PHAP
PHARMACEUTICAL & HEALTHCARE ASSOCIATION OF THE PHILIPPINES

Supplying Safe and Effective COVID-19 Vaccines

Presented by:

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#wearePHAP

PHAP represents the research-based biopharmaceutical Industry in the Philippines

IFPMA

GLOBAL SELF-CARE FEDERATION

Our Members

Abbott, astellas, AstraZeneca, Bayer, Boehringer Ingelheim, Calmoseptine Ointment, Champion, Ferring Pharmaceuticals, Galderma, GlaxoSmithKline, Glenmark, Eisai, Johnson & Johnson, Merck, MSD, mdi metro drug, mundipharma, Novartis, novo nordisk, Otsuka, Panpharma Healthcare, Inc., Pfizer, PharmAsia - Cuvest, Inc., Philusa Corporation, Qualimed Pharma Inc. Quality and Affordability Combined, Roche, RL, Sanofi, Swisspharma Research Laboratories, Inc., Takeda, Taisho Pharmaceutical, Vizcarra Pharmaceutical, Zuellig Pharma, AC Health An Ayala Company, The Generics Pharmacy, Mercury Drug, watsons, IQVIA

PROTECT EVERYONE

NO ONE LEFT BEHIND

STRONGER TOGETHER

Speeding up vaccine development & scaling up manufacturing

REPURPOSE EXISTING & TEST NEW TREATMENTS

Rapidly screen the industry's vast libraries of medicines to identify potential treatments and undertake numerous clinical trials to test new and existing therapies.

SECURE ESSENTIAL SUPPLIES FOR MEDICINES & VACCINES

Work to secure continuity of supply for all essential medicines, and vaccines for patients with other life-threatening diseases, urging governments to implement policies and decisions that facilitate access for all those in need.

SHARE REAL-TIME CLINICAL TRIAL DATA WITH GOVERNMENTS & OTHER COMPANIES

Share real-time clinical trial data with governments and other companies around the world to advance the development of additional therapies.

INCREASE & SHARE MANUFACTURING CAPACITY FOR MEDICINES & VACCINES

Increase our manufacturing capabilities and share available capacity to ramp up production once a successful vaccine or treatment is developed.

SPEED UP R&D OF SAFE & EFFECTIVE VACCINES

Use our expertise and know-how to speed up the development of safe and effective vaccines to prevent COVID-19 in partnership with others.

SUPPORT GLOBAL HEALTHCARE SYSTEMS

Use our medical expertise to support global healthcare systems to manage the unprecedented increase in pressure they are experiencing.

DEVELOP DIAGNOSTIC TESTING & SECURE CONTINOUS SUPPLY

Develop and scale up the capacity of diagnostics testing for COVID-19 patients as much as possible and secure the continuous supply of diagnostic test kits to countries around the world.

Research-based companies are responding & stepping up efforts to develop diagnostics, vaccines and treatments

Review of existing portfolios

Companies reviewed existing drug and vaccine portfolios to see if any research can help with the development of new, or repurposed treatments or vaccines.

These include diagnostics and biomarkers, approved therapies or compounds in development.

Companies engaging in R&D collaborations

Research networks composed of R&D companies, universities, research institutions, governments and NGOs collaborated to fast track the development of diagnostics, treatments and vaccines.

