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APEC Action Plan on Vaccination Across the Life-Course

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APEC ACTION PLAN ON VACCINATION ACROSS THE LIFE-COURSE

“It has never been more apparent that vaccination is critical to the strength of our economies. APEC has a unique role to play in supporting the region’s effective trade, regulation and investment in vaccines to protect our population, both in the midst of COVID-19 and far beyond.”

- Dr. Rebecca Sta Maria, Executive Director of the APEC Secretariat

“Vaccination is one of the world’s most important and cost-effective public health measures. While the priority now is to vaccinate as many people as possible against COVID, we still need to be able to provide robust immunization programs against other vaccine-preventable diseases so that COVID’s impact is not compounded by additional outbreaks. A life-course approach to vaccination requires that immunization schedules and access to vaccinations respond to an individual’s stage in life, their lifestyle and specific vulnerabilities or risks to infectious disease that they may face.”

- Dr. Michelle McConnell, Chair of the APEC Life Sciences Innovation Forum

Executive Summary

Vaccination is one of the world's most important and cost-effective public health measures. By taking a life-course approach to immunization, which entails strategies to maximize protection of populations across age groups and life circumstances, APEC economies can better prevent infection and disease for all populations, fortify themselves against unforeseen challenges, improve economic and social inclusion, and enable economic growth. Nevertheless, despite the compelling case for investing in immunization, there remains insufficient investment in this component of health systems.

The present moment provides a critical opportunity to galvanize decision-makers and cohere the Asia-Pacific region's approach to developing resilient and sustainable life-course immunization programs. Developed by the APEC Life Sciences Innovation Forum (LSIF) Vaccines Task Force and the APEC Health Working Group (HWG), the ***APEC Action Plan on Vaccination Across the Life-Course*** is a comprehensive strategy for enhancing the resilience and sustainability of immunization programs in APEC member economies through the 2021-2030 decade. Over a set of key pillars and policy targets, the action plan puts forth a vision that by 2030, all 21 APEC member economies will have implemented resilient and sustainable life-course immunization programs to protect the health and wellbeing of all populations. This work builds previous international cooperation on vaccination within APEC as well as the World Health Organization (WHO), and aims to support APEC economies in achieving the WHO [Immunization Agenda 2030](#) (IA2030).

The measures that APEC economies introduce now to foster strong life-course immunization programs will help the region face the ongoing COVID-19 pandemic, in addition to improving health systems and pandemic preparedness in the longer-term. Key measures include promoting recognition of the value of vaccination and vaccine innovation; prioritizing access to and uptake of vaccination across the life-course; building whole-of-government capacity in health security and pandemic preparedness; strengthening confidence in vaccination; enabling investment and innovation; accelerating regulatory harmonization; and establishing mechanisms for sustainable immunization financing.

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APEC Action Plan on Vaccination Across the Life-Course: Summary

PILLAR 1: Promote recognition of the value of vaccination and vaccine innovation by policymakers and key decision-makers

Target 1.1:

By 2030, all APEC member economies have introduced standardized systems, based on the respective needs and priorities of economies, to generate data on direct and indirect benefits of vaccination that meet quality standards, including the full societal value, to drive policy decisions and prioritization

Indicator: Percentage of APEC economies that have in place a facility to generate data on both the direct and indirect benefits of vaccination

Target 1.2:

By 2030, all APEC member economies have introduced value assessment frameworks, taking into account both the direct and indirect economic and societal value of vaccination, to help drive policy and decision-making processes in conjunction with other policymaking priorities

Indicator: Percentage of APEC economies that utilize comprehensive value assessment frameworks for the evaluation of immunization programs' health, social, and economic impact to drive vaccine policy and decision-making

Target 1.3:

By 2030, all APEC economies commit to incorporating the latest knowledge and data on the value of vaccination as part of the decision-making processes of leaders in conjunction with other policymaking priorities

Indicator: Percentage of APEC economies that have established a communications plan to translate data and analysis of value of vaccination into policy recommendations accessible to stakeholders

PILLAR 2: Prioritize access to and uptake of vaccination across the life-course for all individuals

Target 2.1:

By 2030, each APEC member economy has established comprehensive domestic immunization calendars and immunization programs that cover all stages of life (including all ages) to provide broad access to protection against vaccine-preventable diseases for all populations

Indicator: Vaccine coverage rate for routine immunizations in each APEC economy, and across the region as a whole

Target 2.2:

By 2030, all APEC economies maximize vaccine coverage for all populations where appropriate – including foreign residents, migrant workers, refugees and stateless persons – through immunization programs that ensure equitable access across the life-course

Indicator: Number of new vaccines, underutilized vaccines, and vaccines with expanded indications introduced into the public immunization programs of each APEC economy over the decade, including booster programs and travel-related vaccinations

Target 2.3:

APEC economies regularly and creatively engage in impactful partnerships with stakeholders to encourage vaccination

Indicator: Percentage of APEC economies that have put in place a team and/or process dedicated to maintaining stakeholder partnerships to incentivize vaccines uptake

PILLAR 3: Build whole-of-government capacity in health security and pandemic preparedness

Target 3.1:

By 2030, all APEC economies have established mechanisms to effectively mobilize resources in order to deliver vaccines during health emergencies

Indicator:

- Establishment of cross-sector dialogue mechanisms or fora to develop strategy for emergency resource mobilization
 - Regular participation by APEC economies in the mechanism
-

Target 3.2:

By 2030, all APEC economies have established recovery strategies for their immunization programs in the aftermath of acute health emergencies situations and/or humanitarian crises

Indicator: Number of APEC economies that have established not only a pandemic preparedness strategy, but also pandemic recovery strategy with “catch-up” immunization embedded into this strategy

Target 3.3:

By 2030, all APEC economies have full surveillance and monitoring capacity to track any risk of health emergencies due to vaccine-preventable disease outbreaks, and to ensure progress towards vaccines uptake across the life-course

Indicator: Percentage of economies that have designed a comprehensive process for collecting and evaluating data on the uptake of vaccines, the status of infectious diseases, changing environmental conditions, and any emerging resistance patterns

PILLAR 4: Strengthen confidence in vaccination and build resilient immunization programs

Target 4.1:

By 2030, all APEC economies have established rapid, agile and responsive systems that can assess areas of systemic vulnerability, identify gaps, and mitigate the risk of threats to confidence

Indicators: Percentage of APEC economies that have put in place a team with the necessary skills and/or process designated to analyze system vulnerabilities and address emerging or potential threats to immunization

Target 4.2:

By 2030, all APEC economies have full monitoring and response capacity to understand crises in vaccines confidence as well as the necessary strategies to address issues

Indicator: Percentage of APEC economies which conduct in depth domestic specific studies to understand barriers to vaccination

Target 4.3:

By 2030, all APEC economies have active and productive channels of engagement with healthcare professionals (HCPs) that help to educate and empower them to advocate for vaccination and provide reassurance to patients with doubts about vaccination

Indicator:

- Percentage of economies that have put in place a communications team and/or process to build skills to manage patients who may be hesitant
 - Percentage of APEC economies with well-defined scheduled for HCP vaccination
-

Target 4.4:

By 2030, all APEC economies maintain communications strategies – including digital strategies – to ensure the dissemination of clear, accessible, and accurate information about vaccination

Indicator: Percentage of APEC economies that have put in place a communications team with the skills to implement a communications program which promotes confidence in vaccination among the public and HCPs

PILLAR 5: Enable investment and innovation in vaccine R&D, manufacturing, and delivery

Target 5.1:

By 2030, all APEC economies establish policies and procedures that foster public-private dialogue between vaccine producers and governments in order to chart an optimal course for encouraging investment in innovation

Indicator: Percentage of APEC economies that have consolidated a private sector strategy to guide engagements with vaccine or broader pharmaceutical producers

Target 5.2:

