PRELIMINARY

ACTaccelerator
ACCESS TO COVID-19 TOOLS

Hosted by World Health Organization

Update on the COVID-19 Vaccine Access

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Member States COVID-19 Briefing

3 December 2020

Objectives of this briefing

- Share an **update on vaccine access**
- Share an **overview of the COVAX current portfolio**
- Share an update on **Indemnification & Liabilities (I&L)**
- Provide an update on **Regulatory**

PRELIMINARY

Update on vaccine access as of Dec. 3

- With recent preliminary efficacy results of various vaccine candidates, **we expect to see the first vaccines delivered before the new year**

- COVAX is committed to delivering vaccine through the Facility as quickly as feasible and is aiming that **participants will receive doses in the H1 2021 with volumes rising to more significant levels in H2**

- To allocate these doses and plan for the broad scale-up, **COVAX will use the agreed mechanisms for equitable and fair allocation**

- As COVAX is operating in a very dynamic environment, **progress is being made on a daily basis on doses available, timing, scale through the Facility**

- **Getting started, at earliest time, and proceeding with full roll out is the highest priority**

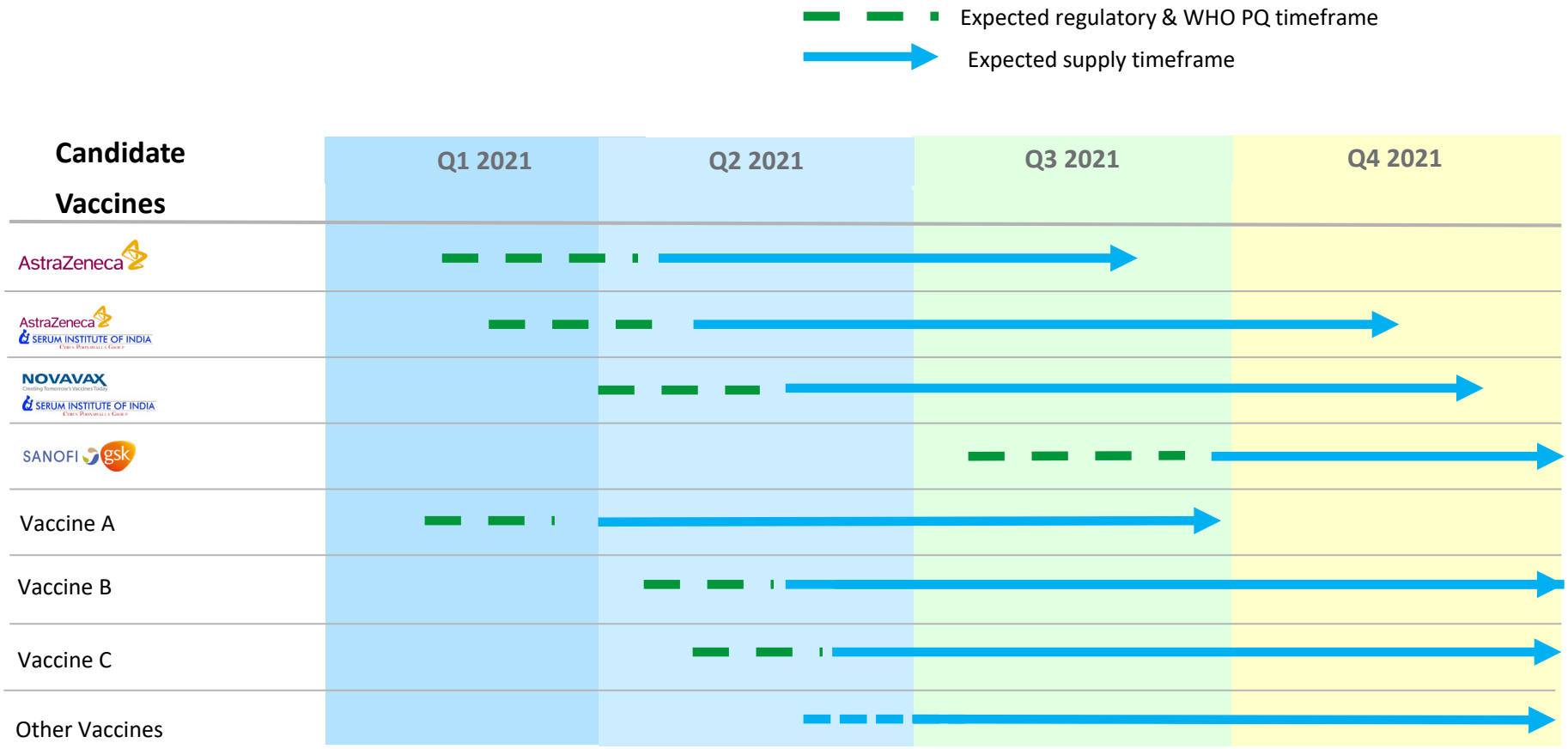
COVAX Facility portfolio currently includes 3 candidates with several expected near-term agreements

