

## **23<sup>rd</sup> MEETING OF THE WHO EXPERT COMMITTEE ON THE SELECTION AND USE OF ESSENTIAL MEDICINES**

**Monday, 21 June to Friday, 2 July 2021**

**World Health Organization, Geneva, Switzerland**

*Joint statement from IAVI and Wellcome*

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More than 100 monoclonal antibodies have been approved in the past 30 years and they have transformed treatment of many diseases; however, their global availability and affordability remains severely limited. This gap in access is expected to widen as monoclonal antibodies become an increasingly large proportion of pharmaceutical company pipelines. In August of 2020, non-profit organizations IAVI and Wellcome published a report titled ["Expanding access to monoclonal antibody-based products. A global call to action."](#)

This report outlines factors impeding access to monoclonal antibodies in low- and middle-income countries (LMIC), particularly within public health systems, and recommends a series of four types of parallel actions to expand global access to affordable antibodies for treatment and prevention of non-communicable and infectious diseases. These include:

1. awareness building and advocacy of the public health and economic benefit of mAbs
2. broader registrations and expanded inclusion of mAbs into WHO guidance, WHO prequalification processes, and essential and national medicine lists
3. application of technological advances to deliver affordable mAbs responsive to country needs
4. creation of new business and partnership models enabling global licensing, manufacturing and supply of affordable mAbs

Relevant to today's meeting and the recommendations listed above, in the past 4 years more mAbs for non-communicable diseases have been included in the WHO Essential Medicine List. However, significant delays exist in incorporation of these mAbs into LMIC medicine lists and their access in these countries is still severely limited. There is also a growing number of mAbs approved and in development for infectious diseases, including COVID-19, HIV, RSV and Ebola. This presents an opportunity for expanded inclusion of such mAbs that can prevent and treat infectious diseases, into national and essential medicine lists.

There is an urgent need to better understand and shorten the time lag between inclusion of mAbs in the WHO EML and national medicine lists. A broader awareness of the public health and economic benefit of mAbs will help bridge this gap. Collaborations with low- and middle-income countries to set agendas for mAbs based on the greatest local LMIC health needs, in the areas of research and development, financing, procurement, and delivery strategies, will drive regional and global partners to identify pathways to their access.

Following the launch of the call-to-action report, IAVI and Wellcome have invested in global webinars to raise awareness to the public health value of mAbs to drive commitment and engagement of global stakeholders to action. A two-part webinar series, in partnership with Unitaid and the Department of

Biotechnology, Government of India, discussed the value of mAbs for COVID-19 and how to make them globally accessible. These discussions have highlighted the importance of investments in innovation to design mAbs with favorable product profiles for more convenient and affordable delivery, rapid prequalification and broad registrations, the role of regional manufacturers to meet global supply, and the importance of new platforms for pooled procurement, distribution and equitable allocation of mAbs. While mAbs for COVID-19 are likely to pave new ways for access to mAbs for other diseases, there is also an urgent need for LMICs to prioritize and elevate country-specific mAb agendas into their public health systems.

IAVI and Wellcome, together with regional stakeholders and global partners, are organizing a series of events to address the severe gap in availability and affordability of mAbs in the African sub-continent. These events are intended to define specific health needs in Africa for which mAbs would be most beneficial, highlight actions needed to strengthen and harmonize regulatory and policy frameworks, and trigger investments needed by key global stakeholders to support accessibility to mAbs in Africa. Now is the time for a coordinated global response to ensure mAbs are accessible in all countries and for all diseases.