By 2030, all APEC economies maintain mechanisms to enhance producers' understanding of local demand and health needs, in order to inform R&D and reduce the commercial uncertainty of new investments

Indicator: Percentage of APEC economies that have consolidated a private sector strategy to guide engagements with vaccine or broader pharmaceutical producers

PILLAR 6: Accelerate regulatory harmonization for vaccines across APEC economies

Target 6.1:

APEC-wide endorsement of and adherence to a set of agreed regulatory practices including adherence to globally recognized regulatory harmonization recommendations and guidelines, in order to ensure effective supply chains and sufficient inventory

Indicator:

- APEC-wide endorsement and recommendation for members to implement globally recognized regulatory harmonization guidelines for vaccines
 - APEC workshops and capacity building to support implementation
-

Target 6.2:

By 2030, all APEC economies have undertaken capacity building initiatives to accelerate adoption of globally recognized recommendations and guidance on regulatory harmonization for vaccines

Indicator: Percentage of economies where capacity-building trainings have been designed and initiated, involving coordination between global vaccine producers, local producers, and regulators

Target 6.3:

Continuing multisectoral collaboration within and across APEC economies to ensure robust supply chain and access to vaccines across the globe

Indicator: APEC endorsement of recommendations on global vaccine supply chain security and incentives for investment and expanded access

PILLAR 7: Establish proven & innovative mechanisms for sustainable immunization financing

Target 7.1:

By 2030, all APEC economies make commitments on economy-wide immunization funding

Indicator: Percentage of APEC economies that have written and introduced an Economy-wide Immunization Plan with provisions for the life-course and concrete proposals for financing strategies

Target 7.2:

Establishment of joint platforms within and across APEC economies in order to foster collaboration to identify and resolve financing challenges

Indicator: Percentage of APEC economies with health or other officials participating in an APEC-wide dialogue on financing strategies for immunization programs

Target 7.3:

Each APEC economy utilizes decentralized strategies to the extent necessary in its given context, in order to facilitate local alignment of funding and needs

Indicator: Percentage of APEC economies that have conducted an investigation of the feasibility, benefits, and risks of introducing decentralized strategies into their immunization plans

ABOUT APEC

The Asia-Pacific Economic Cooperation (APEC) is a regional economic forum consisting of 21 member economiesⁱ who aim to create greater prosperity for the people of the region by strengthening health systems in support of inclusive and sustainable economic growth. APEC operates as a cooperative, multilateral forum. Member economies participate on the basis of consensus and respect for views of all participants. There are no binding commitments or treaty obligations within APEC. Commitments are undertaken on a voluntary basis and the principle of consensus and are implemented as appropriate based on the individual circumstances and conditions in each economy. Capacity building programs play an important role in APEC as technical skills, resources, and capabilities vary considerably across the 21 member economies. The APEC Action Plan on Vaccination Across the Life Course was developed in accordance with these fundamental principles and guidelines.

FRAMEWORK

Developed by the APEC Life Sciences Innovation Forum (LSIF) Vaccines Task Force and the APEC Health Working Group (HWG), the ***APEC Action Plan on Vaccination Across the Life-Course*** is a comprehensive strategy for enhancing the resilience and sustainability of immunization programs in APEC member economies through the 2021-2030 decade. By taking a life-course approach to immunization, APEC economies can better prevent infection and disease for all individuals, thereby protecting their populations, fortifying against unforeseen challenges, improving economic and social inclusion, and enabling economic growth. Investing in health systems that prioritize immunization will also enable effective delivery of new vaccines as they become available, which will be of crucial importance in the face of emerging health challenges such as the COVID-19 pandemic.

This action plan builds previous international cooperation on vaccination, namely the World Health Organization (WHO) “Decade of Vaccines” (2011-2020) and Global Vaccine Action Plan. In 2020, APEC Economic Leaders endorsed the [Kuala Lumpur Declaration](#), which stated: “We reaffirm the need to cooperate constructively on COVID-19 including the research and development, production, manufacturing and distribution of diagnostic tests, essential medical products and services, therapeutics and vaccines. We highlight the importance of facilitating equitable access to safe, quality, effective and affordable vaccines and other medical countermeasures that are vital to safeguard people’s health and well-being, while incentivizing innovation.” In 2021, the APEC Ministers Responsible for Trade Meeting Joint Statement stated: “Recognising the role of extensive COVID-19 immunisation as a global public good, we urgently need to accelerate the production and distribution of safe, effective, quality-assured, and affordable COVID-19 vaccines.” Ministers also recognised the importance of ensuring the safety, efficiency, and resilience of supply chains for

ⁱ Australia; Brunei Darussalam; Canada; Chile; People’s Republic of China; Hong Kong, China; Indonesia; Japan; Republic of Korea; Malaysia; Mexico; New Zealand; Papua New Guinea; Peru; The Philippines; Russia; Singapore; Chinese Taipei; Thailand; The United States; Viet Nam

COVID-19 vaccines and related goods for the region's recovery from the COVID-19 pandemic.

As we look towards the next decade, more work is needed to tailor global strategies and approaches to regional contexts. This action plan, over a set of key pillars and policy targets, aims to enable APEC economies to achieve the WHO [Immunization Agenda 2030](#) (IA2030), with a focus on fostering vaccination across the life-course.

Vision

By 2030, all 21 APEC member economies will have implemented resilient and sustainable life-course immunization programs, with the objective of achieving widespread uptake of vaccination across the life-course and thereby protecting the health and wellbeing of all populations.

Pillars

The core recommendations of the APEC Action Plan on Vaccination Across the Life-Course are to:

1. Promote recognition of the **value of vaccination and vaccine innovation** among policymakers and key decision-makers;
2. Prioritize access to and uptake of **vaccination across the life-course** for all individuals;
3. Build whole-of-government capacity in health security and pandemic preparedness;
4. Strengthen **confidence in vaccination** and build resilient immunization programs;
5. Enable **investment and innovation** in vaccine R&D, manufacturing, and delivery;
6. Accelerate **regulatory harmonization** for vaccines across APEC economies; and
7. Establish proven and innovative mechanisms for **sustainable immunization financing**.

Each pillar above is addressed in the following sections, each with the following structure:

- **Context** to establish the key issues that APEC economies face in implementing the pillar;
- **Targets** which establish an achievable outcome;
- An **Indicator** to measure progress against the Target;
- **Actions** for APEC economies to consider implementing in order to accelerate progress.

BACKGROUND

The ***APEC Action Plan on Vaccination Across the Life-Course*** is a comprehensive strategy for enhancing the resilience and sustainability of life-course immunization programs in APEC member economies through the 2021-2030 decade. With more resilient and sustainable life-course immunization programs, APEC economies can better prevent infection and disease for all individuals, thereby protecting their populations, improving their economic and social inclusion, and accelerating potential economic growth. The current COVID-19 pandemic underscores the exigency of protecting populations and ensuring the highest possible coverage against vaccine-preventable diseases.

Vaccination is one of the world's most important and cost-effective public health measures. Vaccines save between 2 and 3 million lives every year, and are expected to keep millions of people out of poverty over the coming decade, clearly indicating a strong societal return on investment.^{1,2} Vaccination can also reduce the risk of antimicrobial resistance (AMR) that emerges from the misuse of antibiotics against infectious diseases, which in itself is projected to take 10 million lives annually by 2050.³ Along with sanitation and water safety, vaccination stands as one of the most impactful life-saving public health interventions.