COVAX Facility portfolio currently includes signed commitments with **3 candidates across 2 technology platforms**

- Sanofi and GSK to support COVAX with **200 million doses** of adjuvanted, recombinant protein-based COVID-19 vaccine
- SII deal gives AMC92 economies access to vaccines licensed from Novavax and AstraZeneca: **200 million doses** of COVID-19 vaccines

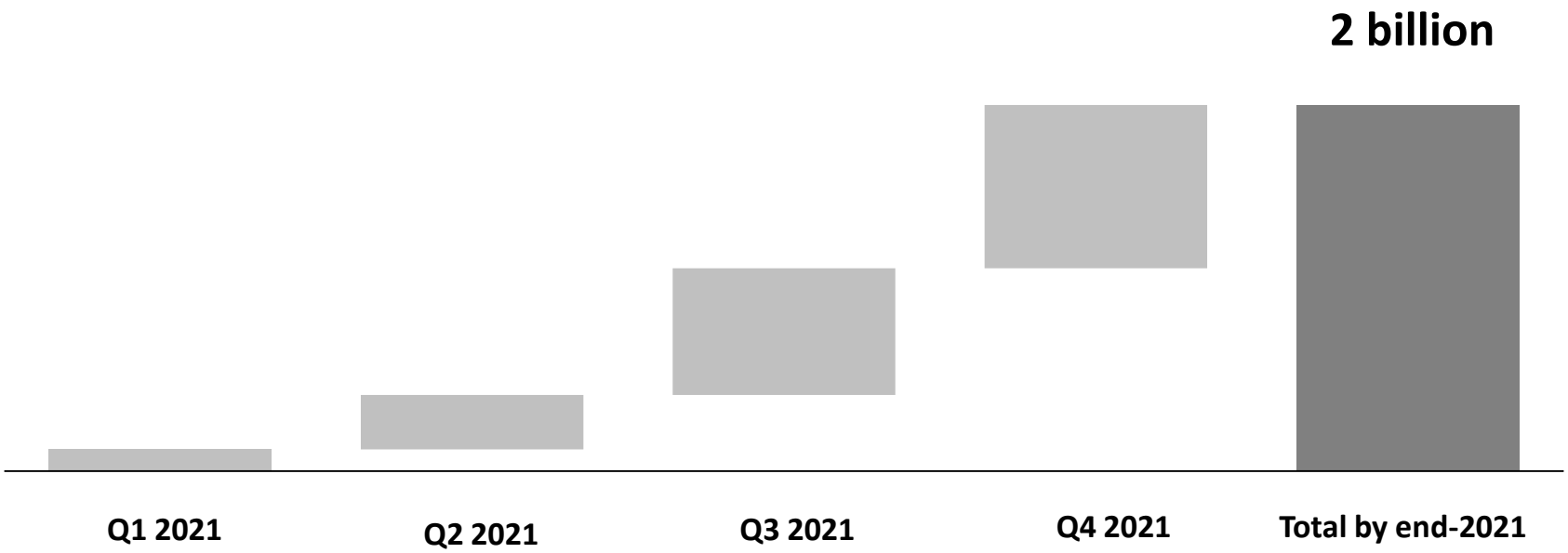
Several candidates are in near-term MoU agreements