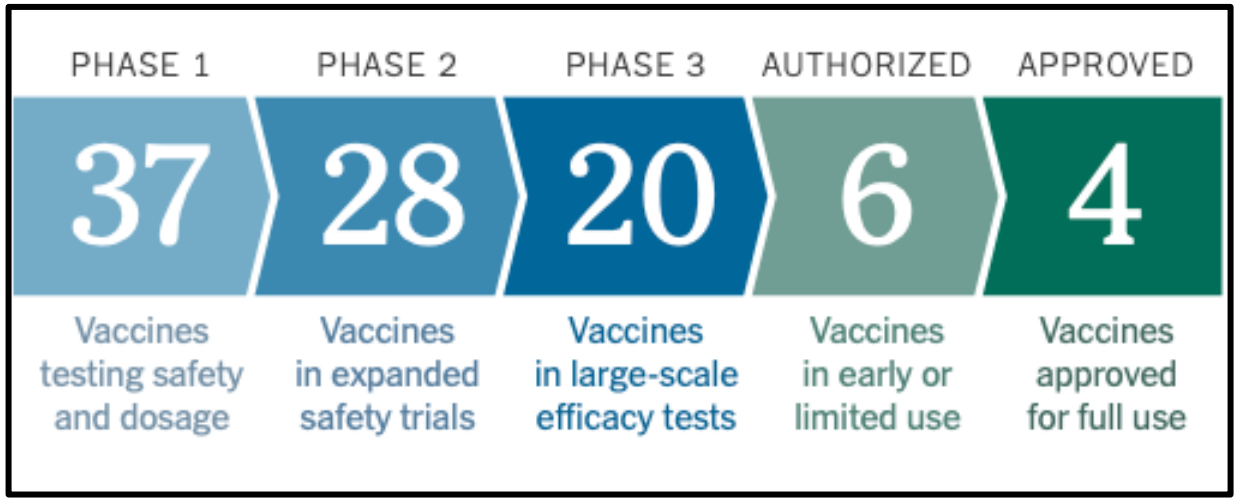
Some of these networks include CEPI, IMI, ACT Accelerator, among others.

Fast-tracking the clinical development

An outbreak paradigm was taken to facilitate the development and conduct of clinical trials, significantly cutting the time without compromising safety and efficacy.

IFPMA. COVID-19 hub. Accessed from https://www.ifpma.org/covid19/
The COVID-NMA Initiative. Accessed from https://www.covid-nma.com/dataviz/#void
The COVID-19 Candidate Vaccine Landscape. Accessed from https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines
Status of COVID-19 Vaccines within WHO EUL/PQ Evaluation Process. Accessed from https://extranet.who.int/pqweb/sites/default/files/documents/Status_COVID_VAX_16Feb2021.pdf
Lurie, et al. 2020. Developing COVID-19 Vaccines at Pandemic Speed. Accessed form https://www.nejm.org/doi/pdf/10.1056/NEJMp2005630?articleTools=true

In less than a year, we now have 3 vaccines listed for WHO Emergency Use List



Leading vaccines

Developer	How It Works	Phase	Status
Pfizer-BioNTech	mRNA	2 3	Approved in several countries. Emergency use in U.S., E.U., other countries.
Moderna	mRNA	3	Approved in Switzerland. Emergency use in U.S., U.K., E.U., others.
Gamaleya	Ad26, Ad5	3	Early use in Russia. Emergency use in other countries.
Oxford-AstraZeneca	ChAdOx1	2 3	Emergency use in U.K., E.U., other countries.
CanSino	Ad5	3	Limited use in China.
Johnson & Johnson	Ad26	3	
Vector Institute	Protein	3	Early use in Russia.
Novavax	Protein	3	
Sinopharm	Inactivated	3	Approved in China, U.A.E., Bahrain. Emergency use in Egypt, other coutries.
Sinovac	Inactivated	3	Approved in China. Emergency use in Brazil, other countries.
Sinopharm-Wuhan	Inactivated	3	Limited use in China, U.A.E.
Bharat Biotech	Inactivated	3	Emergency use in India.

THE COMPLEX JOURNEY OF A VACCINE

R&D

APPROVED
Safe & effective by a regulatory authority.

1 2 3 4 5 6

:ACTURING CHAIN

DAY "0"
Vaccine manufacturing involves 6 basic steps. Each step can be performed in different sites situated in different countries.

FILLING
The vaccine is filled into the final container. This could be a vial or a prefilled syringe.

PACKAGING
The vaccine in the final container is labeled in accordance with regulatory requirements and packed, ready for shipping to the customer.

LOT RELEASE
Quality assurance confirms the product has been manufactured and tested in accordance with the correct procedures. The national regulatory

+/- 24 MONTHS
Vaccine of consistent quality.

A vaccine typically travels through several different sites before being ready for shipment.

Quality Control represents up to **70%** of manufacturing time.

