



**Irish Pharmaceutical
Healthcare Association**



Opening remarks by IPHA and BPCI, the biopharmaceutical industry's representative bodies, at the Oireachtas Committee on Enterprise, Trade and Employment about the proposed TRIPS waiver for Covid-19 vaccines and treatments

11th May, 2022

Good morning.

Thank you for inviting us to the Joint Oireachtas Committee on Enterprise, Trade and Employment. IPHA and BPCI are here jointly as the representative organisations for the research-based biopharmaceutical industry.

Our remarks are set against a backdrop of low Covid-19 case numbers, high rates of vaccination, and avoided mortality and serious illness from the disease. It is more than 16 months since Annie Lynch, the 79-year-old Dubliner, became the first person in Ireland to be vaccinated for Covid-19. Since then, almost 11 million doses of Covid-19 vaccine have been administered. More than four million people are fully protected against the disease.

The efficient rollout of the vaccination programme attests strongly to the capacity of the Department of Health and the Health Service Executive to respond to an emergency. The biopharmaceutical industry, whose work with others led to the discovery, development and manufacture of Covid-19 vaccines and treatments in record time, is proud of our achievement too.

But while Ireland has a world-class Covid-19 vaccination rate, much of the world remains unprotected.

That must change. We want as many people as possible vaccinated for Covid-19 as fast as possible, no matter where they live. The response to this pandemic, to future ones and to all other diseases depends on stable conditions for the discovery, development and production of vaccines and treatments. Speed of delivery and global equity of access to Covid-19 vaccines and treatments, and the protection of intellectual property rights, are not mutually exclusive. They are complementary.

To thrive, innovation depends on intellectual property protection. It is the certainty that shields the risky business of investing in research and development. Most of it fails. The global patents system is the basis for innovation. The proposed TRIPS waiver is a serious risk to the global patents system.

Waiving intellectual property rights will not accelerate global Covid-19 vaccines access. Production is not the problem. There are already more than enough vaccines for the world. The problem is they are not getting to the people who most need them fast enough.

The effort to vaccinate the world for Covid-19 is limited by vaccines administration, not by vaccines production. By the end of June, 16.3 billion doses of Covid-19 vaccines will have been produced since the start of the pandemic. At the end of January, there were 12 billion Covid-19 vaccine doses produced, including 3.4 billion mRNA vaccines. Of the 12 billion, 10 billion were administered. The speed of Covid-19 vaccines production is outpacing their administration.

The cause of global Covid-19 vaccine inequity is the capacity of some countries, mostly developing nations, to absorb, distribute and administer the doses they get. In some of these countries, Covid-19 vaccine hesitancy is high. There are reports of shortages of syringes and medical equipment, as well



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as the destruction of significant quantities of doses of expired vaccines. This is not to blame countries for shortcomings. Rather, it is a signal to all of us to do more to help.

By the end of last month, Covax, the vaccine distribution programme backed by the World Health Organisation, had delivered 1.43 billion Covid-19 vaccine doses to 145 countries. Africa has received around 672 million doses. In January, 96 million doses were shipped to Africa - more than double the amount shipped six months before that. But Covax is now only shipping Covid-19 vaccines to countries on demand to ensure the right volume at the right time. The World Health Organisation has reported that up to 3.5 million Covid-19 vaccine doses have been destroyed.

Mike Ryan, the Executive Director of the World Health Organisation's Health Emergencies Programme, has indicated that global vaccines access is affected more by demand-side challenges than supply-side ones. The Africa Centres for Disease Control and Prevention has asked that all Covid-19 vaccine donations be paused until later this year because hesitancy and logistical hurdles are hampering administration.

Our industry has met the challenge of global production by investing in existing sites and in voluntarily entering over 370 licensing agreements with manufacturing partners with the skills and technology needed to produce Covid-19 vaccines to the highest regulatory standards. Further production capacity expansions are planned, especially in Africa. For Covid-19 treatments, over 150 voluntary partnerships are in play.

Often, global supply of vaccines and medicines is managed from a small number of manufacturing sites, with production of the drug substance - known as the active pharmaceutical ingredient - concentrated in one site. Building manufacturing sites across multiple continents is impractical and unnecessary. Importing and exporting raw ingredients is complex. Early in the pandemic, that process was exacerbated by trade barriers like export restrictions. For one mRNA vaccine, there are some 280 raw ingredients. Local regulatory approval is needed where manufacturing sites are located. The right skills are not always available locally. Until 2020, there was no mRNA vaccine manufacturing anywhere in the world.

Waiving intellectual property rights for use in manufacturing sites with very limited capacity, or to be made available to companies with no track record or experience manufacturing complex medicines such as vaccines, could result in the diversion and hoarding of critical raw materials and weakening already strained supply chains. That could lead to fewer, inferior or even unsafe vaccines.

A draft proposal, released in March, by the World Trade Organisation puts forward a 'limited waiver' or 'modified compulsory licensing provisions' for Covid-19 vaccines and treatments. We consider these proposals as serious risks to global public health. Voluntary production partnerships have been shown to work. We must avoid dampening research and development. That would damage health outcomes, as well as potentially costing jobs in locations where there is significant biopharmaceutical investment.

According to the European Patent Office, a waiver would lead to a 37% drop in research and development for Covid-19-related products like vaccines and treatments. The impact would disproportionately be felt in higher-income countries where research and development activity is more likely to be concentrated.



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Multilateral solutions are needed to strengthen healthcare system capacity for Covid-19 vaccine administration and to empathetically tackle vaccine hesitancy. Efforts must focus on developing economies. Two-thirds of the 1.3 billion people living in poverty are in middle-income countries. Lower middle-income and upper middle-income countries are home to 75% of the world's population and 62% of the world's poor. A collaborative effort to protect vulnerable populations against Covid-19 must involve a coordinated effort between industry, the global health community, governments and non-government organisations to help bridge gaps in cold chain and service delivery, insufficient workforce capacity and challenges with demand and vaccine confidence in some countries.

Our industry is part of the effort to achieve global vaccines equity. We believe there are six ways to achieve that goal:

1. Continue to surge production of Covid-19 vaccines and treatments through in-company investments in sites and voluntary onboarding of suitable manufacturing partners;
2. Eliminate trade barriers so that the free flow of vaccines, ingredients and medical goods and supplies across borders is facilitated in the global supply chain;
3. Increase dose-sharing, with developed countries giving developing ones much more of their surplus vaccine doses faster;
4. Support country readiness, building the capacity of healthcare systems in developing countries to efficiently absorb, distribute and administer vaccine doses;
5. Combat vaccine hesitancy through education and health awareness programmes, empathetic and tailored community outreach, and influencer activations in mainstream media and on social media platforms; and,
6. Drive further innovation in vaccines and treatments, and work with healthcare systems on planning, to guard against variants of concern and future pandemics.

We cannot afford to undermine innovation. Scientists expect more zoonotic contagion in the future, making intellectual property rights a key part of the public health response. We still have to find answers to the diseases we know about. Globally, there are thousands of medicines in development. Among them are cell and gene therapies to treat, prevent and, potentially, cure some diseases like cancer. This is the dividend of innovation.

Covid-19 has been harrowing, causing sickness and death for so many people. According to the latest estimates, almost 15 million people have died globally - 13% more deaths than normally expected over two years. But without vaccines and, later treatments, the death toll, and lost economic output, caused by Covid-19 would have been so much worse.

This is our industry's contribution to the world - saving lives, guarding against severe illness, and maintaining economic life. We are proud of that contribution, made possible by science. Let us protect it for all our health and for economic progress.

Thank you for listening.

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