COVAX Facility Portfolio – expected regulatory, supply timelines

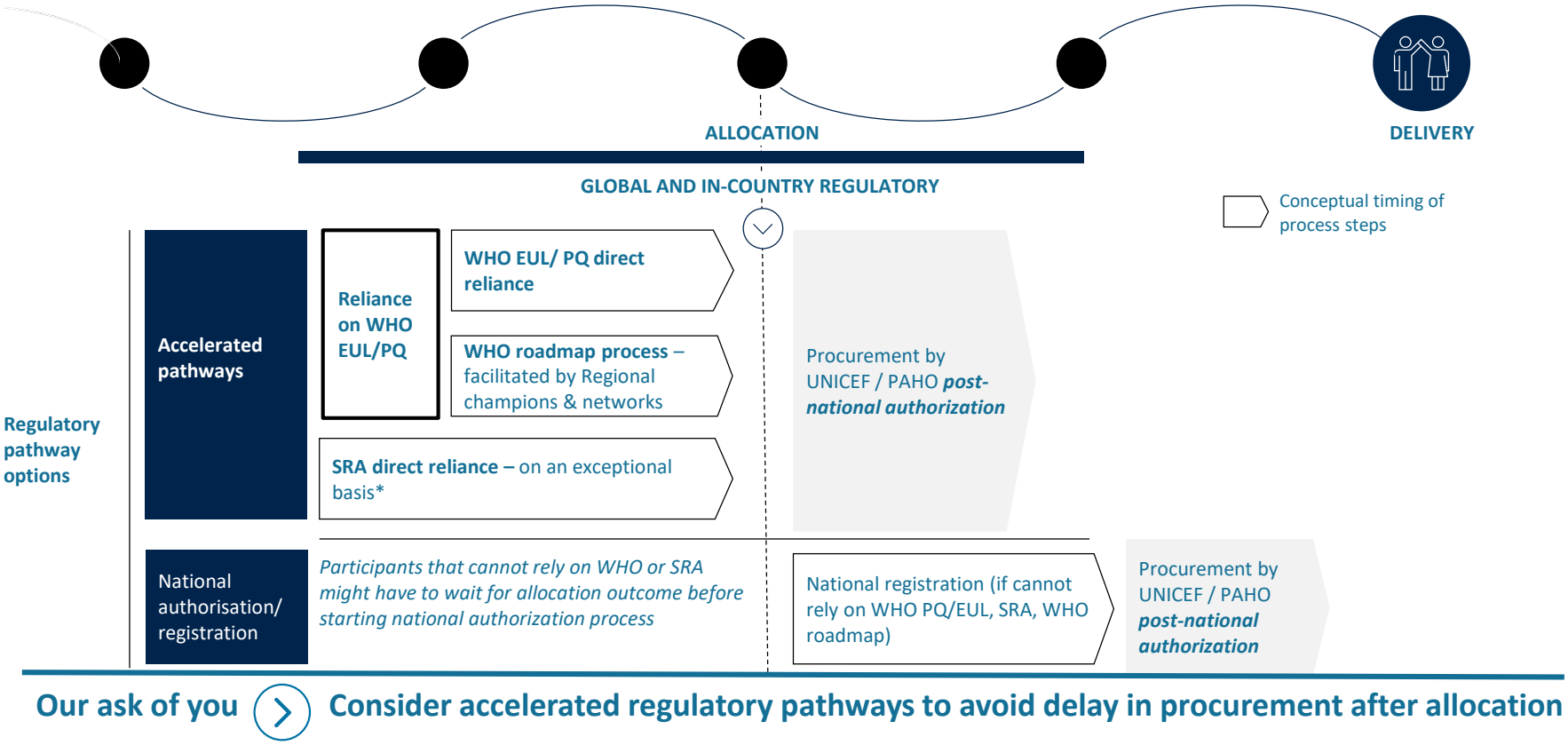


1H – Early equitable access relies on a few front-runner vaccines
2H - Access to large volumes for participants