A life-course approach to vaccination requires that immunization schedules and access to vaccination respond to an individual's stage in life, their lifestyle, and specific vulnerabilities/risks to infectious disease that they may face. This comprehensive approach to disease prevention can improve equity in health outcomes – across gender, age, and social group – while also making an impact that goes far beyond improved health. For societies and governments, significant savings stem from vaccination. This includes reduced health burden on social systems, most notably a reduction in treatment costs (e.g., physician fees, drugs, hospitalization). Such savings have a powerful economic impact worldwide, including in low and middle-income contexts where substantial medical expenditure remains out of pocket.^{4,5} For example, it has been estimated that measles, rotavirus, and pneumococcal conjugate vaccines could ultimately help avert \$4.6 billion in out of pocket expenses in Gavi-eligible economies between 2016 and 2030.⁶ A study of five major EU economies estimated that full implementation of a vaccination program for influenza alone could result in savings of over €1.6 billion in reduced primary care visits and hospitalizations.⁷

In addition to savings, immunization's economic benefits can include mitigating the economic burdens associated with illness-induced wage and productivity loss, especially when immunization takes place across all age groups. One study of a Gavi proposal to extend the use of various childhood vaccines to 75 low-income economies found that the labor productivity benefits from expanded coverage alone could yield a return on investment of 12-18% between 2005 and 2020.⁸ Among adults as well, the impact of addressing vaccine-preventable disease is substantial. In Indonesia, the cost of lost productivity resulting from influenza and resulting lower respiratory tract

infections was estimated at \$866 million in one year alone, with an additional \$19.2 million in direct medical costs.⁹ In the US, the economic burden of adult-vaccine-preventable diseases was found to amount to as much as \$15 billion in a single year.¹⁰

Despite the compelling case for investing in immunization, there remains insufficient investment in this component of health systems. In the APEC region, vaccine coverage rates have stagnated since the turn of the century, with progress among adults and the elderly of particular concern. Given our aging populations and the rising prevalence of chronic diseases, renewed and reenergized efforts are needed in order to improve access to vaccination services across the life-course; disseminate accurate information about the value, safety, and essential benefits of vaccination; and mitigate the impact of health crises in APEC economies.

The present moment, during which the COVID-19 pandemic has emerged as the world's top health, economic, and social priority, provides a critical opportunity to galvanize decision-makers and cohere the Asia-Pacific region's approach to developing resilient and sustainable life-course immunization programs. With widespread infections and a heavy death toll, the pandemic offers a stark demonstration of the opportunity cost of investment in immunization programs, and underscores the importance of protecting populations and ensuring the highest coverage possible against vaccine-preventable diseases. Among its benefits, COVID-19 prevention through vaccination helps to safeguard other ongoing health programs, namely routine immunization programs, from having their resources diverted to emergency response and treatment. This is crucial given that even temporary interruptions of routine immunization programs can lead to secondary health crises, which often predominantly affect the most vulnerable.¹¹

The measures that APEC economies introduce now to foster strong life-course immunization programs will help the region face the pandemic, and will also serve the region well in the longer-term, improving health systems and pandemic preparedness in an era when climate change stands to render major health crises an increasingly frequent occurrence, and the prevention of antimicrobial resistance (AMR) is emerging as a top global priority. This action plan puts forth a series of recommendations that will move the APEC region towards resilient and sustainable life-course immunization programs, and in so doing, actionize and achieve the WHO [Immunization Agenda 2030](#) (IA2030).

APEC economies should move to take measures to:

- Promote recognition of the value of vaccination and vaccine innovation;
- Prioritize access to and uptake of vaccination across the life-course;
- Build whole-of-government capacity in health security and pandemic preparedness;
- Strengthen confidence in vaccination and build resilient immunization program;
- Enable investment and innovation in vaccine R&D, manufacturing, and delivery;
- Accelerate regulatory harmonization for vaccines across APEC economies; and
- Establish proven & innovative mechanisms for sustainable immunization financing.

PILLAR 1: Promote recognition of the value of vaccination and vaccine innovation by policymakers and key decision-makers

A wide array of considerations are important for health policymakers' decision-making, from the pursuit of social justice and health equality to practical concerns around public perception of vaccines and the realities of vaccination program management. However, one of the most important elements that should inform decision-making is recognition of the value of vaccination. Vaccination has a variety of positive impacts that accrue across the life-course, making immunization a wise investment in terms of health benefits, social welfare, and economic development. If policymakers recognize these factors as they consider the value of vaccination, they will be better positioned to make decisions for their health systems.

Life-course immunization yields broad community health benefits. If coverage reaches a certain threshold, the individual protection provided by vaccination may also in turn provide immunity for the wider population, helping to protect unvaccinated individuals, including those whose specific conditions or situations preclude them from vaccinating themselves. Furthermore, mass disease prevention reduces dependence on antibiotics, thereby reducing antimicrobial resistance. These health gains in turn free medical resources to tackle other health priorities.¹²

Immunization programs also yield economic benefits. As demonstrated by a research study conducted in the Philippines, vaccination can induce improvements in test scores in children, which yields a return on investment as high as 21% when translated into the earnings of adults.^{13,14} Furthermore, through the reduction of morbidity and mortality to vaccine preventable diseases, vaccination can bring value to the community by averting high costs for medical treatment and lost wages due to caring for sick children.¹⁵ In addition, the economic value of vaccination goes far beyond childhood vaccines. The review of vaccinations provided during childhood helps ensure adult protection, and as with childhood immunization, economic and social benefits accrue from adolescent and adult vaccination. For example, individuals given the influenza vaccine in the US were found to have an approximately 20% reduced chance of suffering from cardiovascular and cerebrovascular disease and a 50% lower risk of mortality from all causes compared to their unvaccinated counterparts¹⁶. Increased life expectancy expands a country's workforce and increases household earning potential, impacting both social equity and poverty.^{17,18}

Along with proper accounting of full health and economic benefits, one crucial aspect of recognizing the value of vaccination is recognizing the value of vaccine innovation. In order to realize the benefits of vaccination (such as those described above), policymakers will need to foster recognition and appreciation of the innovation process. To this end, it may be necessary to counter popular notions of what innovation is and how it is achieved. For example, leaders in health can ensure recognition of the fact that innovation comes in various forms – not only high-profile breakthrough discoveries, but also “incremental” innovations that improve vaccines' efficacy and delivery (for example, new delivery systems, new formulations, or the

introduction of adjuvants that increase vaccines' potency). After recognizing the value of innovation, decision-makers will be tasked with enabling innovation using the tools at their disposal. Pillar 5 of this action plan offers further discussion of this topic.

A proper valuation of vaccines should also affect how APEC economies approach vaccines procurement. Policymakers, rather than making health procurement decisions in the same way that they might for standard commodities, would benefit from selecting suppliers that present the most economically advantageous options in the long-term. This is especially important given the emerging evidence around the risks of purely price-based procurement models, which include reduced competition, product shortages, and potentially reduced vaccine coverage rates – all of which may endanger the long-term effectiveness of immunization programs. Value-based decision-making on vaccines procurement – considering price in the context of factors such as medical need, disease burden, economic benefit, and the efficacy of the vaccine – can help mitigate such risks, while also incentivizing innovation and optimal health outcomes.^{19,20}

Target 1.1:

By 2030, all APEC member economies have introduced standardized systems, based on the respective needs and priorities of economies, to generate data on direct and indirect benefits of vaccination that meet quality standards, including the full societal value, to drive policy decisions and prioritization.

Indicator:

Percentage of APEC economies that have in place a facility to generate data on both the direct and indirect benefits of vaccination

Actions:

- Ministries of Health in APEC economies should develop and/or improve data collection systems for vaccine recipients of all ages and social groups, in order to monitor and evaluate vaccination's impact with consideration for long-term and indirect effects, including the generation of herd immunity. This may entail systematic studies of the value of vaccines in the post-introduction period.ⁱ
- Ministries of Health should work with thought leaders, leading research institutions, and vaccine producers within their jurisdictions in order to identify priority data needs along the product development and vaccine introduction continuum, and to understand how the content should be customized to specific groups of stakeholders.

ⁱ The World Health Organization's [Full Public Health Value Propositions \(FPHVP\)](#), an approach in development for systematically measuring the broader benefits of vaccination, may serve as a guide or springboard for developing systems within APEC economies.

