Belgian vaccines landscape analysis

Assessment and plan with recommendations for policy proposals to address shortcomings

Report

authored by

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Colophon

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Expert contributors via interviews:	We would like to acknowledge and thank all the interview participants for their time and contribution to the landscape analysis. Conform the GDPR, only the stakeholder groups will be disclosed. Agence pour une Vie de Qualité (AVIQ), Algemene Pharmaceutische Bond (APB), BVAS, Cabinet Public Health, Christelijke Mutualiteit, CHU Saint-Pierre, Domus Medica, Emmaus Groep, FAGG-AFMPS, Fedris, KCE, Kind & Gezin, KU Leuven, MLOZ, ONE, Promotion de la Santé à l'Ecole (service PSE), RIZIV-INAMI, Sciensano, Socialistische Mutualiteiten, SSMG, Universiteit Antwerpen, Université Libre de Bruxelles, Université Libre de Bruxelles – Huderf, Vlaams Agentschap Zorg en Gezondheid, Vlaams Apothekers Netwerk (VAN), Vlaams Onafhankelijk Zorgnetwerk (VLOZO), ZorgnetICURO
Commissioned by	MSD Belgium Inovigate has performed this research and analysis under complete intellectual independence.
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Preface

Belgium scores quite good regarding child vaccination, with an overall vaccination coverage rate in children above 89% in entire Belgium. However, adult vaccination coverage rate is nowhere near this high in Belgium. The complex landscape with various stakeholders involved and no clearly defined plan, roles and responsibilities, interfere with an efficient organisation of vaccination. The Covid-19 crisis highlighted the shortcomings in our current prevention and vaccine landscape (as defined in this report). As we are now at a stage to define feasible, sustainable exit-strategies and measures, this analysis is essential to take into account for the implementation of i.a. a new COVID-19 vaccine. Moreover, vaccination is imperative in the prevention of future virus outbreaks and therefore, this report can be leveraged to define priority actions and a strategy on the long-term.

The analysis of the vaccine landscape was initiated in the fall of 2019 (October 2019) and executed by Inovigate, an independent strategy and management advisory firm, specialised in the European Life Science industry. This study was sponsored by MSD, but the analysis was performed in complete intellectual independence. Expert views were gathered via in-depth interviews with multiple stakeholders in the landscape, between November 2019 and February 2020.

This report has been developed to map the current Belgian vaccine landscape and make policy proposals with measures and policy asks. The ambition of this report is to deeply understand the prevention and complex vaccination landscape in Belgium and identify opportunities for improvement. In addition, international benchmarking was performed to formulate key learnings and opportunities for Belgium. This report provides policy input to hold multi-stakeholder dialogues. Multi-stakeholder engagement and dialogue is key for the development of a successful long-term vaccination strategy and plan.

Antwerp, September 2020

Ingrid Maes
Managing Director
Inovigate BV

Executive Summary

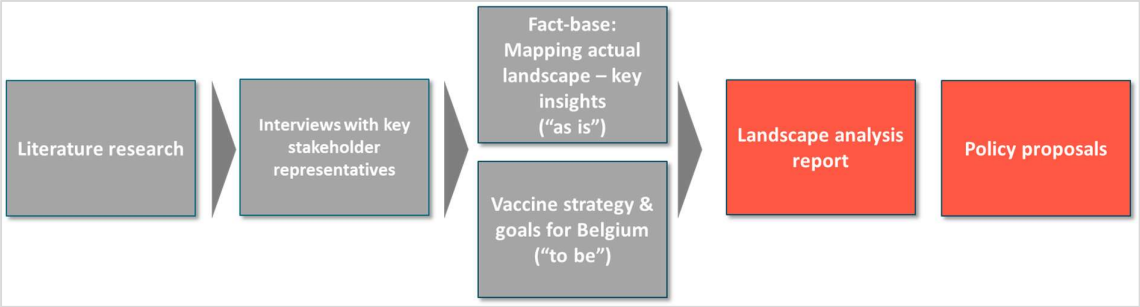
Context and goal of this landscape analysis:
MSD Belgium mandated Inovigate to perform an independent landscape analysis of the Belgian vaccine situation and system during November 2019 - February 2020. This research and analysis have been performed under complete intellectual independence.

The research has been based on (1) interviewing key stakeholders involved with vaccination on federal and regional level and (2) international benchmarking. Based on the interviews and international benchmarking, an independent report has been made summarizing the key insights and recommendations for improvement of the Belgian vaccination system. The strategic policy proposals and plan for making a more performing system in the near future are offered to Belgian policy makers with the aim to improve policy.

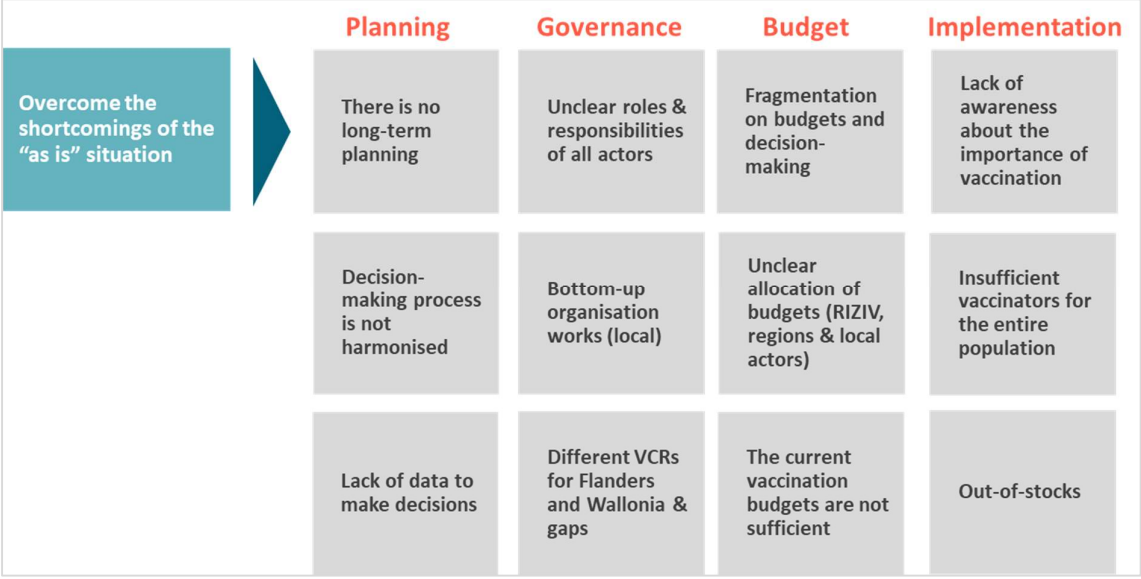
The ambition of this report is to deeply understand the prevention and complex vaccination landscape in Belgium and identify opportunities for improvement. With this report, we provided a plan based on four priority actions and supported by four enablers for a top performing vaccine system, meeting the WHO 2030 requirements.

We hope this report will inspire and facilitate multi-stakeholder discussions to further detail the four priority actions of the vaccination plan for Belgium and build consensus to put them in practice. Readers of this report are encouraged to take contact with us, to contribute to the multi-stakeholder dialogue.

The project approach in steps:



Key findings on shortcomings in the current vaccine system:
It is clear from the interviews that there are multiple shortcomings on planning, governance, budget and implementation level in Belgium.



The shortcomings on planning are lack of long-term planning, and data and harmonisation in decision-making process. Regarding governance, there are unclear roles and responsibilities, different VCRs in the regions (especially a lower VCR

in Wallonia for adolescent and adult vaccines) and missing top-down overarching plan and governance (however the bottom-up organisation works). The shortcomings on budget are based on fragmentation, unclear allocation (federal, regional and local) and insufficient budgets. For implementation, the shortcomings are lack of awareness about vaccination, insufficient vaccinators for the entire population and out-of-stocks. The implications of these shortcomings are observable on all levels.
These shortcomings can be seen as opportunities for improvement to become a leading country in vaccination coverage and strategy. However, this will require alignment, goal setting and integrated action.

