Collaborative registration procedure: Examples of Kyrgyzstan

World Health Organization
REGIONAL OFFICE FOR Europe

Saltanat Moldoisaeva

National Professional Officer on medicines and medical devices regualtion, WHO Country Office Kyrgyzstan

Webinar of the Collaborating Network to assure access to modern DR-TB medicines, December 2, 2020

Summary

- Introduction
- CRP in Kyrgyzstan
- Challenges
- Recommendations

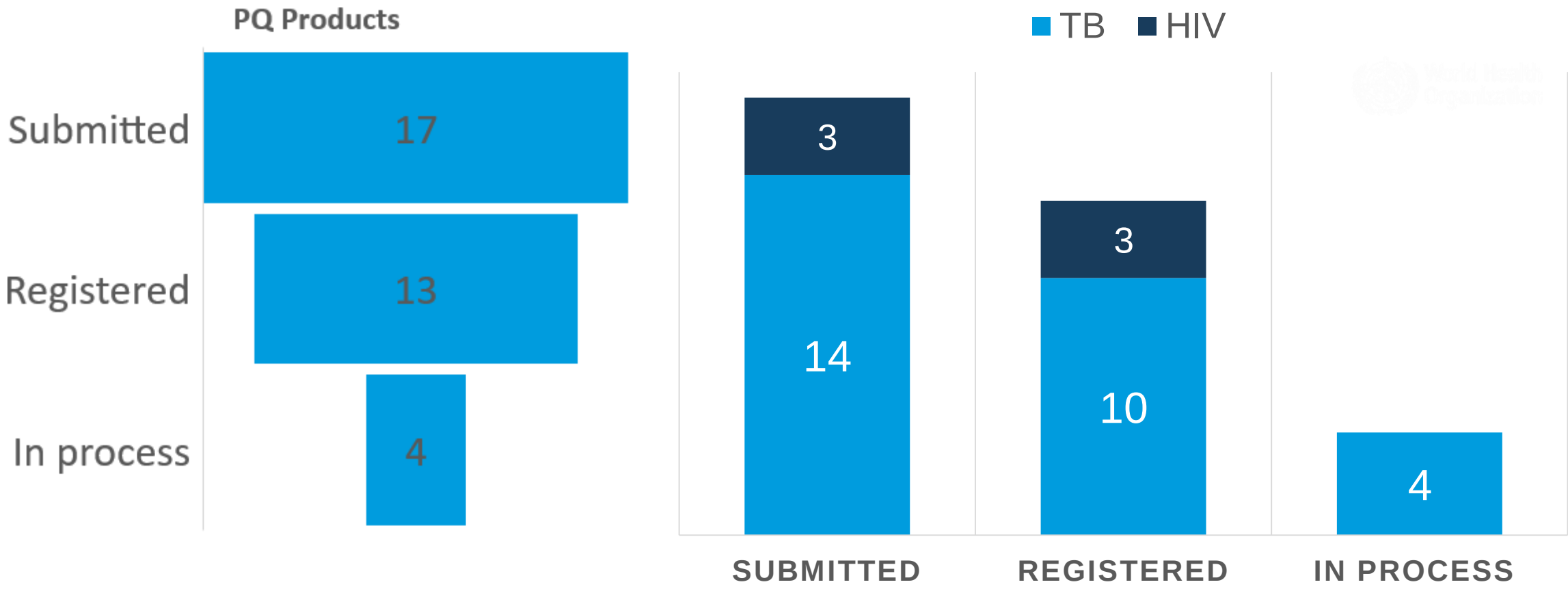
Introduction

- Kyrgyzstan is participating country in the CRP, more actively for the last 2-3 years
- The country transitioning from donor to domestic funding
- Member of the Eurasian Economic Union, fully functioning in 2021
- Accelerated registration procedures for FDA, MHRA, SwissMedic, EMA, Japan PMDA

WHO PQ CRP in Kyrgyzstan (1)