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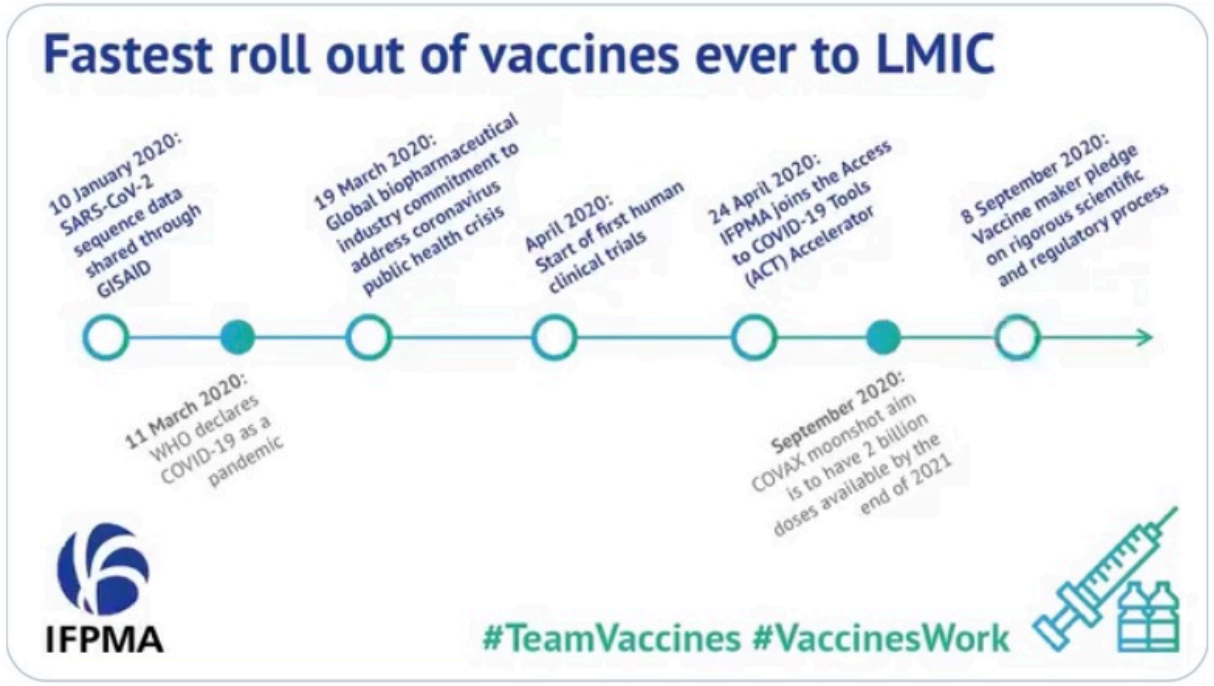
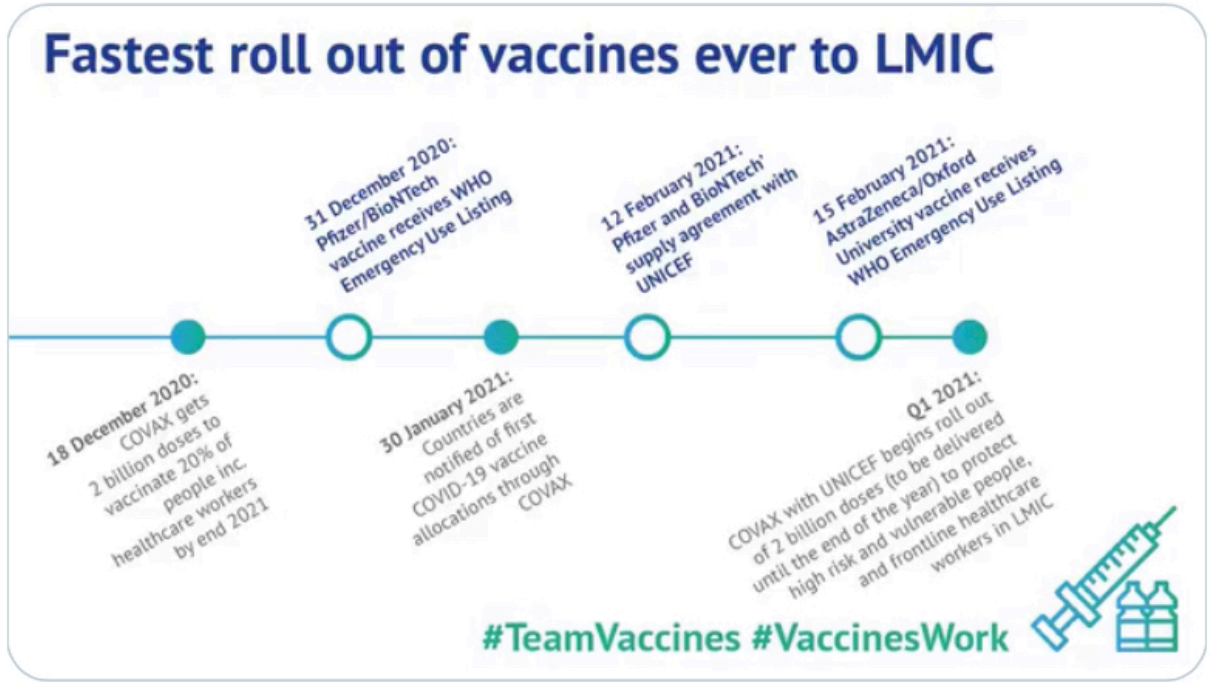
SHIPMENT → DISTRIBUTION