International benchmarking reveals key learnings:
Vaccination systems of various EU countries, Canada, Australia have been investigated and benchmarked. Seven key learnings can be identified from international benchmarking of best practices in other countries.

Key learning	Description
1 Long-term strategy	• Defined strategic priorities and SMART objectives • Resources aligned to the priorities • Clear governance defined and involvement of multiple stakeholders • Use of a framework to detail core functions, strategic priorities & enablers • Horizon scanning to support long-term planning
2 Sufficient budget for prevention & vaccination	• Italy: 4,2% of total health expenditure goes to prevention • Netherlands has the highest expenditure (in €) per capita of €157,9
3 Continuously updated immunization programme	• Whole life course immunization programme covering children, adolescents & adults • Additional recommendations for specific populations • Organisation of catch-up programs • Continuously evolving programs incorporating new, more effective, cost-effective vaccines and new uses for existing vaccines across the life course
4 Increase awareness at the public and HCPs	• Publicly communicated policy, strategy and programmes • Major public awareness program through different channels (incl. traditional and social media) to disseminate evidence-based and trusted information on vaccines and address public concerns • Ensure early access to high-quality information for public and HCPs
5 Updated data system and continuous surveillance	• Whole life immunisation register • Surveillance through rigorous case investigation of suspected cases • National surveillance network with an active monitoring system enabling realtime tracking of outbreaks and vaccine adverse events • Evaluation framework and cycle to assess program delivery effectiveness
6 Increased accessibility and vaccinator capacity	• Adequately skilled immunisation workforce through promoting effective training • Offering vaccination in a more diverse range of settings (e.g. pharmacies) • Ensure healthcare settings to be fully prepared for outbreak
7 Sufficient supply	• Efficient & effective procurement through centralised procurement • Dedicated vaccines manufacturing Innovation centre for clinical trials and for emergency preparedness

Countries with top performing vaccination systems, use standard 'core outcome sets' for prevention (similar to other disease areas), and assess ROI for prevention beyond financial, including other values and benefits such as the demonstration of larger and more transversal value add. Good public health promotes economic growth, social and well-being of a country.

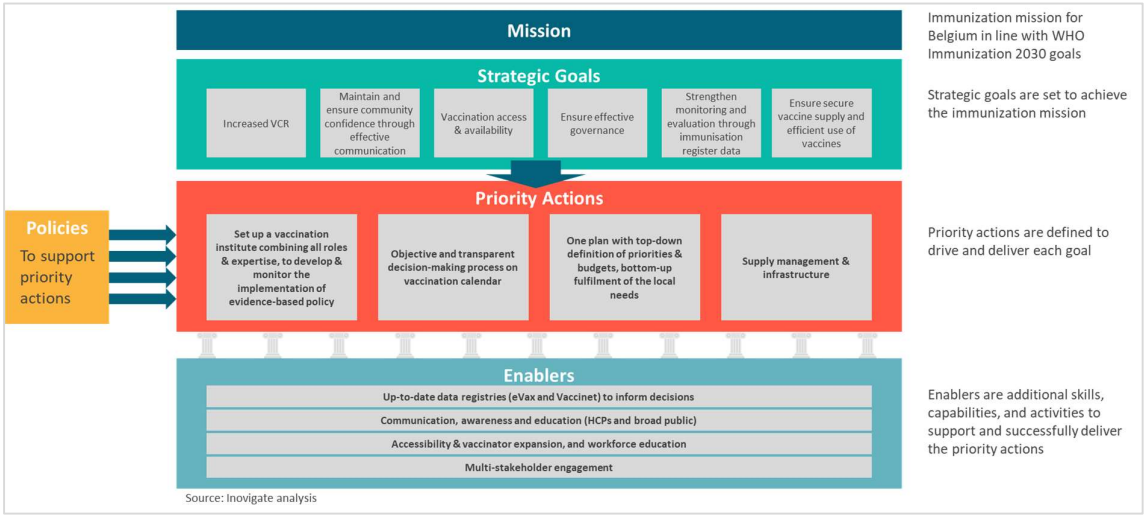
Recommendations and proposed framework:
Based on the interviews and the international benchmarking, a framework has been formulated to articulate the strategic goals, priority actions and enablers. The strategic goals for Belgium are compliant with the WHO Immunization 2030 goals.

WHO Immunization 2030: Strategic Priorities

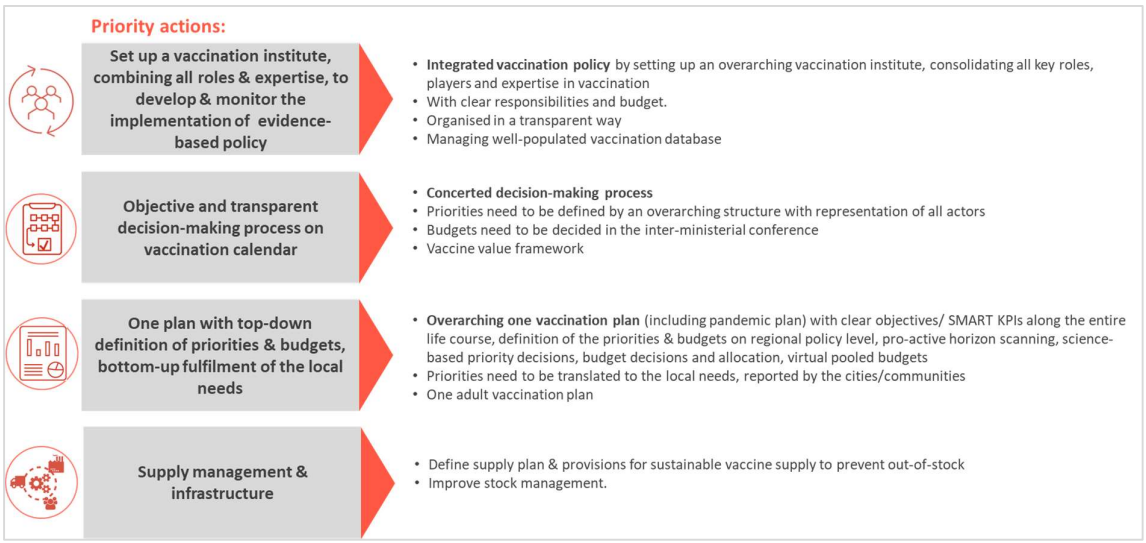
	Objectives
Immunization for primary healthcare and universal health coverage	• To build effective, efficient and resilient immunization programmes that deliver high-quality immunization services as a part of national primary healthcare systems aimed at achieving universal health coverage
Equity and Access	• To ensure that everyone has equitable access to vaccines, irrespective of their geographical location, gender, socioeconomic status or any other factor, that might prejudice their access to services
Ownership and Accountability	• To ensure that everyone, everywhere values immunization and seeks out immunization services, by positioning immunization as an undeniable human right, building community ownership, and strengthening accountability at all levels
Outbreaks and Emergencies	• To maintain and strengthen capacity to prepare for, prevent and respond to vaccine-preventable disease outbreaks, and ensure that those affected by conflict, political instability and other emergencies continue to receive essential immunization services
Life course and Integration	• To realize the full benefits and impact of immunization by establishing and strengthening people-centred platforms to deliver vaccines and additional interventions along the life course, by collaborating with other health programmes and sectors, and by utilising all available opportunities to provide catch-up vaccination
Research and Innovation	• To encourage and intensify the development and adoption of new vaccines and vaccine administration technologies, novel vaccine manufacturing platforms, and programmatic innovations to enhance equitable access to immunization, taking account of ever-changing infectious disease epidemiology and emerging infectious disease threats
Availability and Sustainability	• To ensure a reliable global supply of affordable vaccines of assured quality, as well as a clear pathway for countries to programmatic and financial self-sustainability of their immunization programmes, taking account of global vaccine shortages and transitions out of global support programmes
Economic Advantages*	• Immunization can deliver economic benefits: maintain a healthy and productive workforce; reduce poverty, through avoidance of healthcare costs, lost wages, and lost productivity to illness*

