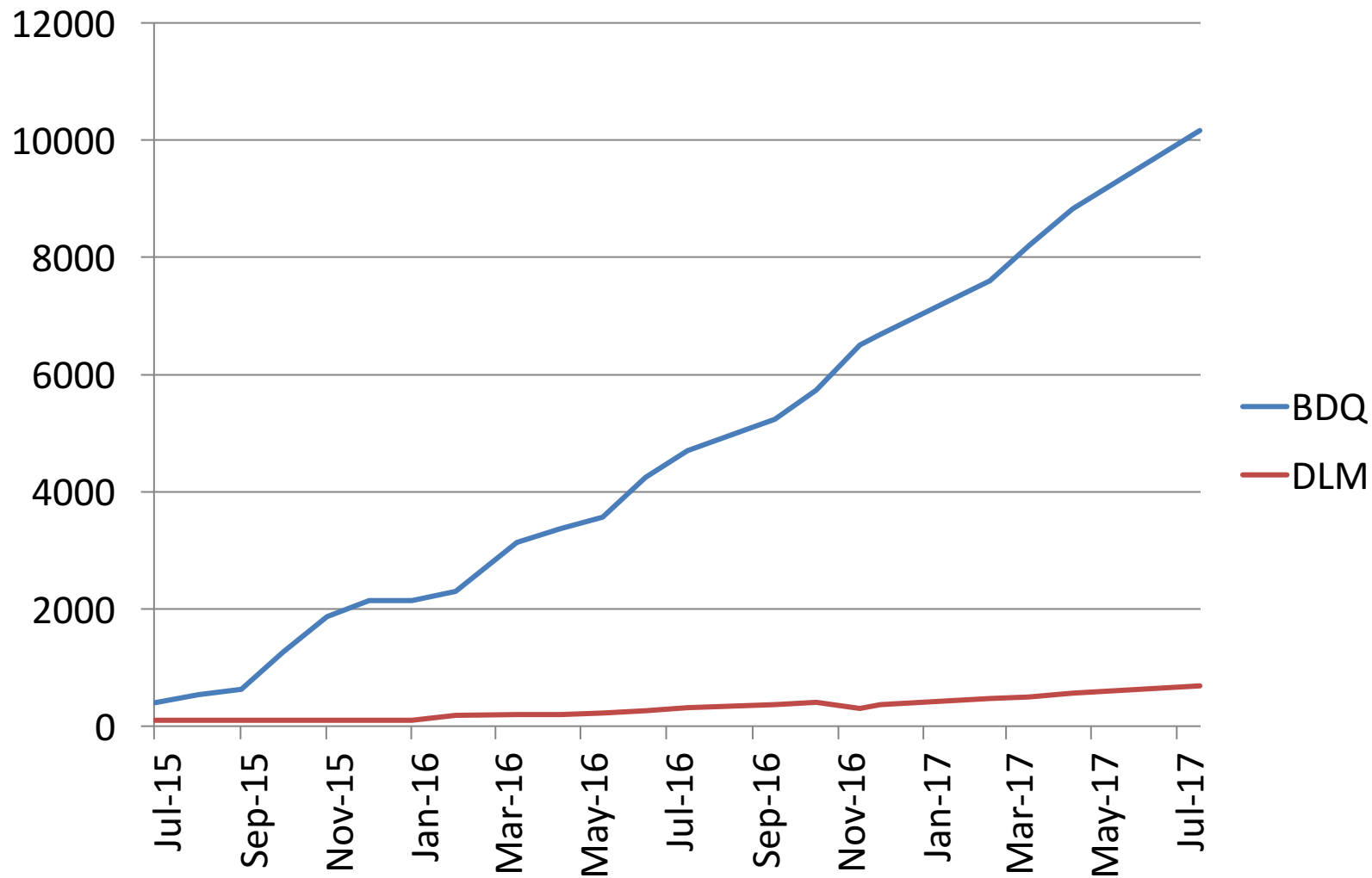
*\*adjusted to exclude compassionate use of DLM in November 2016*

