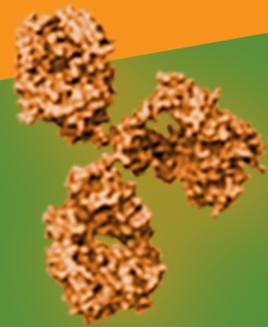




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# Expanding access to monoclonal antibody-based products

A global call to action



# Executive summary

Monoclonal antibodies are one of the most powerful tools in modern medicine. More than 100 of them have been licensed over the past 30 years and they are transforming the way doctors treat, prevent and even cure serious non-communicable diseases, including many cancers and autoimmune disorders. These monoclonal antibody products are significantly more effective than previously available therapies and are often better tolerated and easier to deliver. There's also a rapidly growing pipeline of monoclonal antibodies to treat and prevent many existing and emerging infectious and neglected diseases.

Millions of people around the world stand to benefit both from existing monoclonal antibody-based products and those in development. Rates of non-communicable diseases are on the rise in many developing countries. In addition, there are numerous existing and emerging infectious disease

Identifying pathways to provide affordable, timely and sustainable access to monoclonal antibody-based products across the globe is therefore a global health priority.

There is not a simple solution to this problem. Monoclonal antibodies are more complex and expensive to develop and produce than small molecule generic drugs. And the business and partnership models that have vastly expanded global access to some HIV drugs are not necessarily applicable or sufficient. Ensuring monoclonal antibodies are available and affordable globally will require new ways of thinking, new types of collaboration and new ways of doing business.

This report identifies a series of parallel actions that are required to expand access to monoclonal antibodies. The process starts with advocacy and

**99% of deaths** from respiratory syncytial virus occur in low- and middle-income countries.

**99% of the sales** of Synagis, an antibody-based preventive, are in the US and Europe.

**For global access to monoclonal antibodies to be a reality, these innovative products have to be both available and affordable.**

threats, including COVID-19, Ebola and HIV, for which monoclonal antibodies are poised to play an important role in treatment and prevention. As the COVID-19 pandemic has shown, no country is immune to the threat posed by emerging infectious diseases. If monoclonal antibodies prove to be effective for COVID-19, ensuring prompt, equitable and affordable global access to these products, as well as others, will be imperative.

But as this report details, global access to monoclonal antibody products is now severely limited in many countries. Today, the market for monoclonal antibodies is overwhelmingly in high-income countries. Few, if any, monoclonal antibodies are registered in low-income countries, and those that are registered in many middle-income countries are often unavailable in their public health systems, making them prohibitively expensive. This gap in access will only widen because monoclonal antibodies are an increasingly large proportion of pharmaceutical company pipelines.

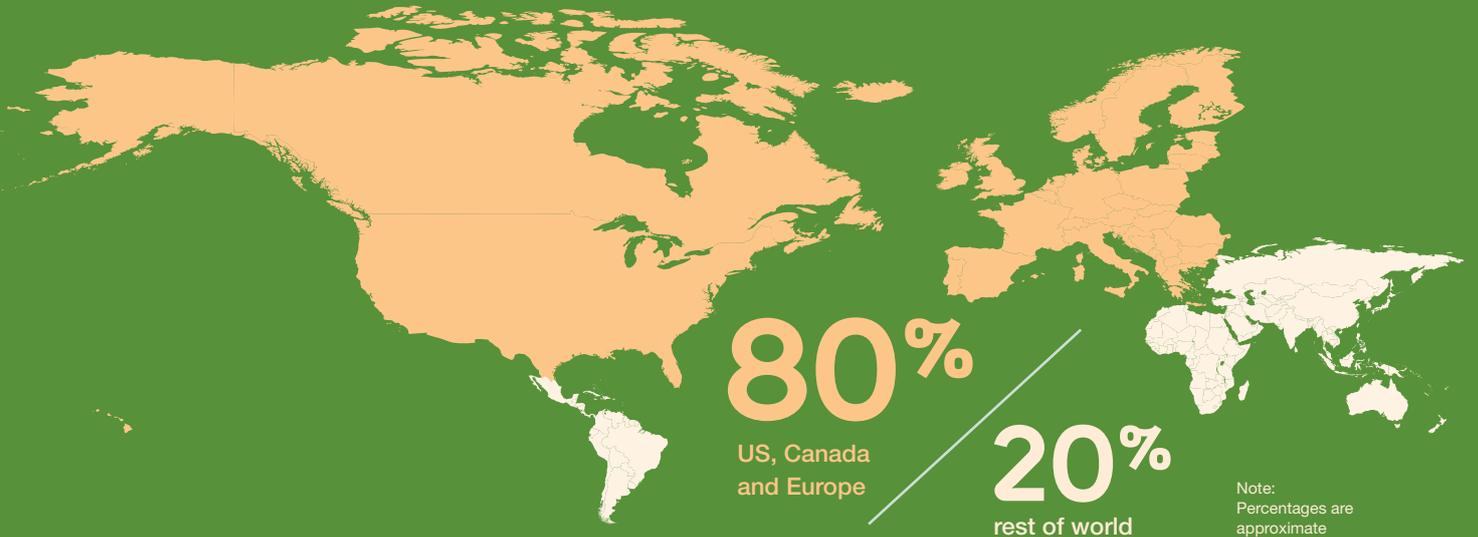
awareness, but it also requires that regulatory and policy issues are addressed, and that technological advances are applied throughout the process of identifying, optimising, producing and delivering more potent, lower-cost monoclonal antibody products. New business models that promote the availability and affordability of these products are also necessary. Together, these actions will make it possible to address the growing inequity to these products, saving or improving millions of lives in the process.

Progress can't come soon enough. The goal of this report is to catalyse discussion, collaboration and action. Pharmaceutical companies, global health agencies, public sector entities, philanthropic organisations and ministries of health must join forces to make global access to transformative monoclonal antibody products a priority, and a reality.

**The time to act is now.**

# Reshaping the monoclonal antibody world

Today's global market for monoclonal antibodies is highly unbalanced.



Ensuring equitable access requires four parallel yet vital commitments.