*Highlighted in the WHO report as one of the benefits of immunization
Source: WHO Immunization Agenda 2030: A Global Strategy To Leave No One Behind, August 2019

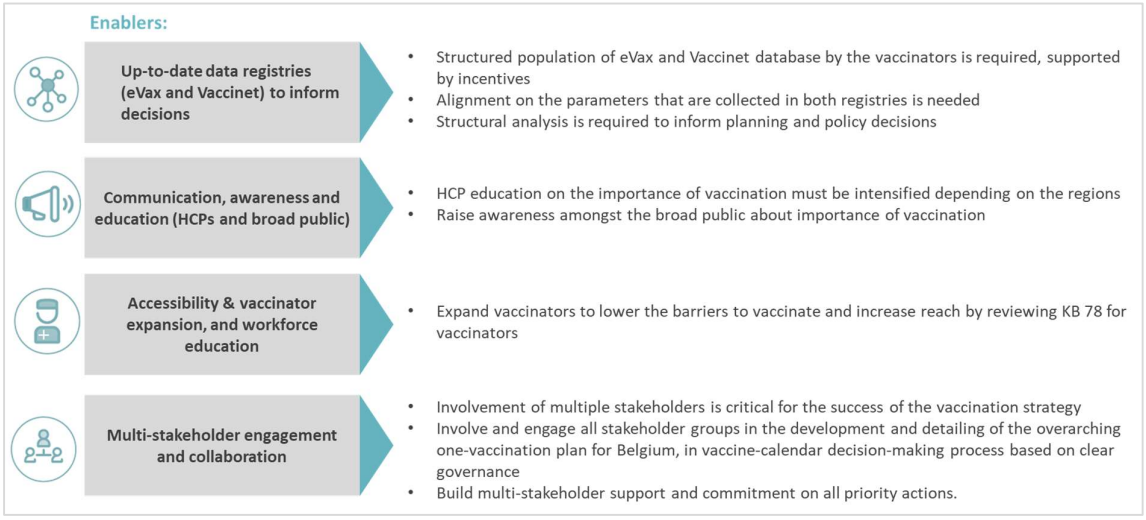
The priority actions outline the policy proposals and recommendations for Belgium to overcome the shortcomings of the actual system, supported by enablers to successfully deliver the priority actions.



The interviews show that there are 4 main priority actions that need to be put in place to overcome the identified shortcomings in the actual system.



The four enablers, to support the execution of the priority actions are:



Recommendations

Based on this landscape analysis, 4 policy actions are formulated, which will make the Belgian vaccination system more performing.

Recommendation 1: Set up a vaccination institute, combining all roles & expertise, to develop and monitor the implementation of evidence-based policy

Integrated vaccination policy by setting up an **overarching vaccination institute**

- Consolidating all key roles, players and expertise in vaccination
- With clear responsibilities and own budget
- Overseeing the implementation of an evidence-based vaccination vision and policy
- Access to an accurate vaccination database
- Organised in a transparent way

Recommendation 2: Objective and transparent decision-making process and value framework on vaccination calendar

The decision-making process, for a new vaccine to be included in a vaccination program, has to be objective and transparent

- Priorities need to be defined by an overarching structure with representation of all actors
- Publication of decision-rationale, priorities and budget allocation, will increase transparency.
- Budgets need to be decided in the inter-ministerial conference, in a transparent manner
- Concerted decision-making process for new vaccines to be included in a vaccination program
- A common standardized **vaccine value framework** should support objective evaluation with
    - Standard 'core outcome sets' for prevention
    - ROI for prevention that goes beyond financial, including economical and societal benefits, requiring an overarching value framework
- Horizon scanning is required for improved decision-making and prepare budgets on the longer-term

Recommendation 3: One plan with top-down definition of priorities and budgets, bottom-up fulfilment of the local needs

Overarching one vaccination plan (including pandemic plan), outlined as a framework to detail core functions, with aligned resources to the **strategic priorities and enablers**, will **support engagement and collaboration of all system stakeholders.**
This plan should combine:

- Well-defined vision, mission and strategic priorities (in line with WHO immunization 2030 goals)
- Clear objectives, defined as SMART KPIs, along the entire life course
- Virtually pooled budgets, translated into priorities and budgets on regional policy level, and to the local needs, reported by the cities/communities
- Pro-active horizon scanning to plan on the long-term, facilitated by proactive sharing of the pipeline by the industry
- Science-based priority decisions (including based on registry data analysis), budget decisions and allocation
- **A continuously updated immunization program,** covering life course immunization, including new, more effective and cost-effective vaccines
- **One-adult-vaccination-plan**
- Additional recommendation for specific populations
- The organisation of catch-up programs
- **Centralised accurate whole-of-life immunisation registry (e-vaccination records),** overarching surveillance network with active monitoring system for whole life surveillance through rigorous case investigation

- Implementation of a **robust system** for prevention, identification and management of immunization incidents. Review factors that impact incidents to better understand, identify and implement best-practice models for continuous improvement
- Addressing how to develop a **common understanding** of the criteria for program success and establish **specific standards** for each element
- **Communicate best practices** to all providers and introduce strategies to implement best practices

Recommendation 4: Supply management infrastructure

Ensure reliable and secure vaccine supply, by improved planning and forecasting:

- **"One plan"** and **collaboration** between authorities and responsible actors will solve out-of-stock issues
- **Centralised stock management and oversight** through implementation of **vaccine inventory system**
- Efficient and effective procurement through **centralised procurement.**
- **work closely and pro-actively with vaccine companies** to support continuous supply of essential vaccines for Belgium
- Explore opportunities to **proactively work with vaccine manufacturers**
- Take steps to **ensure all providers have timely access to vaccines**
- **Dedicated vaccines manufacturing innovation centre** for clinical trials and emergency preparedness.

These recommendations are aligned with the strategic priorities of WHO Immunization 2030.

The 4 priority actions will require further detailing and alignment via multi-stakeholder discussion.

1. Methodology

An independent landscape analysis of the Belgian vaccine situation and system has been performed during November 2019 – February 2020, by performing literature research on the Belgian vaccine landscape and an international benchmarking. In addition, interviews with key stakeholders involved in vaccination on federal and regional level have been performed.

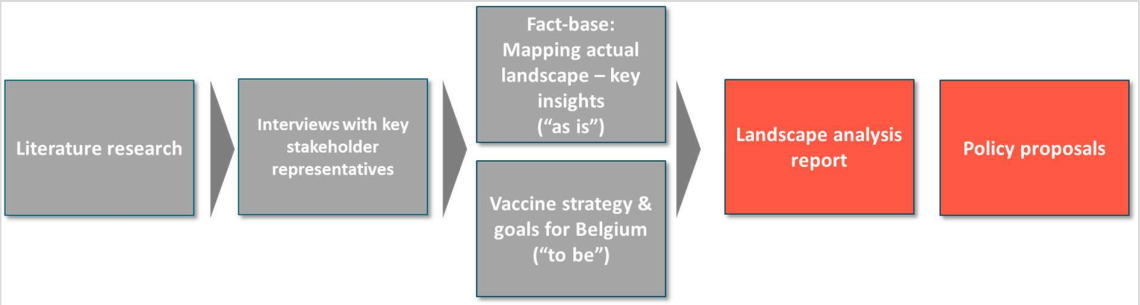


Figure 1 Methodology of the Belgian landscape analysis

Literature research

A literature research has been performed to map stakeholders in the Belgian vaccine landscape and to gather information about the current vaccine policies, calendars and allocated budgets. In addition, an international research has been performed to investigate systems, policies, processes in other countries and to benchmark Belgium. Best practices and key learnings were identified and detailed to inform policy proposals for Belgium.

Stakeholder interviews

Representatives of all stakeholder groups involved in the Belgian vaccine landscape, on regional and federal level have been extensively interviewed. A total of more than 30 structured in-depth interviews were performed to inform this landscape analysis, during November 2019 and May 2020.

