Pilot project for WHO prequalification of biosimilars for cancer treatment:

Why manufacturers should consider participating in the pilot

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- Sustainable Development Goal No. 3:
  - Ensure healthy lives and promote well-being for all at all ages;
  - targets: By 2030:
    - reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being;
    - provide access to affordable essential medicines and vaccines.

An integrated team to assess and position value medicines

- the availability of affordable anti-cancer generic drugs and biologically similar therapeutic agents (biosimilars) will go a long way to reduce overall cost of cancer care
- Expiration of patents on key biotherapeutic products is opening the door for quality-assured similar biotherapeutics (biosimilars) which are expected to contribute to a substantial increase in their availability at affordable prices. (Rationale for PQ of similar biotherapeutic products.)

SBP = Similar Biotherapeutic Product

Benefits for manufacturers of working with prequalification:

- Eligibility for tenders: PAHO and UNICEF have expressed interest to procure so far
- Offers opportunity to improve manufacturing processes not only for product submitted for prequalification but also for other products in the manufacturer's portfolio
- Introduces manufacturers to stringent regulatory processes if not already familiar with these.

Challenges

- Currently no global mechanism for evaluating safety, quality and efficacy of SBPs
- Original reference biotherapeutic may not be on the market in some countries – similar to what?
- Importance of appropriate regulatory framework to address potential risks including product quality, product specific issues, pharmacovigilance…

- As at April 2017:
  - 11 nationally approved versions of Rituximab
  - 5 nationally approved versions of Trastuzumab
- Following prequalification, use of the collaborative registration procedure (CRP) to facilitate NRA registration in recipient countries
- Interested companies to be prepared to share their dossiers with interested NRAs

WHO prequalification serves as a guarantee of good quality for health products, is a reference in terms of internal technical expertise and has the power to convene external expertise

- ✓ Access to donor-sponsored tenders
- ✓ Faster regulatory approval
- ✓ Timely assessment of variations and changes
- ✓ International quality-assured product status (improved image)
- ✓ Recognition of GMP status, beyond prequalified products
- ✓ Increased capacity in quality management systems
- ✓ Target Product Profiles
- ✓ Harmonization of regulatory practices within WHO Member States
- ✓ Reduced operating and manufacturing costs

Participating NMRAs

1. Armenia
2. Botswana
3. Burkina Faso
4. Burundi
5. Cameroon
6. *Caribbean Community (CARICOM)
7. Cote d'Ivoire
8. Dem. Rep. Congo
9. Eritrea
10. Georgia
11. Ghana
12. Kenya
13. Kyrgyzstan
14. Lao PDR
15. Madagascar
16. Malawi
17. Mali
18. Mozambique
19. Namibia
20. Nigeria
21. Philippines
22. Senegal
23. Sierra Leone
24. South Africa
25. Tanzania
26. Uganda
27. Ukraine
28. Zambia
29. Zanzibar
30. Zimbabwe

* CARICOM

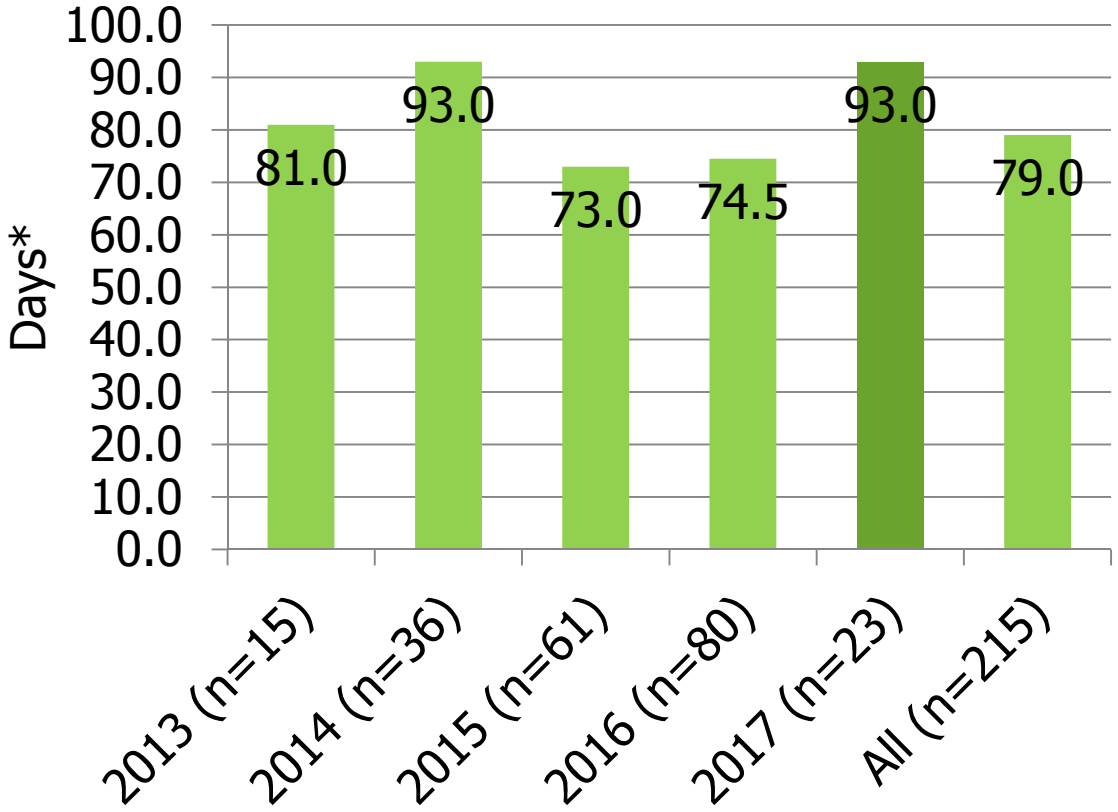
Member States: Antigua and Barbuda, Bahamas, Belize, Dominica, Grenada, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St Vincent and the Grenadines, Suriname and Trinidad and Tobago

Associate Member States: Anguilla, Bermuda, British Virgin Islands, Cayman Islands and Turks and Caicos Islands

As at 12 May 2017

Median time to registration

*Including regulatory time and applicant time



As at 12 May 2017