# Global DLM implementation\*



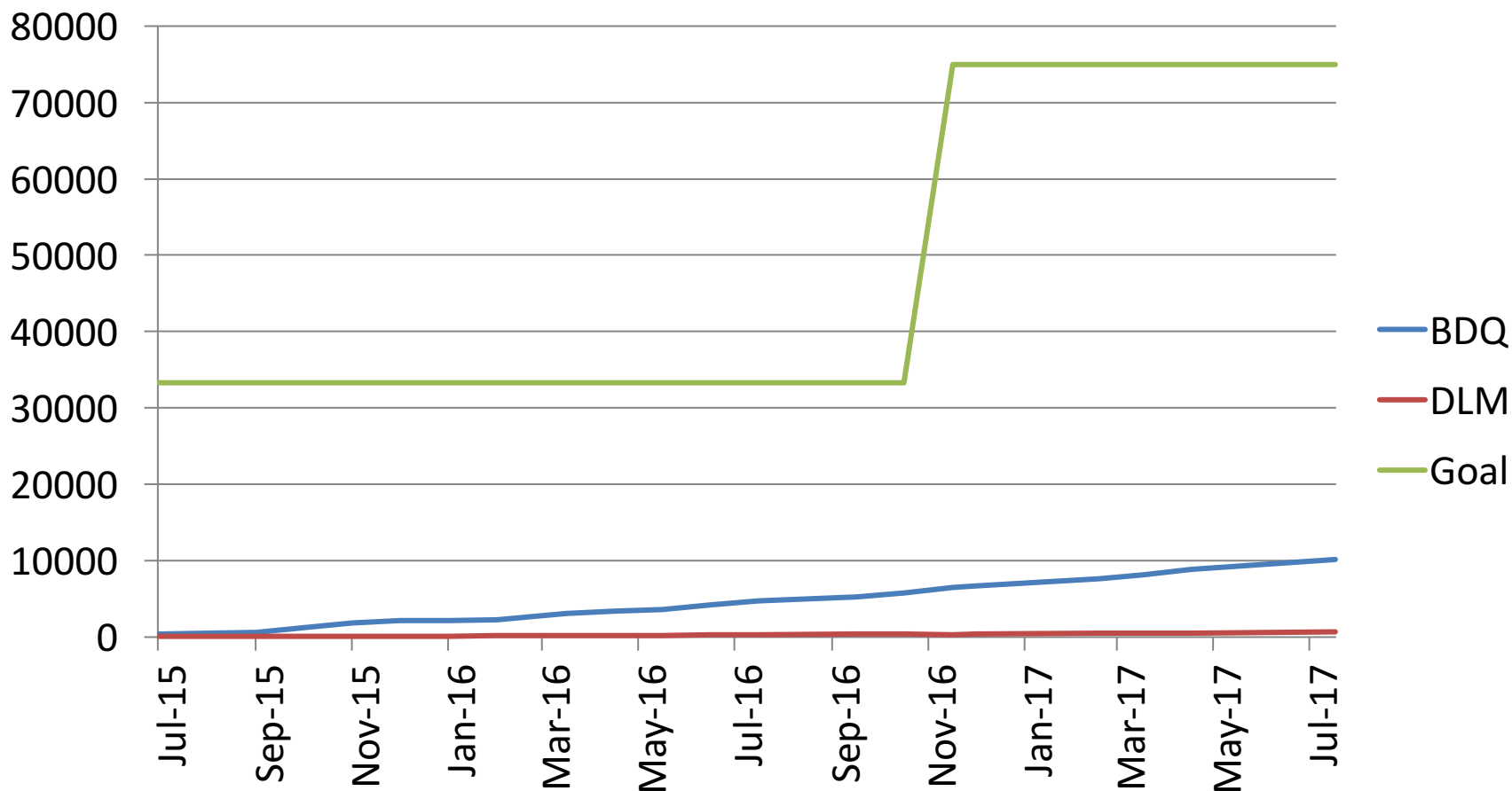
*\*As of 1 July 2017*

# Global Progress: BDQ and DLM



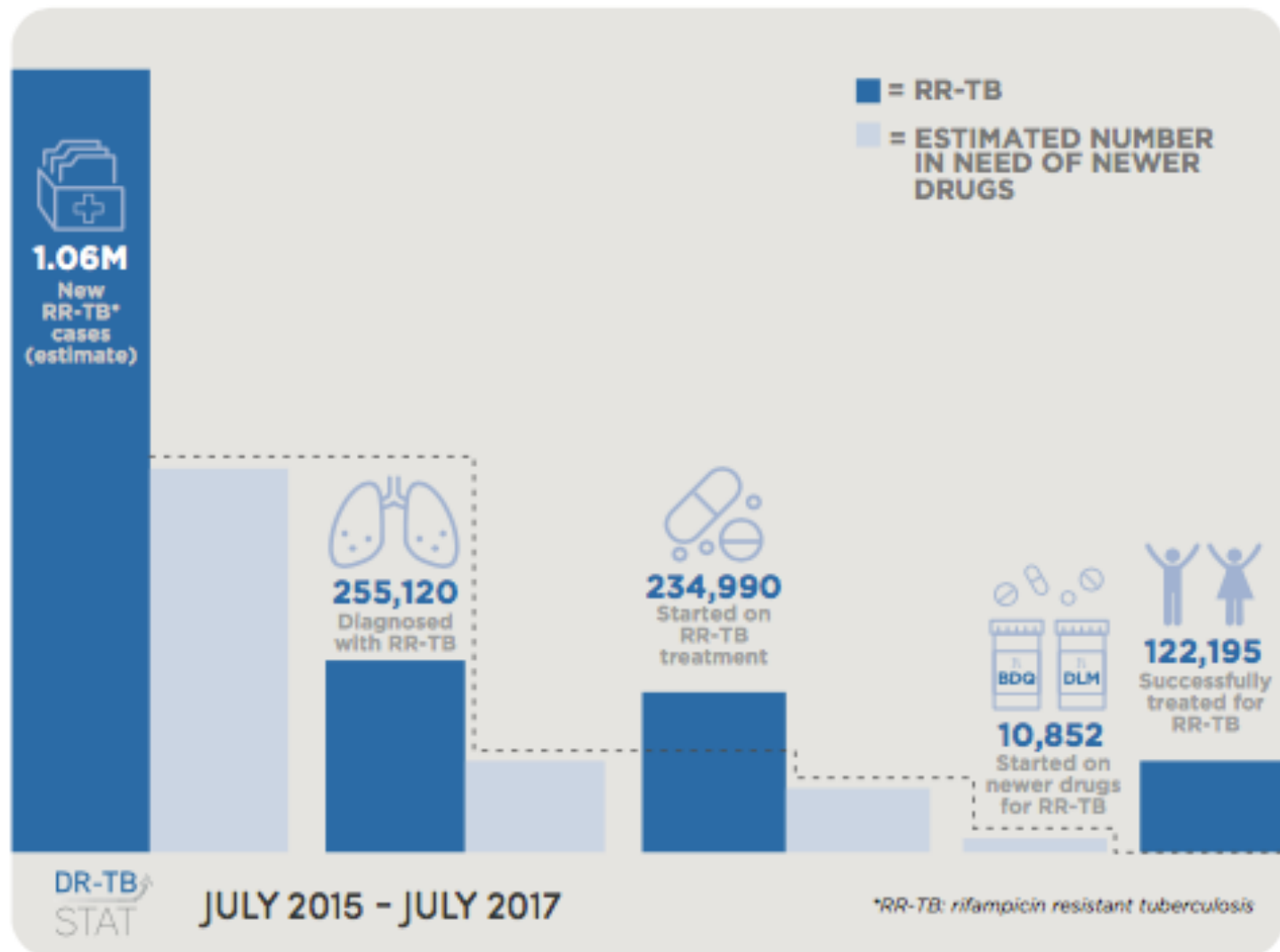
*\*adjusted to exclude compassionate use of DLM in November 2016*

# Global progress: BDQ and DLM versus minimum estimated global need



*\*calculation of global estimated need for new drugs adjusted to reflect cumulative number of patients started on treatment for RR-TB in 2015 and 2016*

# GLOBAL INTRODUCTION OF NEWER DRUG RESISTANT TUBERCULOSIS DRUGS BEDAQUILINE AND DELAMANID: THE GAP BETWEEN NEED AND ACCESS



Sources: WHO 2015 and 2016 Reports; DR-TB Scale-Up Treatment Action Team (DR-TB STAT)

# Uptake of BDQ and DLM: PAHO region

- Brazil is a high-burden TB country and Peru is a high-burden MDR-TB country
- Overall it is estimated that there are more than 7,000 persons in the PAHO region who needed new drugs over the two year period between 2015 and 2017
- Fewer than 150 people in the PAHO region have received newer drugs under program conditions, just over 2% of those who needed them
- PAHO countries that have introduced newer drugs under program conditions: Peru, Haiti and the Dominican Republic
- Brazil: compassionate use access for newer drugs
- Delamanid orders via GDF only for Dominican Republic (4 treatments)
- Bedaquiline orders via GDF only for Dominican Republic (34 treatments), Peru (211 treatments), Haiti (20 treatments), Bolivia (3 treatments)

# References

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