Target 1.2:

By 2030, all APEC member economies have introduced value assessment frameworks, taking into account direct, indirect, economic, and societal value of vaccination, to help drive policy and decision-making processes in conjunction with other policymaking priorities.

Indicator:

Percentage of APEC economies that utilize comprehensive value assessment frameworks for the evaluation of immunization programs' health, social, and economic impact to drive vaccine policy and decision-making

Actions:

- APEC economies collaboratively develop and agree upon a framework for conducting value assessment that considers the full value of vaccination. This includes consideration of the use of health technology assessments (HTA) in order to provide information on vaccine efficacy, cost-effectiveness, and affordability in order to capture the value-for-money of vaccines for the society and government.
- Ministries of Health engage with key stakeholders to define a comprehensive conceptual framework of pathways between immunization and its proposed societal value benefits to contribute to data generation and policy and decision-making.
- National immunization technical advisory groups – the bodies that provide scientific recommendations to their economies' ministries of health to enable evidence-based policies on vaccination – should prioritize representation of experts across different areas of expertise, beyond infectious disease, in order to capture insights on the value of vaccination at the economic, clinical, and societal level.
- Limiting the value of innovation to breakthrough R&D discounts value across the product life-cycle and vaccine ecosystem. Stakeholders should begin to re-frame the evaluation of vaccine innovation to include both breakthrough R&D as well incremental innovation, and to take it into account when conducting value assessments for vaccines.

Target 1.3:

By 2030, all APEC economies commit to incorporating the latest knowledge and data on the value of vaccination as part of the decision-making processes of leaders in conjunction with other policymaking priorities

Indicator:

Percentage of APEC economies that have established a communications plan to translate data and analysis of value of vaccination into policy recommendations accessible to stakeholders

Actions:

- Ministries of Health should clearly and effectively communicate the full societal value of vaccination to stakeholders (e.g., policy-makers, key decision-makers, funders, and legislators) to demonstrate how vaccination aligns with their priorities. This will increase political will and positively influence decisions on public immunization programs, such as new vaccine introduction, expanding cohorts, transition to better products (e.g., combination vaccines or enhanced dosages), funding and procurement, and more.
- Ministries of Health should lend special attention to communicating the value of vaccines innovation, namely through: (i) the categories of innovation across the product and vaccine ecosystem; (ii) the equal importance of breakthrough R&D and incremental innovations; (ii) the notion of innovation as a process to nurture, rather than a single act to enable.
- Utilizing knowledge and data on value of vaccination in their respective contexts, APEC economies should examine their vaccines procurement systems and determine if and where value-based procurement may be introduced in order to incentivize competition, innovation, optimal health outcomes. Global examples that may be followed include the “most economically advantageous tender” (MEAT) approach²¹ or “best value for money”. The execution of health technology assessments (HTAs) may help to provide value-for-money information that shifts focus in procurement from price considerations alone.

VALUE OF VACCINATION DURING A PANDEMIC

The COVID-19 pandemic offers a stark demonstration of the importance of vaccination both during and after a pandemic. Broad access to, and high uptake of, vaccines across the life-course will reduce the economic and public health impact of diseases like COVID-19.

Vaccinations are the main tools allowing primary healthcare professionals to intervene in protecting families and help in developing much-needed herd immunity across their communities. Strengthening immunization programs, therefore, yields both the continuous benefit of routine care before a crisis strikes and the critical benefit of supporting health systems during the crisis by mitigating the impact and incidence of vaccine-preventable diseases which add burden during times of crisis. Having a fully-leveraged immunization program in place when a pandemic like COVID-19 strikes reduces the utilization of hospital beds and critical resources when they are most needed, reduces the incidence of underlying diseases which contribute to severe outcomes, prevents secondary infections in already compromised individuals, and assists in preparation for the implementation of a vaccine when it enters the market.

Because of immunization programs' vital benefits, one crucial consideration is preventing the disruption of these programs during acute health crises, to whatever extent possible. Recent WHO guidance on vaccination in the context of COVID-19 calls for countries to continue the vaccination of newborns as a priority, and continue to vaccinate against influenza and pneumococcal for health workers, adults, and pregnant women wherever feasible. Once COVID-19 is mitigated, countries should reinstate delayed or temporarily suspended immunization services at the earliest opportunity to close immunity gaps.^{1,2} Poor planning for the continuation of routine vaccination can affect trust in vaccination for years to come.

¹ (2020). ["Guiding principles for immunization activities during the COVID-19 pandemic"](#). World Health Organization.

² (2020). ["Immunization in the context of COVID-19 pandemic: Frequently Asked Questions"](#). UNICEF / World Health Organization.

PILLAR 2: Prioritize access to and uptake of vaccination across the life-course for all individuals

Under a life-course approach, vaccination strategies are designed to maximize individuals' ability to protect themselves from infection and maintain good health over the course of their lives and circumstances. It is analogous to a life-course approach to nutrition or exercise – all are important throughout life and help to maximize one's ability to maintain good health. The individual protection provided by vaccination may also in turn provide immunity for the wider population if coverage reaches a certain threshold. Innovations in therapeutic vaccines mean that increasingly vaccines can protect health beyond infancy into adolescence and adulthood, during pregnancy, and for the elderly.

Taking a life-course approach to immunization offers a valuable opportunity to improve health, contribute to a more economically sustainable health system, and promote healthy aging.^{22, 23} The benefits yielded by vaccination are manifold, depending on one's stage in life and individual circumstances:

- Vaccination during pregnancy can benefit a woman and her baby, including providing protection against influenza and/or pertussis, which is associated with hospitalization for the woman and birth defects or death for the baby.
- Childhood and adolescence are ideal times to vaccinate against certain diseases including, among others, those caused by certain meningococcal bacteria or pertussis.
- Vaccinating the elderly can prevent unnecessary hospital admissions and mortality from vaccine-preventable diseases.
- People with underlying or chronic conditions (e.g., diabetes, lung disease or cardiovascular diseases) are more likely to develop serious complications from vaccine-preventable illnesses such as influenza and pneumonia.
- Vaccinating caregivers and healthcare professionals (HCPs) prevents diseases spreading to more vulnerable people, thereby reducing pressure on health systems.
- International travelers (both in-bound and out-bound) may be particularly vulnerable to infectious diseases, for which they have not been vaccinated in their home economies.

By leveling the health risks that different groups face, large-scale life-course vaccination programs are instruments for promoting health equity. There is work to be done to maximize the benefits of vaccination across the entire population in the Asia Pacific region.

Figure 1. A life-course approach to vaccination maximizes the benefits of vaccination for individuals, public health, and society



Source: [The Health Policy Partnership](#)

Target 2.1:

By 2030, each APEC member economy has established comprehensive domestic immunization calendars and immunization programs that cover all stages of life (including all ages) to provide broad access to protection against vaccine-preventable diseases for all populations

Indicator:

Vaccine coverage rate for routine immunizations in each APEC economy, and across the region as a whole

Actions:

- As a key policy initiative, APEC economies should prioritize vaccination for all people, based on their individual risks and lifestyle profiles.
- When designing immunization programs, Ministries of Health should consider for inclusion all existing vaccines, in order to optimize the vaccines' benefits to society.
- APEC economies should review their approaches to designing immunization programs and collecting information by way of mandatory reporting requirements.
- APEC economies should make available sufficient funding and infrastructure to ensure strong, transparent domestic immunization technical advisory groups (NITAGs) and decision-making processes. NITAGs and decision-makers should consist of broad membership that draws upon experts across the life-course.
- In order to strengthen local healthcare systems and the provision of preventive service for all citizens, APEC economies should consider the feasibility of creating new vaccination access points through non-traditional actors in vaccination, such as pharmacists, dentists, community health workers, or school nurses. This is especially critical in contexts where vaccination centers are approaching capacity.