For the extensive interviews with each of the listed interviewees, a questionnaire has been developed covering:

- The current vaccination situation in Belgium
- Improvement opportunities today
- Future vaccination model for Belgium

Each of the interviewees received this questionnaire before the interview to prepare themselves.

Analysis

Based on the various findings and suggestions from the interviews, key insights on the shortcomings in the actual Belgian vaccination system have been outlined. Together with the international benchmarking, recommendations for improvements and a plan for a more performing system in the near future, have been formulated. Finally, these recommendations have been validated with key expert stakeholders and are formulated as policy proposals.

Next steps

This report provides input to hold multi-stakeholder dialogues, bringing together the vaccination actors, more specifically vaccination policy makers, stakeholders responsible for the vaccination implementation and providers of vaccines, including vaccine companies. Multi-stakeholder engagement and dialogue will be key to further detail the four priority actions and build consensus to put them in practice.

2. Belgian vaccine landscape analysis

2.1. Current Belgian stakeholder landscape

Multiple stakeholders are involved in the Belgian vaccination landscape, with varying levels of influence on vaccination decisions and on vaccination calendar campaign and execution. The scheme below provides an overview of the various organisations on federal and on regional level for vaccination.

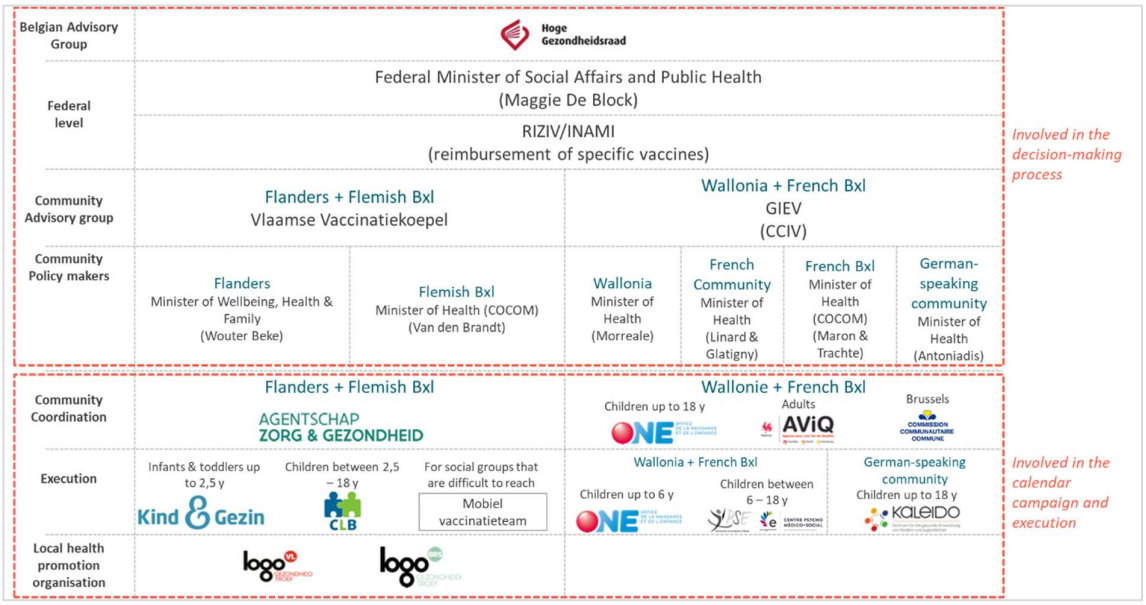


Figure 2 Belgian vaccine stakeholder landscape

2.1.1 Stakeholders involved in the decision-making process

The Superior Health Council (SHC), also called **Hoge Gezondheidsraad (HGR) and Conseil Supérieur de Santé (CSS),** is the independent scientific advisory organ of the Federal Public Service Health and consists of a group of experts developing impartial and independent advisory reports. The SHC functions as the link between the Belgian government and the scientific world regarding various domains linked to public health. The SHC provides scientific advice to policy makers and healthcare professionals with the aim of protecting and improving public health. Vaccination is one of the activity domains of the SHC. The SHC calls on a network of 1400 to 1700 experts from Belgium and abroad for questions. It gives advice regarding vaccinations and the vaccination calendar. This advice forms the basis for the application of vaccination programmes in Flanders, the French Community and the German-speaking Community. In 2017, seven advices related to vaccination were formulated and published, more specifically on poliomyelitis, meningococcal B, varicella, herpes zoster virus, HPV and season-linked flu.

In Flanders, the **Vlaamse Vaccinatiekoepel** is officially installed in 2013, as a working group to advice the Flemish Minister of Wellbeing, Health and Family on the Flemish policy and Vaccination programme implementation based on the scientific advice from the SHC. The advice of the Vaccinatiekoepel is also followed by the Agentschap Zorg en Gezondheid. The Vaccinatiekoepel is composed of different groups of vaccinators (incl. GPs, paediatricians, OBGYNs, Kind & Gezin, CLB,…) and academics and meets at least 4 times per year to discuss the implementation of the vaccination policy in Flanders. It defines the vaccination strategy along the entire lifecycle through a consensus process. It defines the vaccination calendar, the strategy for vaccination of adults, the responsible vaccinators for each target group, the time frame to execute and follow-up vaccination, and the implementation plan for new vaccines. Furthermore, it also formulates advice on how to guarantee a qualitative vaccination programme given market monopolies.

In the French Community, there is currently no counterpart for the Vlaamse Vaccinatiekoepel. Up until end of 2016, the CCIV (Comité de Concertation Intersectorial Vaccination), a committee with multi-stakeholder representation, fulfilled the same role as the Vlaamse Vaccinatiekoepel. Later, the GIEV (Groupe interuniversitaire d'experts en vaccinologie) was established, but this organisation has no multi-stakeholder representation and only includes academic vaccination experts.

The **Federal Minister of Social Affairs and Public Health** is involved in case a vaccine is not included in a vaccination programme but should be reimbursed for specific target populations. In this case, the vaccine could be submitted for reimbursement by the RIZIV-INAMI. There is one vaccine that is an exception to this rule; the rotavirus vaccine, which is included in the regional vaccination schemes, but is still reimbursed by RIZIV-INAMI.

Besides the Federal Minister, De Block, there are 8 other **Regional Ministers** responsible for the vaccine policy in their territory. For:

- Flanders: Minister Beke
- Wallonia: Minister Morréale
- French community: Minister Linard and Valérie Glatigny
- French-speaking Brussels: Minister Maron and Trachte
- Dutch-speaking Brussels: Minister Van den Brandt
- German-speaking Wallonia: Minister Antoniadis.

These ministers are involved in decisions on vaccines to include in the vaccination calendar and monitoring of the vaccination rate.

In 2019, a **new vaccines policy for Flanders** has been published by Minister Beke for the period 2019 – 2024, with two major goals; a high-quality vaccination policy and combat infectious diseases. This policy focuses only on children and at-risk populations and does not cover a life course approach to vaccination.
The objectives and actions for the first goal (high-quality vaccination policy) are:

- Maintain the high vaccination rate as defined by WHO and emphasize the health benefits for the Flemish population
- Preserve the trust of the population in vaccination by taking measures with government and the "Vaccinatiekoepel"
- Evaluate the health objectives of vaccination and develop new objectives, focused on financial sustainability, maintaining high vaccination rate and decreasing socio-economic gradient. Additional vaccinations that are health-economical relevant, to add to the Flemish vaccination scheme, will be required.
- Raise awareness of parents through information and awareness campaigns
- Increase vaccination rate for at risk populations (HCPs, kids, pregnant women,…) by a better registration of influenza vaccination at institutions and companies.

The objectives and actions defined for the second goal (combat infectious diseases) are:

- Eliminate hepatitis B and C in Flanders by 2030
- Monitor measles and accurately intervene at outbreaks
- Planning, surveillance and preparation for the protection of the population against foreign infectious threats
- Collaboration with the federal government is key
- Monitoring and early detection of 40 notifiable diseases to prevent outbreak

For these above-mentioned objectives, no SMART-KPIs have been defined to monitor success and impact of this policy.

