

COVID-19 VACCINE SUPPLY CHAIN AND REGULATORY TRANSPARENCY SYMPOSIUM WORLD TRADE ORGANIZATION Tuesday, 29 June 2021

Session 2: Mapping vaccine manufacturing and trade Ms. Laetitia Bigger, Vaccines Policy Director, International Federation of Pharmaceutical Manufacturers and Associations

When I look back a year and half ago, a deep sense of responsibility has been the driving force behind the unprecedented efforts of the innovative industry.¹

Breaking all historical records in vaccine R&D, manufacturing capacity expansion, and production, today we can really count on several safe and highly effective COVID-19 vaccines.

But from the beginning we knew that scaling up manufacturing capacities would be a daunting task.

So, companies scaled-up vaccine manufacturing at risk, supported by countries' risk-sharing models, even though it was not sure yet which, if any, vaccines in development will be approved by health authorities.

Since the outset of the pandemic, companies have been looking for the right partners that fit the need for scaling up such a complex manufacturing process that you have with vaccines. Biotechs, large pharmaceutical companies, and contract manufacturing organizations are working together, with over 300 agreements, in both developed and developing countries today.²

As mentioned by Mr. Rasmus Bach Hansen before - We are getting the job done. By the end of this month, over 3 billion vaccines will have been made - from zero a few months ago. We are on track to produce an estimate of 10 to 12 billion by vear end. 3,4

To put that into perspective, the global production estimate of vaccines for 2019 totaled 5,5 billion doses.⁵

https://www.wto.org/english/tratop_e/trips_e/techsymp_290621/hansen_presentation.pdf

¹ IFPMA COVID-19 hub https://www.ifpma.org/covid19/

² COVID-19 R&D-based pharma industry's innovative partnership to meet urgent global supply needs https://www.ifpma.org/resource-centre/rd-based-pharmaceutical-industrys-innovative-partnerships-to-meet-urgent-global-supply-needs/

³ Mr. Rasmus Bach Hansen presentation

⁴ WTO YouTube Channel https://www.youtube.com/watch?v=RlvMoJGqoal

⁵ WHO MI4A Global Vaccine Market Report (2020)

By signing up to the ACT-Accelerator in April 2020, we committed to work together with others to ensure fair and equitable access to vaccines – to leave no one behind.⁶

Concretely, this had meant socially responsible pricing, trebling the world capacity in a year time, and committing doses to COVAX⁷ as well as other agreements with developing economies.

Since February, COVAX has successfully shipped over 89 million COVID-19 vaccines to 133 economies.⁸ 1.5 billion doses delivered through COVAX to the AMC92 economies remains within reach with current supply agreements and donated doses by year end.⁷

But, despite a massive effort to scale up and produce billions of doses, COVID-19 vaccines are not equally reaching all priority populations worldwide now.

The pace of COVAX deliveries has been affected by countries, that have supported R&D and manufacturing scale-up at risk to a much-needed global scale, but reserved supply in excess of domestic requirements, and most recently the tragic Indian epidemiological situation and related export restrictions.⁷

While it makes easy headlines, there are no simple solutions to complex problems.

Following the Chatham House global COVID-19 vaccine manufacturing and supply chain summit, in March, we have increasingly been calling for immediate action to improve dose sharing, as well as to tackle bottlenecks in the supply chain and trade restrictions.⁹

This is why we launched the <u>five-steps plan</u> where we call on manufacturers, governments, and non-governmental organizations to work together to take urgent steps to further address this inequity.¹⁰

We believe that action is needed now and must focus on:

⁶ https://www.ifpma.org/resource-centre/pharma-industry-body-joins-as-founding-partner-a-new-global-collaboration-to-accelerate-the-development-production-and-equitable-access-to-new-covid-19-tools/; https://www.ifpma.org/resource-centre/act-accelerator-1-year-anniversary-the-biopharmaceutical-industry-is-committed-to-continue-to-play-a-critical-role-across-act-a-and-accelerate-equitable-and-fair-access-to-covid-19-tools/

⁷ COVAX Supply Forecast (23 June 2021) https://www.gavi.org/vaccineswork/what-does-covaxs-latest-supply-forecast-tell-us and https://www.gavi.org/sites/default/files/covid/covax/COVAX%20Supply%20Forecast.pdf

⁸ COVAX Vaccine Roll-out https://www.gavi.org/covax-vaccine-roll-out

⁹ News release https://www.ifpma.org/resource-centre/meeting-discusses-covid-19-vaccine-manufacturing-bottlenecks-that-must-be-urgently-tackled-for-c19-vaccine-output-to-reach-its-full-potential/ and virtual press briefing https://www.ifpma.org/events-2/virtual-press-briefing-following-the-global-covid-19-vaccine-supply-chain-manufacturing-summit/

¹⁰ Five steps to urgently advance COVID-19 vaccine equity (IFPMA, BIO, EFPIA, Vaccines Europe, ABPI, PhRMA, ICBA) https://www.ifpma.org/resource-centre/five-steps-to-urgently-advance-covid-19-vaccine-equity/

- 1) Stepping up responsible dose sharing; The latest development from G7 countries, which pledged 1 billion doses for low- and middle-income countries in 2021 and 2022, with hopefully more to come now, is extremely encouraging. COVAX announced, last week, an estimated 515 million doses to start becoming available in significant numbers very soon.⁷
- 2) Continuing to optimize production, including through additional voluntary collaborations with trusted partners that can produce significant quantities, without compromising quality or safety.
- 3) Supporting country readiness, to ensure that countries are ready and able to deploy available doses. We are already seeing countries giving back doses, or worse, doses expiring.
- 4) Driving further innovation, the evolution of the virus is a stark reminder that continued innovation will be key. Our scientists are studying how the vaccines perform against the emergence of new variants or are looking into the next generation of vaccines with improved dosage formulations and storage conditions.
- 5) Eliminating all trade barriers to export and further streamline regulatory procedures.

Globally integrated supply chains for COVID-19 vaccines should work at their full potential to produce over 10 billion doses by year end - enough to vaccinate the world's adult population.

This goes hand in hand with

- Expanding and streamlining regulatory review and reliance practices, adopting alternatives to on-site inspections (e.g., virtual inspections), reducing import and release testing requirements and expediting raw materials supplier qualifications for new suppliers; and
- Facilitating the cross-border supply of key raw materials, essential manufacturing materials, vaccines, and prioritizing the movement of skilled vaccine manufacturing workforce.

We are working now with our partners in the COVAX Supply Chain and Manufacturing Task Force to see what can be done to eliminate trade barriers, further streamline regulatory procedures and expedite cross-border supply and movement of skilled workforce to make a difference to ensuring COVID-19 vaccine equity during this critical period – WTO and its members can play an important role there.