SIRTURO® Registration Status as of 31st May 2018

Marketing Authorization Holder (MAH) is Johnson & Johnson or subsidiaries*
Territory covered is home to over 80% of global MDR-TB treated patient burden worldwide.

EXISTING REGULATORY APPROVALS

SRAs

United States	Dec 2012
EU28	March 2014
Japan	Jan 2018

High MDR-TB Burden Countries

Russia*	Oct 2013
Philippines	Oct 2014
South Africa	Oct 2014
Peru	Dec 2014
India	Jan 2015
Uzbekistan*	Oct 2015
China	Nov 2016
Moldova*	Jan 2017
Thailand	Aug 2017
Ethiopia**	Feb 2018
Indonesia	May 2018

S. Korea	Mar 2014
Turkmenistan*	Jan 2015
Armenia*	May 2015
New Zealand	Aug 2016
Hong Kong	Oct 2016
Taiwan	Oct 2016
Turkey	June 2017
Rwanda**	Oct 2017
Uganda**	Jan 2018
Cameroon**	March 2018

ONGOING REGULATORY SUBMISSIONS

Bangladesh	Jan2015	Mexico	Oct 2015
Belarus	Jan 2018	Nigeria**	Dec 2016
Brazil	Feb2017	Tanzania**	Mar 2016
Burundi**	Apr 2016	Ukraine	April 2018
Ghana**	May 2016	Vietnam	Aug 2013
Kenya**	Apr 2016	Kazakhstan*	May 2018

REJECTIONS (due to lack of phase 3 data)

Kyrgysztan*	April 2015
Azerbaijan*	Oct 2015

Additional Formal Recognitions

Iceland, Lichtenstein, Norway – mutual registration recognition with EU

SIRTURO™ included on the "Vital no disponible list" in Colombia

Macao approval "grandfathered" via an import license

* In these countries, MAH is Pharmstandard

** WHO Collaborative Procedure for SRA-Approved Accelerated Registration
https://extranet.who.int/prequal/content/faster-registration-fpps-approved-sras

Source : Johnson and Johnson Global Public Health