We are committed to the urgent, efficient & equitable roll-out of vaccines



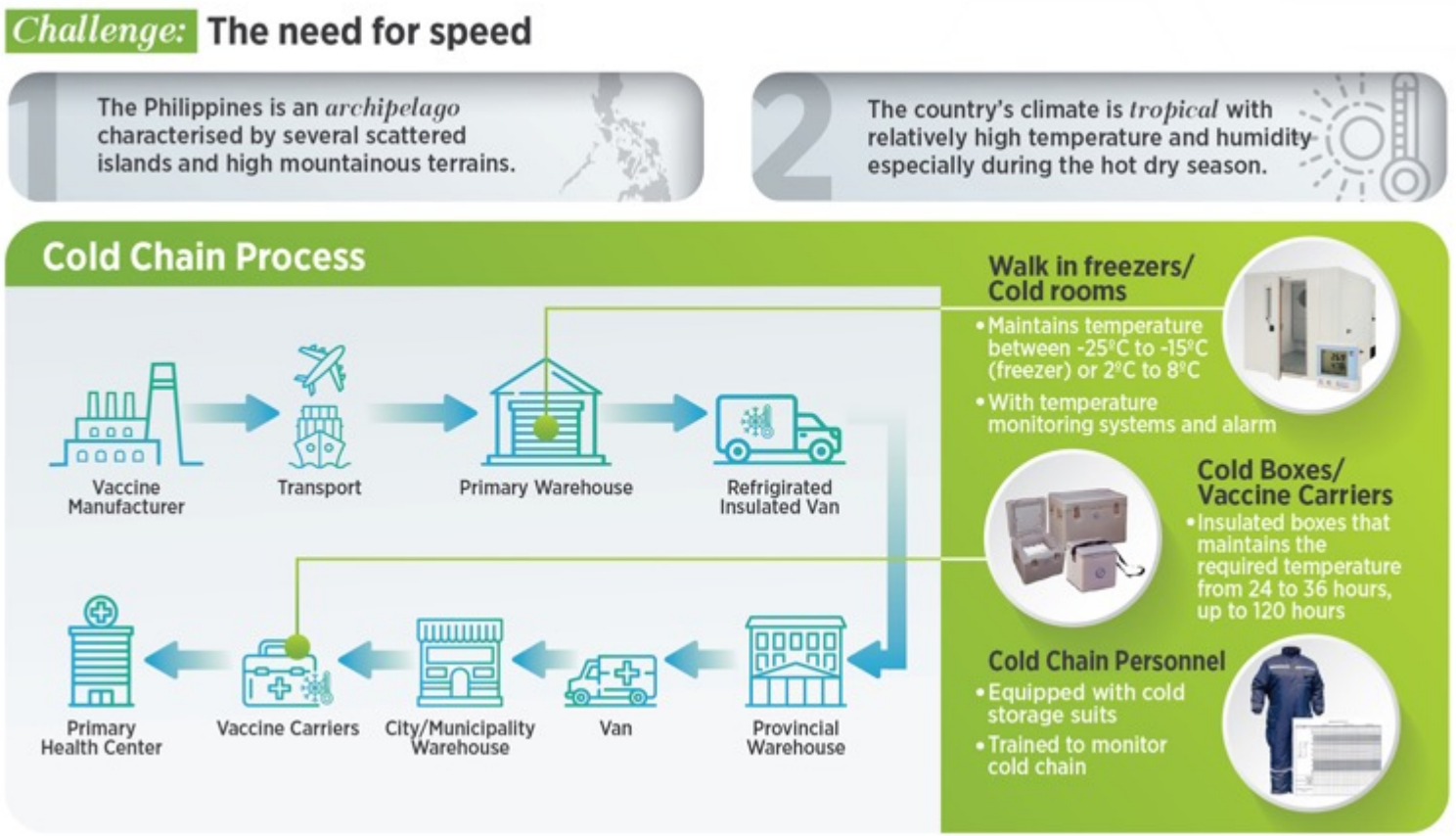


We are in a position to support the vaccine roll-out

GOAL

Safe, efficient and timely distribution & access to an approved COVID-19 vaccine

Potential Covid-19 Vaccine Candidate Storage Requirements	
Description	**Temperature Range**
❄ Cold	2ºC to 8ºC
❄❄ Freezer	-25ºC to -15ºC
❄❄❄ Ultra-Cold	-80ºC to -60ºC



We are committed to leverage on our deep experience & expertise on vaccine rollout

Good Storage Practice

- Quality management system is in place
- Vaccines are handled by well-trained and competent personnel throughout the supply chain
- Regular monitoring and recording of temperature
- Conduct of temparature mapping for areas of fluctuations
- Appropriately equipped tranpsort vehicles for temperature maintenance
- Properly labeled and systems for traceability in place
- Contingency plans for power failure and other cold-chain emergencies

Recommendations:

Air, land and sea connectivity – The pandemic has disrupted the movement of persons and goods. There is need to re-establish these links and prioritize the entry of approved vaccines.

People, facilities and infrastructure – Vaccines need to be shipped and transported in temperature-controlled environment. Vaccines must be handed by trained staff as they are time and temperature-sensitive vaccines.

Border management – Timely regulatory approvals and storage and clearance of ports and health authorities will be crucial.

Security – Vaccines are highly-valuable and that security arrangements will be necessary to ensure shipments are secured.

We are partnering for vaccine rollout

PRIVATE SECTOR INITIATIVES

Integrated logistics for efficient global distribution

