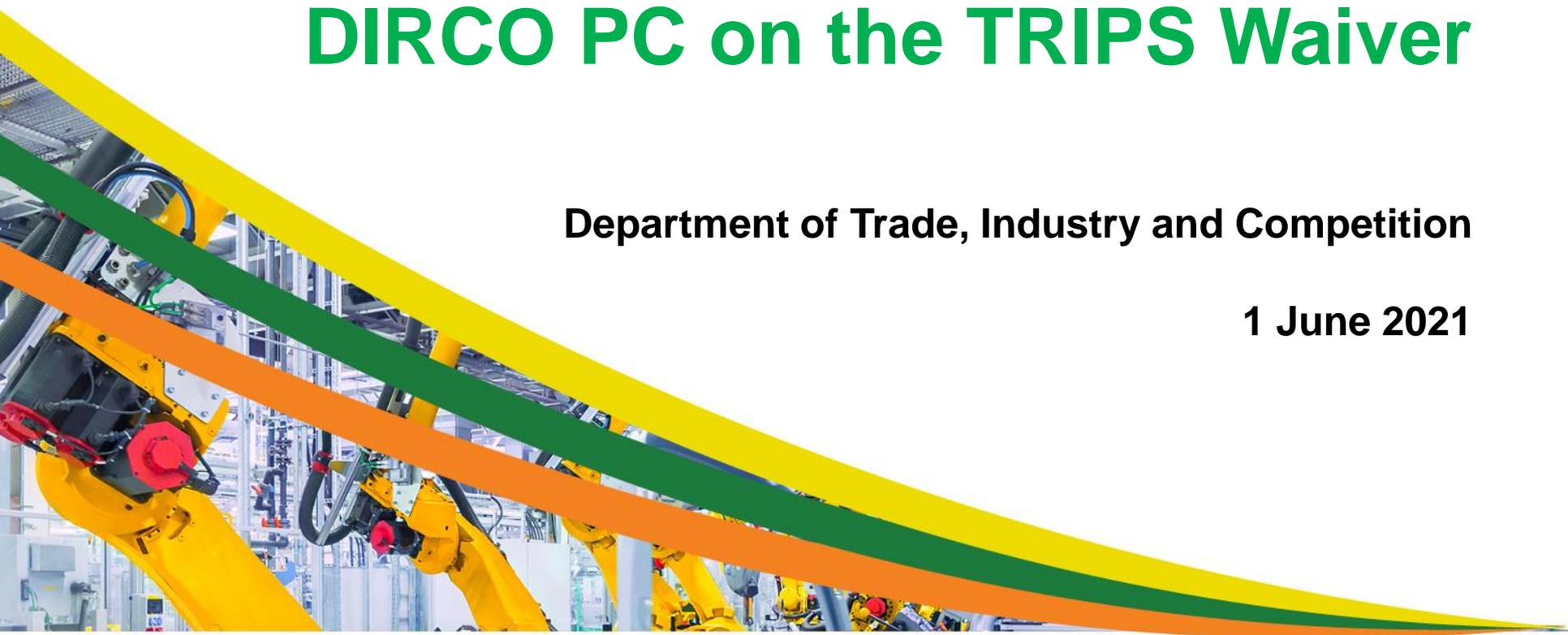


Presentation to the Joint DTIC and DIRCO PC on the TRIPS Waiver

Department of Trade, Industry and Competition

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The Challenge (I)

- Covid-19 represents a major global public health and economic crisis.
- Official figures indicate almost 3.5 million deaths from Covid-19.
- The real death rate is estimated to be between 7 and 13 million.
- Mass vaccination across the world is required to break the global transmission chain.
- Insufficient production and inequitable delivery of vaccines pose ongoing threats to lives, livelihoods and to the global economic recovery.
- In January 2021 the World Bank estimated the economic cost of the pandemic to be US\$ 5.6 trillion.
- That number will rise so long as the pandemic continues.

The Challenge (II)

- The major challenge is the shortage of supplies of vaccines; and inequitable access to available vaccines
- Unless manufacturing is ramped up and supply distributed more evenly, it will be at least another 2 to 3 years before a sufficient number people in low income countries are vaccinated.
- This gives considerable time for the virus to spread, and to mutate into more deadly or contagious strains.
- By 30 May 2021, 1.8 billion vaccine doses are reported to have been administered globally, with 426 million people “fully” vaccinated.
- ±75% of all vaccines have been delivered to just 10 countries.

Objectives of the Waiver

- In order to overcome the supply-challenge, SA and India proposed a waiver of certain provisions of the TRIPS Agreement at the WTO
- The objective of the Waiver is to promote universal access by removing legal impediments to sharing and using intellectual property required for the production of vaccines, diagnostics, and therapeutics.
- The Waiver would signal a multilateral undertaking that IPR rules will not constitute a barrier to boosting global vaccine production.
- It could encourage enhanced regional and international collaboration for development, production and supply of needed medical products.
- It would improve supply and access for countries with insufficient or no manufacturing capacity.