2.1.2 Stakeholders involved in the vaccination execution

The **implementation and coordination** of the vaccination programmes is a responsibility of Agentschap Zorg en Gezondheid in Flanders and ONE (for children) and AVIQ (for adults) in Wallonia. **Agentschap Zorg en Gezondheid** is responsible for providing sufficient and qualitative healthcare to people who need care and to support Flemish citizens to live healthy. To achieve the health objective for vaccination in 2020, the Agentschap developed the Flemish action plan "Vaccinaties 2012 – 2020". The objective was: by 2020, Flanders should have a qualitative vaccination policy focused on the effective protection of the population, along the entire life span, against infectious diseases with a severe impact on quality of life that can be prevented with vaccines.
ONE (Office de la naissance et de l'enfant) is responsible in Wallonia for managing the vaccination programme for children and youth between 0 and 18 year, students in non-university studies and pregnant women. The responsibility of ONE is assuring the promotion of vaccination and arrange ordering and supply of vaccines for the German-speaking Community and for the Brussels Capital Region (COCOM).
AVIQ (Agence pour une vie de qualité) is responsible for adult health, including prevention and surveillance of diseases. In 2017, AVIQ published a plan for health promotion, that includes key objectives for vaccination by 2030, based on transversal topics and thematic topics. Transversal topics include ensuring efficiency, establishing a culture of continuous evaluation, and the development of a network of intersectoral partnerships. The thematic topics focus on the prevention of infectious diseases including a vaccination policy. AVIQ's vaccination policy focusses on four objectives:

- limiting the risk of STDs
- promoting population vaccination and vaccination of high-risk populations
- reducing the risks of infectious diseases and monitor the spread of these diseases
- promoting better insights into infectious diseases.

The actual vaccination of the various target groups is executed per Region, by their respective organisations. In Flanders, Kind & Gezin and the CLBs are responsible. **Kind & Gezin** is responsible for managing the execution of the vaccination programme for babies and children up to 2.5 years old by making the vaccines available for free to this target population and by visiting mothers with infants. The **CLBs** (centra voor leerlingenbegeleiding) are responsible for the vaccination of children from 2.5 years to 18 years old by vaccinating and following-up children at school. The CLB notifies the parents in time about the vaccinations their children need.
The Mobiel Vaccinatie Team focuses on difficult to reach target groups in society such as Roma, victims of human trafficking, homeless people, students of Jewish schools. The Vaccinatie Team goes to the target groups and vaccinates them for free. The team consists of employees of the Provinciaal Instituut voor Hygiëne in Antwerp and the vaccination data are collected in Vaccinnet.

In Flanders, **LOGO's** (Lokaal GezondheidsOverleg) are the local health promotion organisations, commissioned by the Flemish government to achieve the Flemish health objectives on local level. This also includes the qualitative vaccination policy. There are 15 LOGO's in Flanders and Brussels. They have actively organised vaccination campaigns for seasonal flu, for the European vaccination week for traveling abroad and for vaccination during pregnancy.

In the French Community, three organisations are active in the execution of vaccination; ONE and PSE.
ONE is responsible for the execution of the vaccination programme for children up to 6 years old. **PSE** (Services de promotion de la Santé à l'école) **and CPMS** (Centres Psycho-médico-sociaux) are school health service organisations responsible for health and vaccination of children from 6 – 18 years old.

Kaleido DG is active in the German-speaking Community and responsible for health and vaccination of children up to 18 years old. Kaleido DG also targets pregnant women and young mothers to i.a. inform them about vaccination.

2.2. Allocation of vaccine budgets

In 2015, after the implementation of the 6th State reform, the Communities became responsible for the vaccination budget. The total budget for vaccination in Belgium in 2015 was €49,5 million, of which €29 million was allocated to Flanders and € 20,5 million was allocated to the French Community. In Flanders, Zorg en Gezondheid purchases vaccines based on the vaccination calendar and makes them available for free to the population. In the French Community, ONE does the same for Wallonia, French-speaking Brussels and the German-speaking community. The purchase by Zorg en Gezondheid and ONE is organised through tenders for a duration of 4 years through public procurement. The rotavirus vaccine is an exception and is the only vaccine that is included in the vaccination calendar of the regions but is reimbursed by the RIZIV-INAMI.

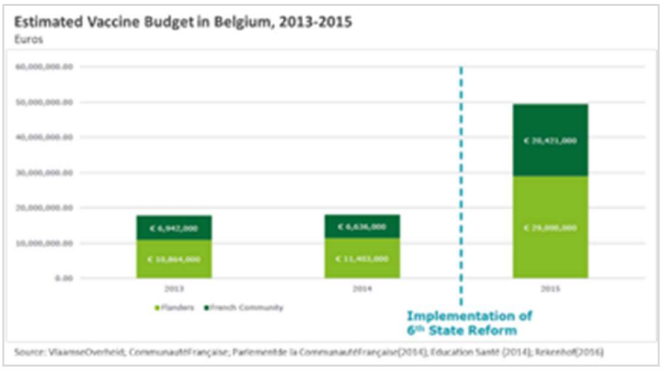


Figure 3 Estimated Vaccine Budget in Belgium, 2013 - 2015

In 2019, a new vaccines policy for Flanders was published by Minister Beke and the allocated budget for 2020 to execute this policy was €70,2 million. This budget is intended for a mix of multiple activities including:

- purchase of vaccines via tender
- execution of the action plan
- maintenance of Vaccinnet
- prophylactic measures regarding notifiable infectious diseases and outbreak management
- support for working groups in preventative care

(duizend euro)

	VAK	VEK
BO 2019	**68.080**	**68.580**
Index	*837*	*837*
Compensaties	*53*	*53*
Andere bijstellingen	*1.244*	*1.286*
BO 2020 excl. overflow	**70.214**	**70.756**
Overflow	*0*	*2.173*
BO 2020 incl. overflow	**70.214**	**72.929**
Aanwending VAK-ruiter		

Figure 4 Budget allocation for vaccines and vaccination in Flanders

- evaluations of prevention programmes, strategies and methodologies
- execution of the heat wave and ozone peak plan
- locoregional health consultation and organisation (Logo's) and partner organisations
- execution of tbc combat
- formulation of travel advices in collaboration with Institute for Tropical Medicine
- advising committee on bioethics
- collaboration with Sciensano
- execution of microbiologic analysis for outbreak management

Specifically, the budget for the purchase of vaccines in Flanders is €28 million in 2020.

For the French Community, the budget for the purchase of vaccines is € 15,8 million in 2020. For the German-speaking region, the budget is €150.000 per year for purchase. Finally, for the French-speaking part of Brussels, the budget for purchase is €1.2 million per year. These budget figures do not include the costs for the communication and organisation of the vaccination.

The RIZIV-INAMI budget, on federal level, for vaccine reimbursement is estimated at € 31,8 million for 2019. The budget spent on the reimbursement of the rotavirus vaccine is estimated to be € 12,5 million. About € 10 million is spent on the reimbursement of influenza vaccines and € 5 million on HPV vaccines. The remaining € 4,3 million is spent on the reimbursement of other population-specific vaccines not included in the vaccine calendar.

2.3. Shortcomings and implications of the current "as is" situation

Multiple shortcomings of the actual vaccination system in Belgium on Federal and regional level were mentioned by the interviewees that can be grouped into four categories:

- Planning
- Governance
- Budget
- Implementation

2.3.1 Shortcomings and implications on planning

The shortcomings on planning, mentioned during the interviews include lack of long-term planning, harmonisation in decision-making process and data to make decisions. Belgium lacks an overarching one plan on the long-term with clear priorities for vaccination, defined goals and KPIs to monitor progress. The current vaccine landscape is too much supply-driven and not sufficiently demand-driven, based on clear health objectives for specific populations. In addition, the decision-making process to include vaccines in vaccination programmes, is not harmonised. The SHC is currently a volunteer-based organisation with members working pro-bono and does not include all vaccination actors. This organisation model is not sustainable on the long-term to support science-based decisions.