Illustrative Volume over time, doses per quarter 2021



There are 4 regulatory pathways for country authorization



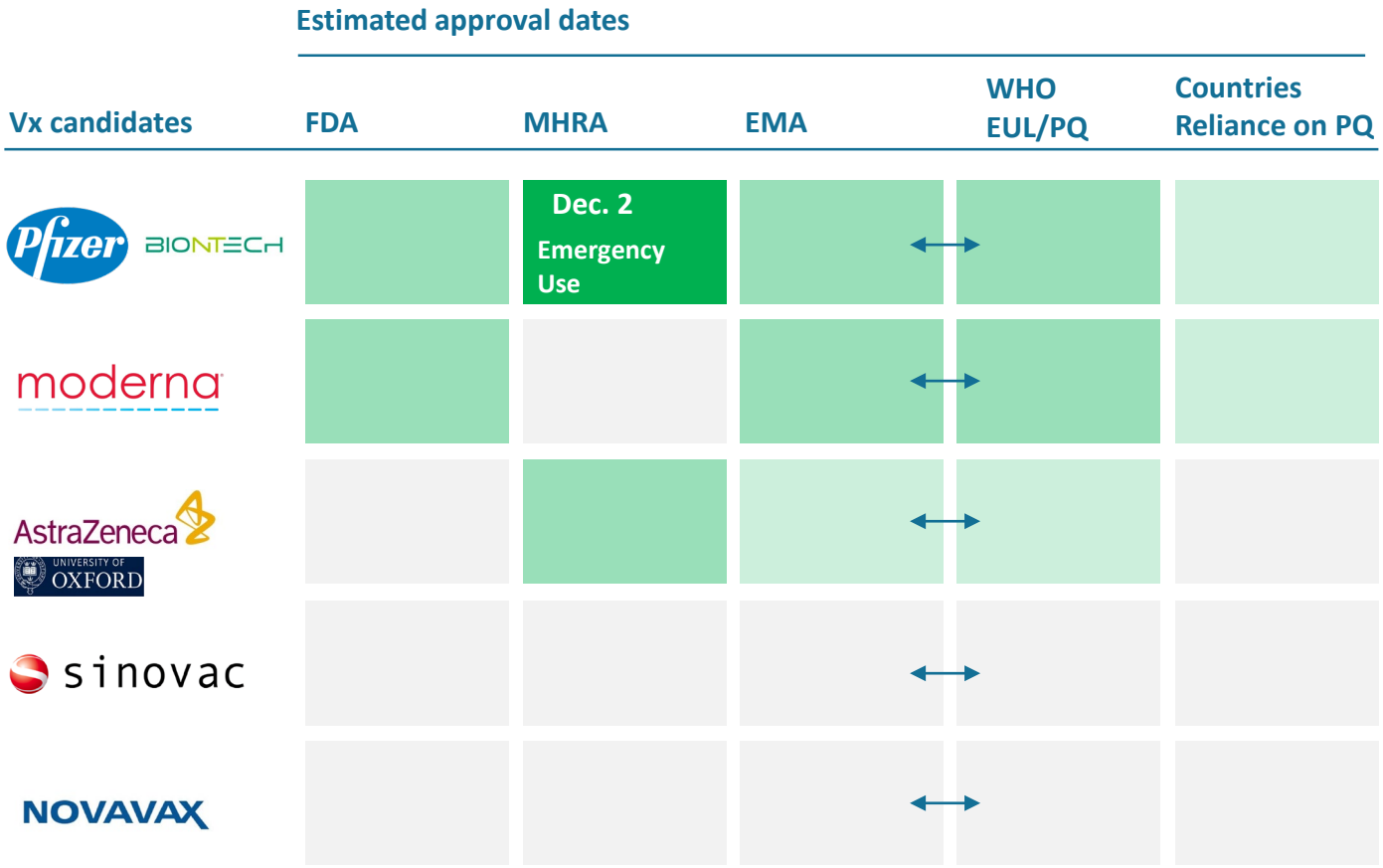
Our ask of you **Consider accelerated regulatory pathways to avoid delay in procurement after allocation**

* SRA reliance to be considered on an exceptional basis, as it would not necessarily include an assessment of the programmatic suitability of vaccine candidates and data sharing could not be facilitated by WHO in that case

Regulatory timeline of key phase III vaccine candidates

Legend (best-case scenarios)

- Vx authorized (emergency or full)
- Approval by End of Dec. 2020
- Approval by End of Feb. 2021
- Approval between March & June 2021 / No info