Waiver discussions

- The African Union supported the Waiver at its February 2021 session
- Discussions have been held through the TRIPS Council of the WTO, on the principle of a Waiver
- The number of formal co-sponsors has grown
- Many countries have now come out in support of the Waiver
- Parliamentarians across the world have supported the call for a Waiver, as have former Heads of State, Nobel Laureates and civil society leaders
- We seek to build wide support across developing and developed countries for the Waiver as part of the global campaign for vaccine access

What is needed

- The key elements required for a successful increase in global supply include
 - Access to intellectual property
 - Technology transfer and sharing of know-how
 - Financing of plant expansion or repurposing of existing plants
- This need to be linked to a more equitable supply-arrangement, including
 - Rights to distribution for pharmaceutical companies in developing countries, esp on the African continent

A Covid-19 Package

In March 2021, the Minister of Trade, Industry and Competition on behalf of SA proposed a package of 5 measures at the WTO:

1. **Scaled-up production** on a voluntary basis, with transfer of technology; production of the drug substance; production of the vaccine through a 'fill and finish' process; and distribution rights
2. **A waiver of IP rights** in specified areas, to enable production without the veto of IP-holders
3. **Transparency** on contract terms and price fairness and stability
4. **No resort to vaccine nationalism** through export controls, agreed at global level; and
5. **An automatic provision** in TRIPS to apply in future pandemics

Capacity-enhancement

- **Aspen**, a South African pharmaceutical company, is currently producing the J&J vaccines in Gqeberha, on a contract basis. It is open to producing the drug substance and to undertake distribution of product, which requires technology transfer and a licensing agreement
- **Biovac**, a Cape Town based company with significant shareholding by the SA government, is also able to produce vaccines and is engaged with global vaccine IP holders
- Both companies can do full and integrated production, based on the outcome of the WTO talks
- Other options are also being looked at for new production, including efforts by the Minister of Science and Innovation to mobilise local know-how
- SA is promoting **African vaccine production** as an explicit objective, looking at manufacturing facilities across the continent

Scope and Duration of the Waiver

- The proposal waives obligations under TRIPS regarding Copyrights; Industrial Designs, Patents and Undisclosed Information (trade secrets).
- The scope covers health products and technologies including vaccines, diagnostics, therapeutics, medical devices, personal protective equipment, their materials or components, and methods and means of manufacture for the prevention, treatment or containment of COVID-19.
- The Waiver would be in force for at least 3 years from the date of a decision.
- The General Council will review the circumstances justifying the waiver, and if such circumstances cease to exist, determine the date of termination.
- The duration has to be practical for manufacturing to be viable.

The State of Play (I)

- SA raised the matter of the relationship between TRIPS and COVID-19 at the G20 Trade and Investment meeting in March 2020.
- The Waiver Proposal was formally introduced by SA and India on 2 Oct 2020 at the WTO.
- Currently 63 WTO Members have co-sponsored the proposal and about 50 others have indicated their support.
- Co-sponsors presented an updated proposal on 21 May 2021.
- A further TRIPS Council meeting was held on 31 May 2021

The State of Play (II)

- President Ramaphosa engaged Heads of State in a number of fora and bilaterally on the Waiver proposal. This included last week's State Visit discussions with President Macron
- The Minister of International Relations & Cooperation engaged counterparts in support of the waiver
- On 30 March, the Minister of Trade, Industry and Competition met with the new US Trade Representative (USTR) to outline the rationale for the Waiver request. On 5 May the US gave its support for the Waiver proposal and subsequently for text-based discussions on vaccines
- A wide range of developing countries, from Africa, Asia, and Latin America back the waiver
- New Zealand offered its support and Australia and Canada indicated more guarded support. EU Members do not have a common view on the proposal as yet. A vote was held in the European Parliament a week ago in support of the waiver

Next Steps

- Co-Sponsors of the Waiver proposal seek to initiate text-based negotiations on the details of the Waiver but require broad consensus amongst WTO Members.
- Further efforts are underway to build consensus on a meaningful outcome that is reached on an expedited basis
- Key issues could be duration of the waiver, its scope and whether it would cover the proposed product range and the identified categories of intellectual property.
- In parallel, discussions are taking place with pharmaceutical companies and with Governments bilaterally to address the obstacles to wider support for the Waiver and the scaling-up of production
- The G7 meeting in the UK this month is an opportunity to seek developed country support
- An extraordinary coalition of countries have been mobilised in favour of the proposed Waiver, placing health and lives as the top priority