The budget allocation to the communities is decided in the inter-ministerial conferences in consensus with the 9 ministers of health, but only few meetings are taking place and they are planned ad-hoc. The budget procedure is long and not transparent. On top RIZIV-INAMI can also decide to reimburse vaccines that are not recommended by the SHC nor included in the vaccination calendar. Also, sick funds can reimburse certain vaccines in their additional insurance package.

Data registration currently happens in 2 different vaccination registries: Vaccinnet in Flanders and eVax in Wallonia. Vaccinnet is well-updated with data on the vaccination status of the Flemish population, but the eVax database is much less populated and less up to date. Not all vaccinators can add patient vaccination data and/or have access to these registries. In contrast to Kind & Gezin in Flanders, ONE in Wallonia does not systematically enter vaccination status of infants into the eVax system (in contrast to Kind & Gezin in Flanders). Adult vaccination and travel vaccines are not well registered in the vaccine registries.

As a result of these shortcoming, it is difficult for HCP to follow-up a patient's vaccination status. Moreover, population data is missing to perform studies on the effectiveness and impact of vaccination programmes and to formulate recommendations. Local needs are also not identified and can therefore not be taken into account for the long-term planning. Recommendations made on a national level by the SHC are sent to the regions responsible for the implementation, which results in a slow process starting from SHC formulating the advice to the actual implementation and vaccination of the population.

2.3.2 Shortcomings and implications on governance

The shortcomings on governance that were mentioned by interviewees are unclear roles and responsibilities and also different vaccination coverage rates (VCR) in the regions.

Currently, the roles and responsibilities of the actors in the vaccination landscape are not clearly defined. There is also a lack of communication between actors and ways to enforce responsibilities and accountability of each actor. There is no Walloon equivalent of the "Vaccinatiekoepel" in Flanders, to translate the national SHC recommendations. In the past, CCIV (Comité de concertation intersectorial vaccination) and later GIEV was responsible for this, but the organisations had no mandate (as is the case for Vaccinatie Koepel). ONE has a mandate and the total budget to organise vaccination in Wallonia. However, their focus is only on children up until 18 years old and pregnant women, which results in the absence of adult vaccination. AVIQ only promotes vaccination in adults but does not organize programmes as it does not have the appropriate budget for it. There is no reporting of ONE to the HCPs about the vaccination, thereby complicating the follow-up of vaccination in children. In addition, there is no accountability of HCPs regarding vaccination reporting resulting in the lack of available vaccination data and occupational health is organised stand-alone.

There is a difference between Wallonia and Flanders regarding the vaccination coverage rate, resulting from differences in implementation of programmes and vaccination schemes. In Flanders, the overall adolescent VCR exceeds 84% for all vaccines in 2016, while in Wallonia, the overall adolescent VCR is much lower. In Wallonia, the adolescent VCRs differ a lot between vaccines and are detailed in the table. The child vaccination VCR is high in both Regions with a VCR of above 92% in Flanders in 2016 and a VCR larger than 89% in Wallonia in 2012. However, in entire Belgium, a gap in adult vaccination can be observed due to the lack of structural vaccination programmes for adults and elderly. These low VCRs enabled the measles outbreak in 2019 in Belgium.

Wallonia adolescent VCR Source: Vaccin studiedag FAGG on 06/12/2019	
MMR-2	86 % in 2017
Polio	73% in 2015
DT/DTPa	73% in 2015
dTap	53 % in 2014
HPV girls	36 % in 2017

However, interviewees indicated that bottom-up local organisation works, as communities are responsible for the implementation of vaccination despite the fact that recommendations are made on a national level. Local levels organise themselves well, despite the missing top-down plan and guidance. Its success is demonstrated in high VCRs in school kids through a well-organized school service system. HPV vaccine in boys was rapidly implemented in Flanders and in Wallonia via the school services. The Mobiel Vaccinatie team in Flanders is also an example of such a bottom-up approach to vaccinate unreached population groups such as homeless. In addition, when the Mexican flu pandemic hit Belgium in 2009, local communities successfully took measures to prevent the virus from spreading.

2.3.3 Shortcomings and implications on budget

The shortcomings on budget, mentioned by the interviewees are budget fragmentation, unclear allocation of budgets (federal, regional and local) and insufficient budgets.

Fragmentation can be observed in the vaccination decision-making process and the fact that the vaccine budget is split over RIZIV-INAMI, Flanders and Wallonia. Decision-making on budgets for vaccines is split over different commissions on federal and regional level, with varying stakeholder representation. Budget allocation to the Regions (Flanders and Wallonia) takes place according to a long budget procedure in the inter-ministerial conferences, that is not transparent. Regions are responsible for vaccination organization, but RIZIV-INAMI still has a budget for vaccines to reimburse on individual level.

Regions deal with closed budgets for the organisation of vaccination programmes and currently purchase vaccines based on separate tenders. Since the 6th State reform, Flanders and Wallonia can each decide themselves to start new programs if they have budget for it. However, their budgets are small and do not grow in time. In the interviews, multiple stakeholders challenged this way of working and wondered why tenders could not be organised jointly, Flanders and Wallonia together, to reduce administrative costs. RIZIV-INAMI reimburses certain vaccines on individual level and at a higher price than Regions can negotiate in the tender. An example is the rotavirus vaccine, which is obligatory by law but still reimbursed by RIZIV-INAMI and not included into the vaccination calendar.

Flanders has a well-organised "Vaccinatiekoepel" to translate national into regional Flemish recommendations but currently there is no Walloon counterpart. Fragmentation in Wallonia is larger than in Flanders with ONE and COCOM responsible for the policy in Wallonia and Brussels respectively. Vaccination budgets are allocated in such manner that ONE disposes of the entire vaccination budget for Wallonia and COCOM of the budget for Brussels. AVIQ, who is responsible for adult vaccination has no budget allocated and can only submit proposals to the minister of health in

Wallonia regarding adult vaccination. In 2019 however, a small budget for a communication campaign on influenza was allocated to AVIQ.

Current vaccination budgets are insufficient to further expand the vaccination programmes, according to the interviewed stakeholders. When a new vaccine is being recommended, additional budget will be needed to keep the registry up to date, train HCPs, set up public awareness campaigns, …

2.3.4 Shortcomings and implications on implementation

The shortcomings on implementation that we have heard during interviews, include lack of awareness about vaccination, having insufficient vaccinators for the entire population and having no buffer stocks for vaccines that are not included in a vaccination programme such as adult vaccines.

Awareness about the value and importance of vaccination is limited in all layers of the population including HCPs. Therefore, the antivax movement in Wallonia is getting traction. HCPs are not always well aware nor convinced about the value and importance of vaccination of specific target populations (e.g. flu vaccination in pregnant women). Also, the vaccination rate of HCPs of around 50%, is insufficient. HCPs need training to systematically populate the eVax/Vaccinnet system to monitor VCRs in the Belgian population. However, GPs cannot follow-up all individuals because not every individual is registered at a GP and vaccination registries are not well populated.

Currently in Belgium, only MDs and nurses can vaccinate, which might still pose high barriers for certain populations that are more difficult to reach. The potential of pharmacists and other HCPs to administer vaccines to increase adult VCR, is not fully utilized. Pharmacists can focus on vaccinating low-risk populations, while the high-risk population remains the responsibility of MDs.

In addition, a large gap in adult VCR can be observed because vaccination in this group depends on the initiative of the individual. Moreover, the French antivax movement in Wallonia has a large influence, resulting in a lower VCR than in Flanders.