Target 2.2:

By 2030, all APEC economies maximize vaccine coverage for all populations where appropriate – including foreign residents, migrant workers, refugees and stateless persons – through immunization programs that ensure equitable access across the life-course

Indicator:

Number of new vaccines, underutilized vaccines, and vaccines with expanded indications introduced into the public immunization programs of each APEC economy over the decade, including booster programs and travel-related vaccinations

Actions:

- In order to broaden and ensure equal access to vaccinations for all adults, APEC economies should initiate gap analyses within their jurisdictions in order to identify age and gender demographics which suffer from under-coverage in domestic immunization programs. Vaccines should be made available and accessible through flexible support programs to under-served communities where coverage gaps exist.
 - Vaccination must be integrated into healthy living and healthy aging policies. To broaden access and drive vaccine uptake, cross-sector collaboration should be instituted in order to support vaccine delivery in non-clinical settings, wherever appropriate.
 - APEC economies should require vaccination reporting for all age groups by all vaccination providers in immunization information systems and provide patient access to their individual records to help drive personal health responsibility for being protected. Electronic databases should collect and share vaccination and infectious disease data, and vaccination data should be available to individuals and healthcare professionals.
 - Where necessary, Ministries of Health should promote changes in legislation or immunization policy in order to extend the focus of leadership beyond early childhood immunization.
 - Ministries of Health should proactively engage in dialogue with vaccine manufacturers in the private sector on the design of new programs, thereby ensuring alignment between program design, feasibility, and supply.
-

Target 2.3:

APEC economies regularly and creatively engage in impactful partnerships with stakeholders to encourage vaccination

Indicator:

Percentage of APEC economies that have put in place a team and/or process dedicated to maintaining stakeholder partnerships to incentivize vaccines uptake

Actions:

- APEC economies should work to educate the public on immunization across the life-course. Efforts may include public awareness campaigns, in coordination with key media outlets and figures; and school/university education programs, as part of broader efforts to build vaccines confidence and normalize vaccination beyond childhood.
- Given research demonstrating the impact of immunization on the labor force, APEC leaders should engage with employers and business councils in order to highlight the importance of keeping the workforce healthy and to build support for improved vaccination. Impactful steps could include setting up work-site vaccination clinics, or subsidization by employers of their employees' immunization.
- Healthcare professionals should be educated on the benefits of life-course vaccination and supported to be vaccinated themselves.

LIFE-COURSE IMMUNIZATION HELPS LIMIT THE IMPACT OF PANDEMICS

Developing and administering vaccines to confront crises like COVID-19 requires consideration of the life-course. Immunization programs can achieve greatest success in protecting populations by prioritizing communities based on life circumstances such as profession or living conditions. Given that certain individuals are unable to take part in risk reduction measures such as telecommuting and social distancing due to the demands of their employment or the density of their communities, immunization programs need to ensure that vaccination reaches those groups most at risk of contracting and spreading disease. Programs also need to increase immunization access to populations of adults that may not currently have it.

PILLAR 3: Build whole-of-government capacity in health security and pandemic preparedness

The World Health Organization has identified epidemic preparedness as one of the 13 urgent health challenges for the next decade.²⁴ The world has already begun to feel the urgency of this issue; between 2011 and 2018, the organization tracked 1483 epidemic events in 172 economies, marking what it called “a new era of high-impact, potentially fast-spreading outbreaks that are more frequently detected and increasingly difficult to manage”.²⁵ Climate change is expected to amplify the threat of infectious disease, as new populations face exposure to vector borne diseases and changing seasonal disease patterns shift the timing, duration, and pattern of transmission.^{26,27}

Recent health crises such as Ebola, SARS, and Zika have captured global attention, and for good reason; estimates of the economic loss from the 2014-2016 West Africa Ebola outbreak, for example, reach up to \$53 billion²⁸, and the World Bank has stated that even conservative estimates predict future severe pandemics to destroy up to 1% of global GDP²⁹. The present COVID-19 pandemic provides yet more compelling cause for concern about our preparedness for future of health emergencies—according to the IMF, world output is anticipated to be 3% lower by 2024 than pre-pandemic projections suggested³⁰. In addition to their economic toll, unforeseen health emergencies such as COVID-19 can also lead to the disruption of routine immunization services and the diversion of health resources, increasing the risk of spreading other preventable illnesses while containing the immediate crisis.³¹

In addition to the economic boon that prevention through vaccination offers, immunization programs also undergird health security by helping the world forestall the growing risk of antimicrobial resistance (AMR), i.e., mutation in microbes that renders existing antibiotics ineffective. Since 2016, many stakeholders in the pharmaceutical industry have adhered to the Roadmap for Progress on Combating Antimicrobial Resistance, which includes recommendations for how to balance the need for improved access to treatments with the imperative for proper use of such treatments to avoid increasing the risk of AMR.³² Among the roadmap’s key points is a commitment that antibiotics be used only as needed, and an endorsement of vaccination as a tool to improve the stewardship of antibiotics, avoid overuse, and mitigate the threat of AMR.

Such considerations underscore the exigency of continued efforts to track diseases, identify weak points in global response mechanisms, and take strides to combat the looming risk of pandemics. Outbreaks due to vaccine-preventable diseases can be avoided by robust disease surveillance programs, routine vaccination, and other preparedness measures.

Target 3.1:

By 2030, all APEC economies have established mechanisms to effectively mobilize resources in order to deliver vaccines during health emergencies

Indicator:

- Establishment of cross-sector dialogue mechanisms or fora to develop strategy for emergency resource mobilization
- Regular participation by APEC economies in the mechanism

Actions:

- Economies should prioritize coordination of global, regional, economy-wide, and community/local governance mechanisms in order to support equitable, transparent, and timely decision-making on the allocation of essential vaccines and mobilization of trained human resources. Strengthen mechanisms for rapid access to vaccines in emergencies, outbreaks or pandemics. The private sector may play a key role in this effort, through measures such as advance purchasing agreements in order to protect supply; and dialogue on how to implement new means for rapid scaling-up of production to meet surge requirements and rapid access.
 - Where appropriate, replace centrally-defined menus of supported vaccines with new systems in which economies are enabled to prioritize among marketed vaccines based on local needs.³³
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Target 3.2:

By 2030, all APEC economies have established recovery strategies for their immunization programs in the aftermath of acute health emergencies situations and/or humanitarian crises

Indicator:

Number of APEC economies that have established not only a pandemic preparedness strategy, but also pandemic recovery strategy with “catch-up” immunization embedded into this strategy

Actions:

- Ensure immunization recovery plans are embedded into outbreak and emergency response.
- Ensure a continued supply and availability of all needed vaccines, including needed vaccines that see lower levels of demand.
- Although economies should commit to protecting routine immunization services during emergency situations, they should also embed into their recovery plans

measures to facilitate “catch-up” vaccination programmes in places where services have been disrupted due to health crisis.

Target 3.3:

By 2030, all APEC economies have full surveillance and monitoring capacity to track any risk of health emergencies due to vaccine-preventable disease outbreaks, and to ensure progress towards vaccines uptake across the life-course

Indicator:

Percentage of economies that have designed a comprehensive process for collecting and evaluating data on the uptake of vaccines, the status of infectious diseases, changing environmental conditions, and any emerging resistance patterns

Actions:

- Maintain domestic data on vaccine data across the life-course, for example through immunization information systems (IISs), in order to determine performance of immunization programs and inform changes to coverage or approach.ⁱ
- Establish regional norms around collecting and tracking of the most up-to-date information on disease and immunization; this includes tracking of emerging AMR patterns.
- Continue and boost support for research into the epidemiology of outbreaks in order to inform response and prevention of emergencies, thereby also enabling rapid mobilization of resources.
- Ensure that surveillance is climate-informed and considers how changing environmental conditions will influence the landscape of disease risk.
- Strengthen relations and communications with manufacturers in order to ensure that all stakeholders understand supply needs in each economy.
- Expand research and community engagement to identify and address the underlying causes of outbreaks.