Indemnification and liability and compensation

Details

- All vaccines supplied through COVAX will undergo a rigorous regulatory process and will be approved for general use
- Given the speed and scale of deployment, manufacturers are unwilling to self-insure for product liability claims and are requiring all participants receiving vaccine doses to indemnify them against such claims
- **Lack of such an indemnification by a participant will limit access to vaccines**
- To decrease time and transaction costs in negotiating indemnity provisions between AMC participants and manufacturers, Gavi is negotiating with manufacturers to have a consistent approach on indemnification across manufactures
- In order to limit the number of claims brought under national courts and to provide fair compensation to injured vaccine recipient, if any , COVAX partners are looking to establish a **global compensation mechanism to cover unexpected serious adverse events (SAEs)** for AMC92 participants to access

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Next Steps

- Legal review to determine if the indemnification requirement and/or accessing the compensation mechanism requires **implementing legislation**
- If implementing legislation is required, **participant to take all necessary steps to enact such legislation as soon as possible** before supply of vaccines under COVAX begins
- COVAX is working to obtain the **cooperation of the International Development Law Organization (IDLO)** to assist interested AMC-eligible participants in respect of the above, should they so desire

What we are doing to prepare for arrival of vaccine…

- **Engaging with manufacturers and securing supply** from a large, diversified portfolio
- **Standing up a fair and equitable allocation mechanism** that ensures all participants get vaccine from the COVAX Facility at the same time
- **Raising funding** for the COVAX AMC financial instrument to support AMC eligible participants
- **Developing a No-Fault Compensation Scheme** to ensure Indemnification and Liability issues do not delay delivery of doses to AMC economies
- **Implementing a governance mechanism** to ensure the voices of all participants are heard
- **Engaging with participants** to support joining COVAX and preparing for the arrival of doses

…and what you can be doing

- **Build A National Task Force** - Form a group responsible for putting the planning together; assign a leader/focal point.
- **Develop a national plan** - Use all partners and planning tools available
- **Secure additional financing** - Work with the World Bank and other MDB financing teams to confirm eligibility, apply for financial resources
- **Prepare for delivery now** – Focus on **indemnification and liability**, prime your **regulatory processes**, and prepare any needed infrastructure
- **Communicate actively** - Keep an open line with the COVAX Facility

Back-up slides

Latest results from Pfizer/BioNTech, Moderna, AstraZeneca and Gamaleya

	Pfizer/BioNTech (Approved by MHRA on Dec. 2)	Moderna	AstraZeneca / University of Oxford	Gamaleya National Center of Epidemiology and Microbiology
Platform	mRNA	mRNA	ChadOx 1 vector	Ad26 >> Ad5 prime-boost
Date of press release	November 18, 2020	November 30, 2020	November 23, 2020	November 24, 2020
Preliminary point estimate of vaccine efficacy	**95% (p<0.0001)**	**94.1% (p<0.0001)**	**70% (p<=0.0001) (pooled)** **90% and 62% (LH and HH regimens[1]) (p<=0.0001)**	91.4% 28 days post dose I (7days post dose 2) Statistical significance not reported
Phase 3 study enrollment	43,661 participants to date, 41,135 of whom have received a second dose of the vaccine candidate	>30,000 participants	UK trial - 12,390 subjects, 2,742 with LH (90% efficacy) UK/Brazil trial– 10,300 HH 62% efficacy	40,000 participants 22,000 vaccinated with the first and >19,000 with second doses of the vaccine
Total number of cases	**170 cases (8 in vaccine group)** **10 severe cases (9 in placebo, 1 in vaccine group)**	**196 cases (11 in vaccine group)** **30 severe cases (incl. 1 death), all in placebo group**	**131 cases across 2 trials** **No severe cases in vaccines**	**39 cases** **No information provided on case severity**
Cold chain	-80^{0}C, 2-8^{0}C for up to 5 days	-20^{0}C, 2-8^{0}C for up to 30 days	Storage, transport and handled 2-8^{0}C for up to 6 months	2 versions: • Lyo 2-8^{0}C • Liquid Frozen -200C
Plans for licensure	Plan to submit US FDA for EUA and EMA and WHO PQ	Submitted on Nov 30th: EUA with US FDA and EMA conditional marketing authorisation	EMA, MHRA, PQ	Emergency authorization in Russia Plan for global license

1 LH – Low dose followed by High dose, HH – 2 doses of high dose formulation