

Roche Position on enabling Access through Collaborations and Patent Pools

At Roche, we are turning advances in medical and data science into innovative diagnostics and life-changing treatments for patients. We are constantly innovating to develop and deliver products for the benefit of millions of people around the world. Roche strongly believes that robust intellectual property (IP) systems stimulate innovation and economic growth for the benefit of society as a whole¹. It is Roche's desire to provide access to its diagnostics and medicines as broadly as possible.

- ✓ Roche strongly believes that the originator² is in the best position to react quickly and to provide access in an emergency situation.
- ✓ In case its own capacity is not sufficient, the originator is also best placed to collaborate with qualified partners of his choice. If Roche is not able to identify qualified and trustworthy partners, Roche will consider collaboration with the Medicines Patent Pool or other voluntary patent pools to identify and assess such partners.
- ✓ As part of a collaboration with a trustworthy and qualified partner, Roche will also consider sharing know-how and engaging in technology transfer.
- ✓ It is Roche's principle that patient safety and speed of access to medicines and diagnostics are decisive for any collaboration.

Background and Roche's Position

Roche strongly believes that the originator is in the best position to provide access and to react quickly in an emergency situation since he has already established production facilities and is in possession of all technical and

¹ For more details see «Roche Position on Intellectual Property»

² It is understood that the originator is either the patent owner or its exclusive licensee.

medical know how needed to ensure high quality products and to further upgrade production capacity, if necessary. This is especially relevant for complex biologics. In general, the manufacturing of those involve many steps which may influence the structure of the medicine and thus potentially the effect on the patient.

Roche is one of the largest biotechnology companies in the world, with leading expertise and production capacity and we are uniquely positioned to make biologic drugs and diagnostics available around the world. In case Roche's own capacity is not sufficient, we are also best placed to collaborate with qualified partners which already have a proven track record in manufacturing of biologics, to make sure that sufficient quantities can be produced in high quality and in time.

If Roche is not able to identify appropriate qualified partners, Roche will explore collaboration with the Medicines Patent Pool³ or other voluntary patent pools to assess potential partners in order to broaden access for patients. In case a qualified and trustworthy partner is identified, Roche will also consider the sharing of know-how and technology transfer. Patient safety and speed of access to medicines and diagnostics remain of paramount importance and constitute a decisive factor for any foreseeable collaboration.

This position paper was approved by the Sustainability Steering Committee and the Corporate Executive Committee in May 2021 and entered into force then.

³ Some background on patent pools: One of the first examples of a patent pool had been the Medicines Patent Pool (MPP) for the voluntary licensing of patents in the field of HIV drugs. In view of the present COVID-19 pandemic, Costa Rica had made a request at the WHO to set up an instrument which would allow the inclusion of other forms of IP, such as know-how and the transfer of technology in addition to the licensing of patents. This finally resulted in a broadened mandate for the MPP to cover, in addition to HIV and HCV products, medicines and diagnostics to deal with the ongoing COVID-19 pandemic. As a consequence of the "Solidarity Call to Action", the World Health Organization (WHO) has created C-TAP to promote open science and to accelerate the development of COVID-19 products by pooling data, know-how and IP through non-exclusive licensing and transfer of technology. MPP also collaborates with the WHO through C-TAP.