ⁱ For example, the [Australian Immunization Register \(AIR\)](#), which collects comprehensive vaccine uptake data across the life-course.

COVID-19: A CASE IN POINT FOR THE URGENCY OF ENHANCED SECURITY AND PREPAREDNESS MEASURES

A crisis like the COVID-19 pandemic illustrates the importance of the targets above. In order to guarantee adequate crisis response, APEC economies will need global and regional coordination, sustained local capacities, comprehensive emergency plans of action, and robust surveillance of the health landscape.

Emergency preparedness also entails an ability to maintain necessary vaccination and other health services even in the face of large, unforeseen crises. During health crises such as COVID-19 or Ebola, many economies experience disruption of routine vaccination programs as resources are diverted. Economies should put in place “catch-up” measures to ensure that immunization programs can resume quickly, and health systems can be revamped to withstand future disruptions.

PILLAR 4: Strengthen confidence in vaccination and build resilient immunization programs

Despite the wide-ranging societal benefits of vaccination, the success of immunization programs depends on public confidence in these interventions. Confidence in vaccines, in turn, can only be achieved when there is public trust in the vaccination eco-system. This includes trust in the safety and efficacy of vaccines, as well as confidence in the healthcare professionals and systems that administer vaccines. Leaders and healthcare professionals must proactively communicate the benefits of vaccination, and the processes that underpin the development, licensure, quality and manufacturing of vaccines must all be perceived by the public as transparent, credible, and effective.

Vaccine hesitancy, meanwhile, refers to a resistance to vaccines and vaccination services despite the availability of vaccines. Hesitancy is not just about the small but vocal minority of the population that is anti-vaccination. Rather, hesitancy happens along a broad continuum of opinion that ranges from anti-vaccination at one end to vaccine acceptance at the other end.³⁴ Vaccine hesitancy is complex, and a person's hesitancy may change depending on the context of time, place, and the specific vaccine.³⁵ Factors contributing to hesitancy include low levels of trust in vaccines, as well as elements such as vaccines complacency (i.e., low perceived risk of vaccine-preventable diseases), and lack of convenient access to vaccines (due possibly to geography or affordability).³⁶

The World Health Organization (WHO) identified vaccine hesitancy as one of the top ten threats to global health in 2019.³⁷ Worrying signs of hesitancy have emerged across the globe, from developing economy contexts where vaccination programs have not yet been fully implemented and effectively socialized³⁸ to contexts such as the US, where despite the initial eradication of measles in 2000, reported cases are rising.³⁹ Vaccine hesitancy is a complex, context-specific phenomenon, subject to multiple influences, from genuine safety concerns to manipulation of public perceptions for political or financial ends. Furthermore, decreasing occurrence of vaccine-preventable diseases can diminish public memory of their devastation, allowing hesitancy to rise.⁴⁰ All of these influences become more powerful in an era of rapid digital dissemination of information and ideas. Social media platforms and mass media therefore have a major determinative influence on the messages received by the public for or against vaccination, along with traditional influencers such as community and religious leaders with deep understanding of local context.

Refusal of vaccination despite the availability of services may lead to suboptimal coverage rates, and unless efforts are made to improve public confidence in vaccination, there is a risk that gains made in combating the morbidity and mortality of infectious diseases will be lost. Increased public information on immunization will therefore be needed to raise the public's awareness that immunization is a vital good.

Target 4.1:

By 2030, all APEC economies have established rapid, agile and responsive systems that can assess areas of systemic vulnerability, identify gaps, and mitigate the risk of threats to confidence

Indicators:

Percentage of APEC economies that have put in place a team with the necessary skills and/or process designated to analyze system vulnerabilities and address emerging or potential threats to immunization

Actions:

- More work is needed to establish understanding of local considerations (i.e., the specific context, popular attitudes, and behavior in each economy) that impede confidence in vaccination in each APEC economy. Following global best practices, such as the WHO Tailoring Immunization Program (TIP)⁴¹, economies should build this understanding and develop bespoke strategies to anticipate risks and increase confidence in vaccination.
 - Efforts to build confidence in vaccination would benefit from increased use of digital communication tools to monitor attitudes, promote pro-vaccination information, and rapidly respond to misinformation and rumors.
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Target 4.2:

By 2030, all APEC economies have full monitoring and response capacity to understand crises in vaccines confidence as well as the necessary strategies to address issues

Indicator:

Percentage of APEC economies which conduct in depth domestic specific studies to understand barriers to vaccination

Actions:

- More research is needed to gain better insight into the determinants of public trust, as well as the mix of factors that are most likely to sustain public trust. Governments should promote research and education on vaccination and the factors that contribute to the immunization system and track attitudes over time as issues are identified and addressed.
 - Apply learnings and implement strategies to address barriers to vaccination e.g. these could include infrastructure issues, e.g., ability to physically get to the point of vaccination.
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Target 4.3:

By 2030, all APEC economies have active and productive channels of engagement with healthcare professionals (HCPs) that help to educate and empower them to advocate for vaccination and provide reassurance to patients with doubts about vaccination

Indicator:

- Percentage of economies that have put in place a communications team and/or process to build skills to manage patients who may be hesitant
- Percentage of APEC economies with well-defined scheduled for HCP vaccination

Actions:

- Studies indicate that the recommendation or endorsement of a HCP significantly influences vaccine uptake. As such, economies should provide support for programs and resources that systematically educate HCPs about the benefits of life-course immunization, enabling them to more effectively engage with patients, address their concerns, and ensure uptake.ⁱ
- Ensure that HCPs themselves have their own immunization records up to date, as they are regularly in contact with members of the public who may not be able to be vaccinated themselves and are therefore otherwise putting the health of their patient at risk.ⁱⁱ

Target 4.4:

By 2030, all APEC economies maintain communications strategies to ensure the dissemination of clear, accessible, and accurate information about vaccination

Indicator:

Percentage of APEC economies that have put in place a communications team with the skills to implement a communications program which promotes confidence in vaccination among the public and healthcare professionals

Actions:

- APEC economies should work with leading digital media platforms on development of policies and strategies to leverage their platforms to disseminate

ⁱ Possibly modeled on successful examples such as Public Health France's website vaccination-info-service.fr, which provides resources providing HCPs with thorough explanation of the different vaccines' effectiveness, side effects, and composition. See: <https://professionnels.vaccination-info-service.fr/>

ⁱⁱ Related policies include that introduced by Australia in 2018, requiring all government-subsidized providers of residential aged care to facilitate the annual influenza vaccine for all staff and volunteers. See: IFPMA (2019). ["Implementing a Life-Course Approach to Immunization: Lessons Learned from International Best Practice in Policy and Programming"](#)

positive information about vaccination and counter misinformation, possibly achieved through a social media taskforce or coalition.ⁱ

- APEC economies should support public awareness and outreach campaigns, in collaboration with civil society organizations and various potential community influencers, from teachers to social networks to entertainers, in order to communicate the importance of immunization.
- The above communications strategies may focus on topics such as how the immune system works, how vaccines are developed, and how they work. They should also help socialize the notion of a life-course approach to immunization, and the importance of protecting citizens throughout their life. This would help to address the perception that pediatric vaccination is more important than vaccination at other ages.
- Strategies should be tailored to specific social concerns, such as hesitancy rooted in religious concerns, or the gender-related barriers of caregivers and health workers to accessing immunization services.

STRENGTHENING CONFIDENCE IN VACCINATION TO ENSURE AGGRESSIVE RESPONSE TO COVID-19 & SUSTAINED IMMUNIZATION ECO-SYSTEMS IN ITS AFTERMATH

Even in cases such as the COVID-19 pandemic, where there is near-universal concern and demand for public health solutions, vaccine hesitancy has emerged among the public. In many areas, a surge in activity and misinformation from anti-vaccination groups was identified in advance of the arrival of vaccines on the market. In such moments of health emergency, reassuring the public about the importance of vaccination and instilling confidence in newly-developed vaccines is critical. Once developed, vaccines must meet very high safety and effectiveness standards, ensured by robust development and approval measures that are communicated to the public. If this is not achieved, confidence across all vaccines may be undermined for the long term.