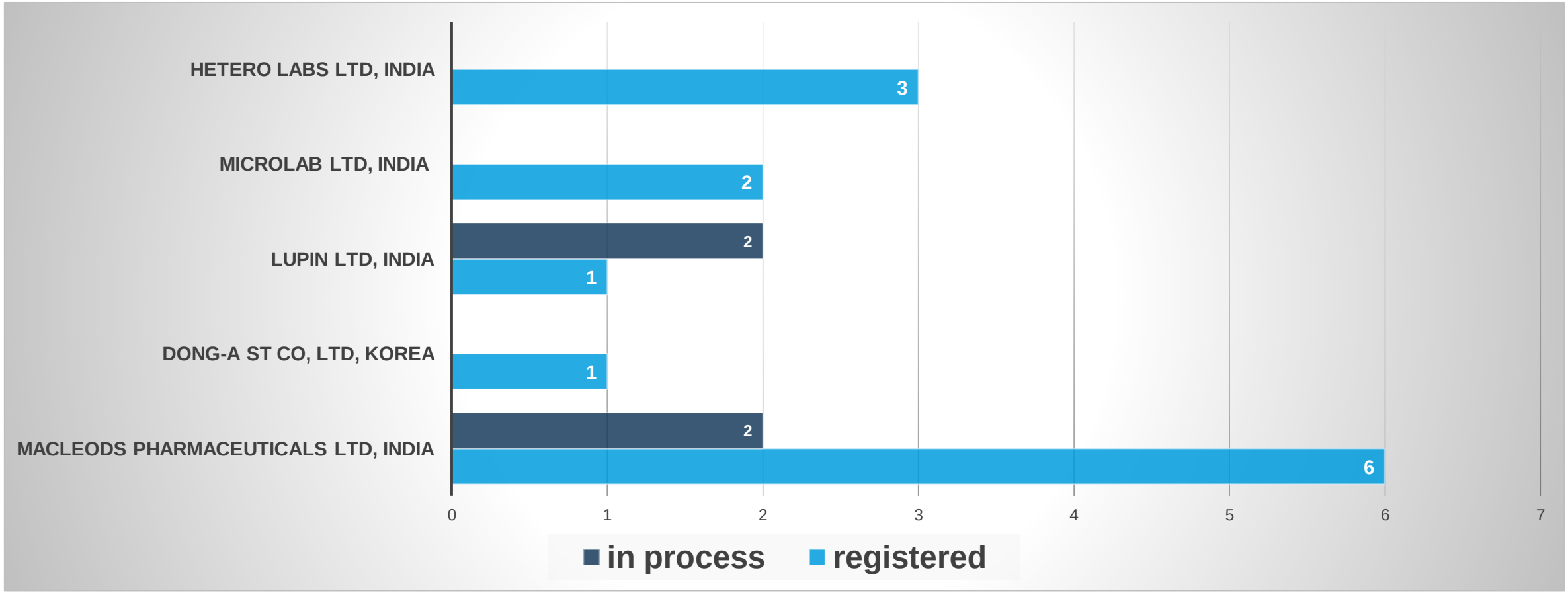
- Three focal points:
- Asel Turdalieva, MA unit
- Maya Musaeva, MA unit
- Nazi Abdrasulova, GMP inspectorate
- Timeframe 45 days, variation within 2 months

WHO PQ CRP in Kyrgyzstan (2)



WHO PQ CRP in Kyrgyzstan (3)

Pipeline of applications, by company



Challenges

- Common market with EUU – centralized and decentralized procedures starts from 1 January 2021
- CRP is not in the legislation of the EUU

Recommendations

- SOP on registration procedure is developed and in process of approval
- SOP on post-approval changes have to be developed
- More communication with Manufacturers. They should be properly informed about the new process's existence, the scope of the products for which this is applicable; possible deviations from standard national requirements; differences from current registration practices; and the benefits that come with participation.

Thank you!

Any questions or comments
smoldoisaevas@who.int

WHO Country Office, Kyrgyzstan

52-54 Orozbekov Street

720040, Bishkek

Kyrgyz Republic

WHO_Europe

facebook.com/WHOEurope

instagram.com/whoeurope

youtube.com/user/whoeuro

World Health Organization
REGIONAL OFFICE FOR Europe

Weltgesundheitsorganisation
REGIONALBÜRO FÜR Europa

Organisation mondiale de la Santé
BUREAU RÉGIONAL DE L' Europe

Всемирная организация здравоохранения
Европейское региональное бюро