Emerging Issues in Global Regulatory Pathways for TB Drug Regimen Development and Evaluation:

Industry perspective

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Bedaquiline filed in countries representing > 60% global burden

Janssen has filed regulatory submissions in:

- South Africa
- China
- Philippines
- Vietnam
- India
- Colombia
- Thailand
- Peru
- Indonesia

* Pharmstandard is MAH
Key Successes

- US FDA accelerated and EMA conditional approval based on Phase IIB data

- Inclusion of bedaquiline in WHO interim guidance and in CDC guidelines

- Accelerated regulatory approval timelines in Russia (6 months) and South-Korea (4 months)
Regulatory approval timelines after local submission

- ± 6 months: 4 countries (Approved in U.S.A., Russia*, South-Korea)
- ± 1 to 1.5 year: 3 countries
- ± 2 years: 4 countries
- ± 4.5 years: 1 country

* MAH Pharmstandard

Note: Expected timelines are subject to change
Major challenges for products addressing public health issues

- Lack of expedited review and accelerated approval pathways
- Lack of harmonized regulatory requirements, challenging regulatory environment
- Limitation of PhIIB versus PhIII program with respect to patient subgroups
How to accelerate regulatory evaluations

• How can NMRA processes be aligned with expedited registration processes from health authorities, such as FDA and EMA. Is a mutual recognition procedure a viable option for solutions to global public health issues?

• How to align requirements for a TB product to avoid delays in registration and to avoid duplication of efforts (prior AND post-approval)?

• How can real world evidence be efficiently gathered to fill in data gaps for well-defined patient sub-groups for a reportable disease such as TB?
WHO Collaborative Procedure

- To facilitate and accelerate national registration of products

- Proposal to extend procedure to finished pharmaceutical products approved by SRA such as FDA/EMA

- How to maximize the participation of TB and MDR-TB (high) burden countries?
Regulatory approval is an important step

But not all barriers are gone once product is registered

- The development program is still ongoing, maintenance of the registrations, updates of the local labels

- Development of local infrastructure to ensure responsible distribution, appropriate use and active pharmacovigilance reporting

- Clear understanding of roles and responsibilities of all parties (NMRA, MOH, manufacturer, NTP) in working together on appropriate use

- Ensure dialogue between local Departments of Health and NRMA Review Committees
Our ‘Ask’ from CPTR

Think about all of the challenges to come up with strategies and processes to speed up registrations and support appropriate use.

To have real impact, we have to act now!
THANK YOU !