Additionally, no matter how successful a vaccine may be, broader confidence in following a health crisis depends on sustained, large-scale efforts to build public trust, provide accurate and scientifically sound information, and communicate the importance of immunization. The social and economic toll of COVID-19 should serve to motivate APEC decision-makers to commit over the coming decade to strengthening immunization systems and giving serious attention to the threats to vaccine confidence within their economies.

ⁱ For example, Facebook's recently introduced feature designed to combat the spread of anti-vaccine misinformation in the US; when users search for vaccine-related content, visit vaccine-related Facebook groups and pages, or tap a vaccine-related hashtag on Instagram, a pop-up window connects the user to the US Centers for Disease Control and Prevention for credible information on vaccines. See: Facebook (2019), "[Combatting Vaccine Misinformation](#)".

PILLAR 5: Enable investment and innovation in vaccine R&D, manufacturing, and delivery

Investment in vaccine innovation has led to world-changing breakthroughs. The Bill & Melinda Gates Foundation has stated that consistent gains in childhood mortality – due in large part to vaccination – have meant over 120 million lives saved since 1990⁴². Historically, the vaccine industry has been a high-growth industry, boasting a growth rate double that of the rest of the pharmaceutical industry over the past two decades. Furthermore, it is expected that vaccines will play an increasing role not only in prevention but in treatment of certain illnesses, including hepatitis B and HPV. Nevertheless, there are signs that the pace of vaccine innovation is on the decline. Troubling signs in the industry include slowing revenue growth, a flattening development pipeline, declining numbers of vaccine candidates that reach clinical studies, and various remaining unmet needs.⁴³

There may be several reasons for this slowing pace of innovation. As vaccines are introduced for the “low-hanging fruit”, remaining target illnesses become more complex, with several implications for the development of new products. Research becomes more challenging and time-intensive, regulatory scrutiny rises, timelines for approval lengthen, and consequently production becomes costlier. These more challenging products may also have greater commercial uncertainty. Furthermore, the increasing technical challenges of innovation have meant a convergence in the success rates of development for vaccines and other biologics. Given the higher potential revenues of blockbuster biologics, the opportunity cost and relative attractiveness of investment in vaccines may be in decline.

In pillar 3, the looming threat of devastating and economically costly outbreaks such as COVID-19 was discussed, along with the need to fight back against antimicrobial resistance. Health security measures are crucial to solving these issues, but they are insufficient without continued investment in expanding and fortifying the global vaccines portfolio. In order to continue advancing innovation and R&D, steps should be taken to incentivize investment in vaccines, possibly through tackling the rising costs and commercial uncertainty that contribute slowing innovation.

Target 5.1:

By 2030, all APEC economies establish policies and procedures that foster public-private dialogue between vaccine producers and governments in order to chart an optimal course for encouraging investment in innovation

Indicator:

Percentage of APEC economies that have consolidated a private sector strategy to guide engagements with vaccine or broader pharmaceutical producers

Actions:

- Vaccine producers may partner with regulators to establish a standard engagement process for the initial stages of innovation development. This would provide producers guidance on the design of trials, approval processes, and market access policies in enough time to properly prepare for regulatory requirements and/or challenges.
 - In those cases where the production of needed vaccines may not be fully sustained by market demand alone, public-private partnerships will be necessary to explore in order to fill the funding gap.
 - Regulatory harmonization measures, discussed in detail in Pillar 6, may also help to increase clarity on the necessary processes for bringing new vaccines to market, thus increasing the commercial attractiveness of investment. This is especially important in the case of regulating post approval changes to vaccines, a key element of gradual product innovation.
-

Target 5.2:

By 2030, all APEC economies maintain mechanisms to enhance producers' understanding of local demand and health needs, in order to inform R&D and reduce the commercial uncertainty of new investments

Indicator:

Percentage of economies that have put in place a process for sharing data on vaccines demand and health needs among key stakeholders in the innovation and production pipeline

Actions:

- The measures discussed in Pillar 3 regarding health security, particularly surveillance of data on disease, can help vaccine producers and other stakeholders to understand current market demands, forecast future demand, and identify ripe targets for investment.

COVID-19: ENABLING RAPID VACCINES INNOVATION TO CONFRONT ACUTE EMERGENCIES

Much of the public and private research currently underway on COVID-19 is being funded by governments. Where possible, APEC economies may help advance innovation by encouraging or mandating collaboration and data sharing as part of its funding agreements. Additional collaboration can be facilitated through global and regional partnerships such as the Access to COVID-19 Tools (ACT) Accelerator, which brings together global health actors including CEPI, Gavi, the Global Fund, and UNITAID with private sector partners and other stakeholders to accelerate the development, financing, and production of vital health technologies.¹ Additionally, the WHO is leading development of a global framework to guide allocation of limited vaccine supply towards public health goals based on transparent criteria. The APEC region may consider what capacity it has to bring together key regional stakeholders to work towards similar goals with a focus on regional dynamics and priorities. A variety of rapidly enacted new regulatory measures may also help chart the course for innovation in the context of crises like COVID-19, as is discussed more extensively in pillar 6.

¹ (2020). [*"Commitment and call to action: Global collaboration to accelerate new COVID-19 health technologies"*](#). World Health Organization.

PILLAR 6: Accelerate regulatory harmonization for vaccines across APEC economies

Regulatory harmonization is the process of aligning regulatory requirements across economies or regions over time through the adoption of internationally recognized standards and practices. The U.S. FDA defines it as “the process by which technical guidelines are developed to be uniform across participating authorities”.⁴⁴ Regulatory harmonization enables both regulatory authorities and industry to pursue a shared commitment to protect public health. Rather than lowering standards, harmonization yields benefits across regulatory authorities (RAs), vaccine producers, and patients by enabling more efficient processes and more rapid access to quality medicines without negatively impacting public health.⁴⁵

Robust regulatory systems are essential to ensure the safety, quality and efficacy of vaccines, while also ensuring supply security and patient access. RAs concern themselves with all aspects of vaccine development, including enforcing pre-clinical and clinical testing, establishing the framework by which manufacturers are granted licenses to operate, and authorizing companies to market products.⁴⁶ Furthermore, given that vaccines are biological products – with the inherent variability of living organisms – great care must be taken to maintain quality control by monitoring products’ performance and regulating lot release, i.e. ensuring that each vaccine batch meets the specifications of its approved marketing authorization. RAs are at the helm of this work. Across these many responsibilities, however, the emergence of difficult or divergent requirements across domestic RAs can create obstacles. The vaccine regulatory ecosystem in particular has experienced increasing complexity in recent years. This complexity may have adverse consequences for patient access to innovation, as divergent and additive processes result in delays in regulatory reviews and place strains on the vaccine supply chain, while not adding significantly to safety, quality, and efficacy.

A significant area of improvement in the vaccine regulatory ecosystem is the adoption of post-approval changes (PACs) i.e., the reformulations and improvements made on medications over the course of the product life-cycle. PACs are a natural component of life-cycle management of vaccines, in order to facilitate process improvements, implementation of new regulatory requirements, maintenance, and capacity extensions. Many PACs require regulatory authority approval prior to implementation and release of product. Today, it can take up to 5 years from the first regulatory filing to the final approval by all relevant regulatory authorities for each PAC, meaning delaying by 5 years access to a new version of a vaccine, with all the subsequent risk of shortage of this vaccine for the slowest economies in terms of variation adoption.⁴⁷ Individual economy requirements are often highly heterogenous, and one change may entail many different data requirements, different review times and unaligned outcomes. This complexity results in inefficiencies in supply chain, as manufacturers need to produce multiple versions of a product in order to comply with different

domestic regulations. These complexities risk supply interruptions, discourage and delay continuous improvement, and stifle innovations.