PARTNERING WITH GOVERNMENT

Pooling of all government and private sector efforts for vaccine roll-out

AC Health
An Ayala Company

ZUELLIG PHARMA
making healthcare more accessible

We are also not immune from this pandemic

- Significant contraction in the pharmaceutical market (-11%, Q3 2020), worse for the ethical/ prescription market (-18.2%, Q3 2020)
  - Reduction in hospital visits (-72%)
  - Significant increase in operational costs
- Imposition of price control measures at the height of the pandemic
  - Phase 1: 133 products, up to 50%
  - Phase 2: 73 products, up to 93%
  - Target expansion: 2,394 products
- Proposals for vaccine indemnification shouldered by the pharmaceutical industry
- Regulatory delays, country specific requirements (e.g. local phase IV trials)
- Partners vs suppliers
- Over regulation vs collaboration
- Uncertainty of business environment

Challenges in Logistics

Fluctuating Forecasts and Inventory

Unforeseen and unplanned expenses

Changing policy environment

We need to work together to make the region 'Pandemic Proof'

ENVIRONMENT CONDUCIVE TO INNOVATION

AMGEN · ascletis · BD · BIOMÉRIEUX · Bristol-Myers Squibb · 康希诺生物 CanSinoBIO · CUREVAC · CSL Behring Biotherapies for Life™ · CytoDyn · EUSAPharma · FUJIFILM FUJIFILM Holdings Corporation · GILEAD · Humanigen · inovio · IPSEN Innovation for patient care · moderna · NeuroRx · NOVAVAX · OncoImmune · phs Pharmstandard · REGENERON SCIENCE TO MEDICINE · ROIVANT SCIENCES · SERUM INSTITUTE OF INDIA Cyrus Poonawalla Group · SHIONOGI · SINOPHARM · sinovac · SK biopharmaceuticals · synairgen · teva · ucb · 中源协和 VCANBIO

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#wewillnotrest
#wearePHAP
#TeamVaccines

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