Vaccinnet and eVax are used as the basis for ordering vaccines but there are no local buffer stocks for vaccines not included in a vaccination programme. Out-of-stock of vaccines can also be observed at the pharmacists. In case of out-of-stock or limited stock, dialogue is set up between the different actors to solve the problem. However, there is no plan and early dialogue between authorities and responsible actors to **prevent** out-of-stock situations and improve planning and stock management. Finally, HCPs in Wallonia still mainly order vaccines paper based as it is not obligatory to order via eVax, in contrast to Flanders with obligated electronic orders via Vaccinnet.

In conclusion, these above-mentioned shortcomings on planning, governance, budget and implementation level are opportunities for improvement. To become a leading country in vaccination coverage and strategy we need to address these shortcomings and implement alignment, goals setting, planning and integrated action.

3. International benchmarking and key learnings

John Hopkins Bloomberg School of Public Health published a study in February 2020 (Privor-Dumm, Vasudevan, Kobayashi, & Gupta, 2020), in which it conducted an archetype analysis of 34 countries worldwide. The analysis is based on the priorities and approach underlying the adult immunization decision-making and implementation processes in countries who recommend adult vaccines in their national schedule. The study focused on three vaccine-preventable diseases (VPD) in adults: influenza, pneumococcal and herpes zoster.

Four distinct archetypes in adult vaccination were found:

- Disease prevention-focused: The National Immunization Technical Advisory Groups (NITAGs) in these countries had considered most of the adult vaccines. Countries used their own disease burden / disease impact evidence as well as evidence from other countries in their decision-making. Own adult surveillance and formal adult vaccine working groups on their NITAG are also in place. Some countries (UK and the Netherlands) highly valued the economics in their decision-making. Regarding implementation, significant variation in performance was found. Reasons for this varied and included lack of national adult registries, equity focus, sufficient advocacy and centralization.

  Countries include UK, US, Canada, Germany, the Netherlands, France

- Health security-focused: A majority of countries belonged to this group. Countries are characterised by their common motivation to take action namely: outbreaks, VPD threats and natural disasters. These countries also have a centralised decision-making process and registries for monitoring and surveillance.

  Countries include Australia, Italy, New Zealand, Greece, Japan, Mexico, Argentina

- Evolving adult focus: Many countries lack a strong NITAG for adult vaccine decision. However, some have healthy ageing policies or immunization strategies, but only Brazil has both in place. Belgium and Ireland were early adopters for some vaccines such as Pneumococcal conjugate vaccine (PCV). In addition, Belgium has published an adult immunization strategy (Superior Health Council, Basisvaccinatieschema 2019). Countries in this archetype also varied in their public financing for recommended adult vaccines.

  Countries include Belgium, Spain, Ireland, Norway, Sweden, Brazil, Columbia

- Child-focused and cost-sensitive: Focus in the vaccine public market is children vaccination. Adult immunization is not prioritised and no adult vaccine working groups were found on the three VPDs that were analysed nor policies around adult immunization. Regarding implementation, the countries require patients to pay out of pocket for adult vaccines with some exceptions for influenza (e.g. in Switzerland influenza vaccines is covered through insurance). In these countries, child health and vaccines are prioritized because of the limited resources.

  Countries include Switzerland, Russia, India, Peru, Philippines

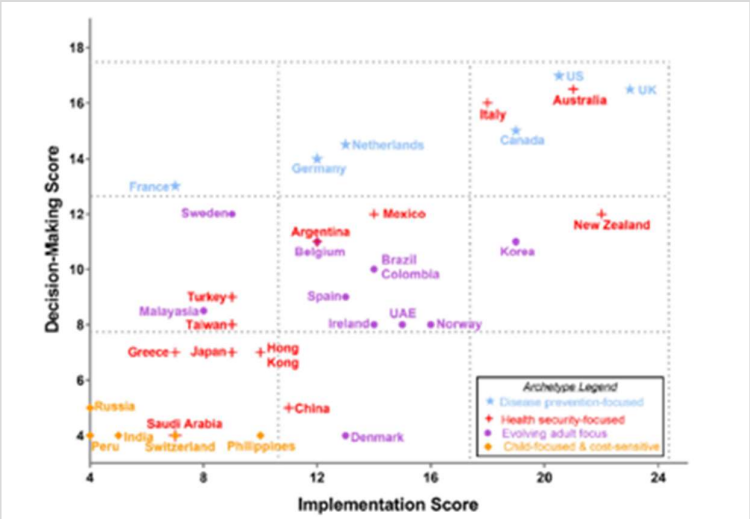


Figure 5 34 countries worldwide plotted according to their Adult Vaccine Archetype

Source: Privor-Dumm, L., 2020

In addition, seven key learnings have been identified, based on international benchmarking and analysing best practices from other EU countries, Australia and Canada. An overview of the seven key learnings is outlined in the table below.

International key learnings	Description
Having a long-term strategy and plan	• Defined strategic priorities and SMART objectives • Resources aligned to the priorities • Clear governance defined and involvement of multiple stakeholders • Use of a framework to detail core functions, strategic priorities and enablers • Horizon scanning to support long-term planning
Sufficient budget for prevention and vaccination	• Italy: 4,2% of total health expenditure goes to prevention • Netherlands has the highest expenditure (in €) per capita of €157,9
Continuously updated immunization programmes	• Whole life course immunization programme covering children, adolescents and adults • Additional recommendations for specific populations • Organisation of catch-up programmes • Continuously evolving programmes incorporating new, more effective, cost-effective vaccines and new uses for existing vaccines across the life course
Increase communication and awareness of the broad public and the HCPs on vaccination	• Publicly communicated policy, strategy and programmes • Major public awareness programme through different channels (incl. traditional and social media) to disseminate evidence-based and trusted information on vaccines and address public concerns • Ensure early access to high-quality information for public and HCPs
Updated data systems and continuous surveillance	• Whole life immunisation register • Surveillance through rigorous case investigation of suspected cases • National surveillance network with an active monitoring system enabling real-time tracking of outbreaks and vaccine adverse events • Evaluation framework and cycle to assess programme delivery effectiveness
Increased accessibility based on broader utilisation of vaccinator capacity	• Adequately skilled immunisation workforce through promoting effective training • Offering vaccines in a more diverse range of locations (e.g. pharmacies) • Ensure healthcare settings to be fully prepared for outbreak
Secure vaccine supply	• Efficient and effective procurement through centralised procurement and supply management • Dedicated local vaccines manufacturing centre for clinical trials and for emergency preparedness

In the following paragraphs, the best practices are detailed and illustrated with examples from various countries. More country examples are listed in annex, at the end of this report.

3.1. Having a long-term strategy and plan

Multiple countries have defined a strategic framework with clear goals and priority actions. In the UK, a measles and rubella elimination strategy has been defined that is framed around four building blocks in line with WHO's European Vaccine Action Plan. Australia has defined eight strategic priorities in its National Immunization Strategy 2019 – 2024. British Columbia (Canada) has defined a strategic framework with four goals, each with priority actions. Public Health England defined an infectious disease strategy using a framework to detail core functions, strategic priorities and enablers. Core functions are foundations required to achieve the organisational mission. The strategic priorities will focus effort and represent specific programmes that contribute to achieving the core functions. Enablers are the skills, capabilities and activities required for a successful delivery of the core functions and strategic priorities. Involvement of multiple stakeholders is critical for the success of this strategy and a specific multi-stakeholder engagement and governance model has been put in place.

Figure 6 Australia's National Immunization Strategy 2019 – 2024

Having these long-term strategies and plans in place result in multiple benefits on different levels:

- improved VCRs in the entire population, including adults
- effective monitoring, using registries and surveillance through rigorous case investigation
- communication, education and awareness that is evidence-based
- effective governance
- ensure secure vaccine supply
- ensure adequately skilled immunisation workforce and capacity
- horizon scanning to facilitate long-term planning.