Collaborations and recommendations to achieve regulatory harmonization do exist, including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). The WHO, for its part, has long recognized the value of globally harmonized standards, emphasizing it in the 2011-2020 Global Vaccines Action Plan, and supporting a range of global and regional harmonization initiatives.⁴⁸ However, political will and collaborations are needed to accelerate adoptions. In order to balance high standards of vaccine safety and quality with efficient supply chains and timely vaccine access, economies should move towards the harmonization of regulatory requirements, reduce unnecessary administrative hurdles, and quicken access to necessary vaccines and medicines.

Target 6.1:

APEC-wide endorsement of and adherence to a set of agreed regulatory practices including adherence to international standards globally recognized regulatory harmonization recommendations and guidelines, in order to ensure effective supply chains and sufficient inventoryⁱ

Indicator:

- APEC-wide endorsement and recommendation for members to implement globally recognized regulatory harmonization guidelines for vaccines
- APEC workshops and capacity building to support implementation

Actions:

- Achieve APEC-wide consensus around a set of good regulatory practices, as determined by a consensus-based definition, to which each economies regulatory agencies can adhere.
- Achieve an APEC-wide endorsement of best practices in vaccines manufacturing and quality control.
- Where feasible, promote mutual recognition agreements across APEC economies procedures.
- Where feasible, promote shared evaluation of product registration initiatives across APEC economies.
- Vaccine producers can collaboratively consolidate a list of key regulatory and supply chain obstacles and requirements in areas such as post-approval changes

ⁱ The APEC Life Sciences Innovation Forum, through the [Regulatory Harmonization Steering Committee](#), has also laid out an agenda for regulatory convergence; while global cross-sectoral guidance on the issue has emerged through the OECD [Recommendation of the Council on Regulatory Policy and Governance](#).

(PAC) and labeling and packaging, to use to launch joint discussions with regulators on areas of concern.

Target 6.2:

By 2030, all APEC economies have undertaken capacity building initiatives to accelerate adoption of globally recognized recommendations and guidance on regulatory harmonization for vaccines

Indicator:

Percentage of economies where capacity-building trainings have been designed and initiated, involving coordination between global vaccine producers, local producers, and regulators

Actions:

- Multi-sectoral collaboration to build regulatory capacity and innovative platforms around which to implement globally recognized harmonization guidelines consensus.
-

Target 6.3:

Continuing multisectoral collaboration within and across APEC economies to ensure robust supply chain and access to vaccines across the globe

Indicator:

APEC endorsement of recommendations on global vaccine supply chain security and incentives for investment and expanded access

Actions:

- Multisectoral dialogue and review of policies that impact the global vaccine supply chain and incentives for investment and expanded access, along with recommendations for improvement.

COVID-19: REGULATORY HARMONIZATION TO ENABLE ROBUST AND COORDINATED GLOBAL RESPONSE

Compounding the issue of economies monopolizing or hoarding certain medical supplies and products, regulatory obstacles may also impede the movement of vaccines to countries and regions where they are direly needed. Divergent requirements on the part of regulatory authorities can slow inter-regional access to COVID-19 vaccines as they enter the market. Furthermore, given the unprecedented speed with which vaccines are being developed currently, it is likely that vaccine producers will contend with complicated processes for post-approval changes to vaccine formulation. Accelerated regulatory clearance pathways for COVID-19 clinical studies, such as have been set up by the European Medicines Agency, the UK Medicines and Healthcare products Regulatory Agency, and the US Food and Drug Administration, should be considered in APEC economies as well in order to enable development. At the same time, any measures to accelerate regulatory processes during emergency times should be measured by oversight in order to ensure the continued safety and efficacy of the products that are developed and marketed.

In addition to facilitating regulatory harmonization now, stakeholders should also aim to resist the imposition of new regulatory burdens in the aftermath of the pandemic. For example, several economies had already begun policies of localization of pharmaceutical manufacturing in order to support the domestic economy while increasing access to medications. While this approach could in theory have merits, problematic elements include the magnitude of capital expenditure necessary to initiate commercial-scale operations in a new site, and uncertainty around the quality control and/or approval processes in place in new manufacturing locales.

¹ (2011). *“Increasing access to vaccines through technology transfer and local production”*. World Health Organization.

PILLAR 7: Establish proven & innovative mechanisms for sustainable immunization financing

Vaccine development is a complex and intensive undertaking, requiring mastery of multiple technologies, funds for laboratory research, clinical trials and manufacturing facilities, sophisticated scale-up processes, and rigorous safety monitoring. More broadly, health costs across the board and across geographies are increasing as a function of expanding and aging populations; the rising burden of non-communicable diseases; and the rise of new technologies. With an expanding array of needs and consistently high costs, deeper investment in vaccines is necessary to insure against coming health threats. There is an exigency for heads of state, including officials from ministries and related sectors of APEC economies, to mobilize diverse and sustainable sources of domestic financing necessary to achieve the goal of immunizations across the life-course.

Target 7.1:

By 2030, all APEC economies make commitments on economy-wide immunization funding

Indicator:

Percentage of APEC economies that have written and introduced an Economy-wide Immunization Plan with provisions for the life-course and concrete proposals for financing strategies

Action:

- APEC economies should develop ambitious, fully-costed and funded domestic life-course immunization plans that are consistent with domestic legislative and policy frameworks and aligned with domestic health plans.
 - Funding should be sufficient to enable access to new, innovative vaccines across the life-course, and to build resilient and sustainable program capacity and infrastructure.
 - Plans should include commitments to explore innovative financing mechanisms that source funds from outside of the traditional means, and create incentives that improve program performance. This may include trust funds, credit guarantee schemes, performance-based financing, and/or impact bonds.
-

Target 7.2:

Establishment of joint platforms within and across APEC economies in order to foster collaboration to identify and resolve financing challenges

Indicator:

Percentage of APEC economies with health or other officials participating in an APEC-wide dialogue on financing strategies for immunization programs

Actions:

- APEC economies to seek multi-sectoral collaboration in identifying financing challenges and in developing potential innovative solutions to improve sustainable financing for universal health coverage, including immunizations across the life-course.
- Develop plan for those developing economies that stand to take on the full burden of immunization financing in the near to medium-term, as they graduate from external aid programs, e.g., Gavi. This may include broader embrace by industry and governments of a differential pricing strategy, distinguishing price levels for different income groups, either on an inter-economy or intra-economy basis.^{i,ii}

Target 7.3:

Each APEC economy utilizes decentralized strategies to the extent necessary in its given context, in order to facilitate local alignment of funding and needs

Indicator:

Percentage of APEC economies that have conducted an investigation of the feasibility, benefits, and risks of introducing decentralized strategies into their immunization plans

Actions:

- Decentralization, when proper accountability and incentive mechanisms are put in place, has been found to move public health systems closer to local priorities.⁴⁹ APEC economies should carry out analysis of the feasibility of local/community procurement as a strategy in their respective contexts, either for broad use or in the case of stock-outs.
- Local/community piloting of new vaccines offers an opportunity to assess costs of delivery, taking items such as labor and facilities into account, while also assessing a local population's receptiveness.

ⁱ For discussion on differential/equitable pricing, see: Access to Medicine Foundation, "Are pharmaceutical companies making progress when it comes to global health?"

ⁱⁱ For example, Pfizer's approach: [Global Vaccine Differential Pricing Approach](#)

ENSURING THE COVID-19 RESPONSE IS WELL-FUNDED AND THE RESULTING VACCINES ARE AFFORDABLE

Billions in funding has been required to develop and deploy vaccines for COVID-19. In addition to pushing forward development, economies will also need to strategize for affordability for their populations. Across APEC economies, the use of traditional and innovative financing mechanisms – from loans to bond-financed immunization programs to purchase commitments with producers – will be vital to ensure efficiency use of limited resources to address the present needs, certainly in lower- and middle-income economies.

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