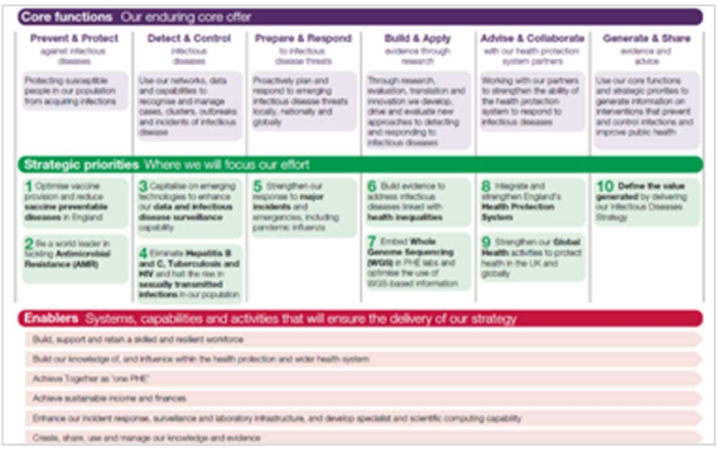


Figure 7 PHE's infectious disease strategy - framework

3.2. Sufficient budget for prevention and vaccination

Budget allocated to prevention and vaccination in Belgium is much less than that in other European countries. Italy (4,2 % of total health expenditure) and the Netherlands (€157,9 per capita) lead prevention spending in the EU-14 countries as illustrated below. In 2016, the proportion of national healthcare spending devoted to prevention, has decreased from 2.1% to 2% in Belgium. Also, in other European countries, this proportion has decreased as illustrated in Figure 12. Nonetheless, in European countries, the prevention budget accounts for less than 5% of the healthcare spending.

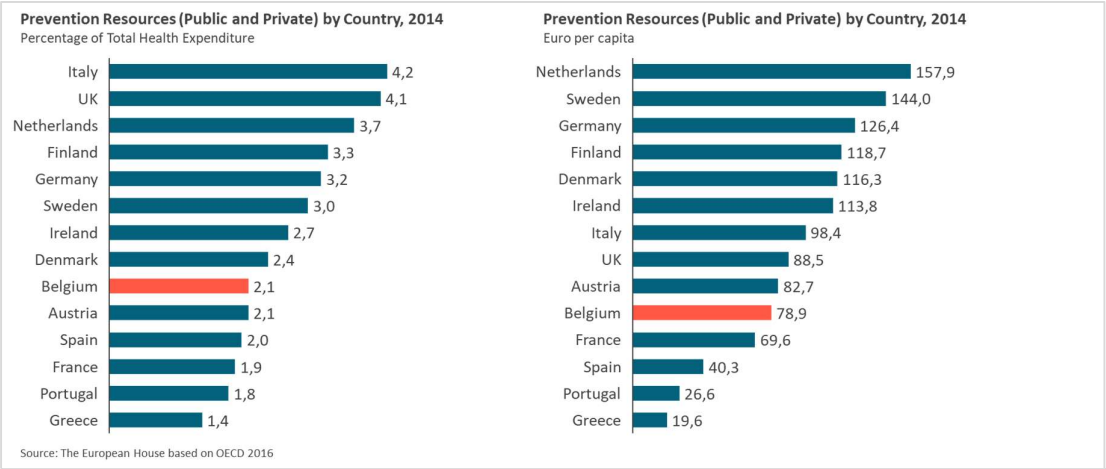


Figure 8 Prevention spending in European countries

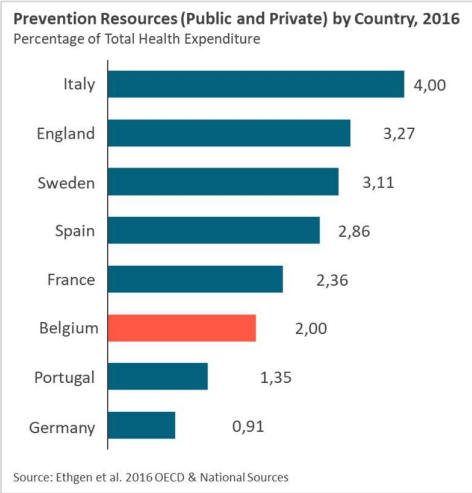


Figure 9 Proportion of national healthcare spending, devoted to prevention has decreased from 2,1% to 2% in Belgium, in 2016

In Canada, the British Columbian (BC) Immunisation framework also emphasises budget availability as a specific goal; build the capacity of the immunization programme to ensure long-term sustainability. In this goal, one of the strategies is to seek continued investment and ensure alignment of the funding to achieve the priority objectives.

Figure 10 Immunize framework - Investment strategy

3.3. Continuously updated immunization programmes

Best practice countries illustrate that national immunization programmes should cover the entire life course including children, adolescents, adults and elderly. Additional recommendations on vaccination in specific populations and catch-up programmes are essential to reach or maintain a vaccination coverage. Local teams and communities also play a key role in the implementation of the vaccination programmes. Close collaboration between national and local level is imperative in order to achieve the defined goals and to address the local needs. Finally, immunization programmes should continuously evolve over time by incorporating new, more effective or cost-effective vaccines and new uses for existing vaccines across the life course.

Figure 11 UK Measles and rubella elimination strategy - central role of the local teams

3.4. Increase communication and awareness of the broad public and the HCPs on vaccination

Raising awareness at HCPs and the public is imperative to reach and maintain high VCRs in the population. Publicly communicating about the policy, strategy and programmes is essential. Major public awareness programme through different channels (incl. traditional and social media) are imperative to disseminate evidence-based and trusted information on vaccines and address public concerns. In addition, access to evidence-based information should be ensured for the broad public and HCPs. All best practice countries have included communication and awareness as a key action in their strategies.

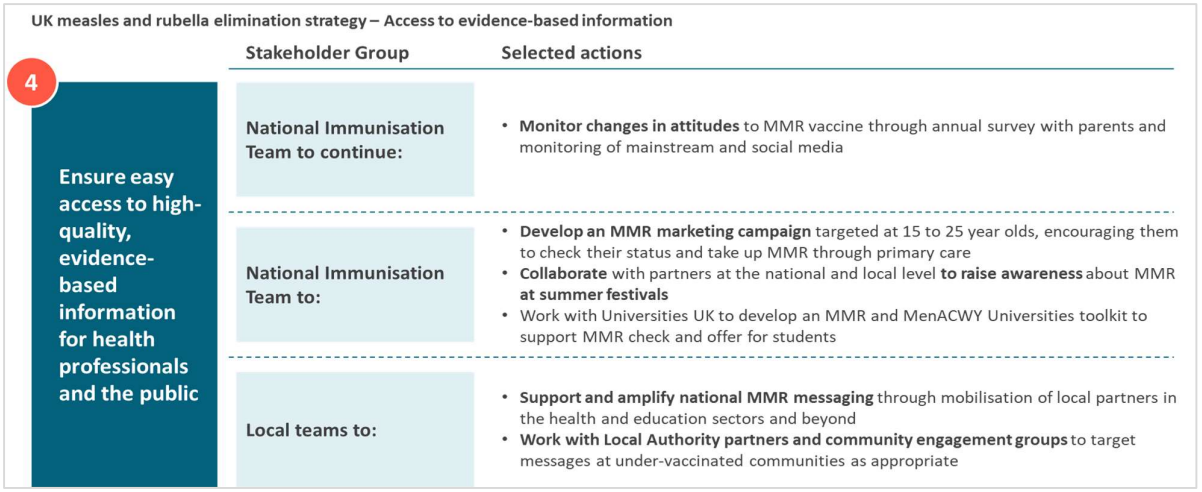


Figure 12 UK measles and rubella elimination strategy - Access to evidence-based information

3.5. Updated data system and continuous surveillance

Monitoring outcomes of vaccination programmes and systematic surveillance are imperative to enable real-time tracking of outbreaks and vaccine adverse events. Systematic collection of this data in a whole life immunization registry, enables evidence-based insights that can support and inform policy decisions. In addition, systematic surveillance through rigorous case investigation of suspected cases, should be facilitated by a national surveillance network with an active monitoring system that enables real-time tracking of outbreaks and vaccine adverse events. Finally, an evaluation framework and cycle is required to assess programme delivery effectiveness.

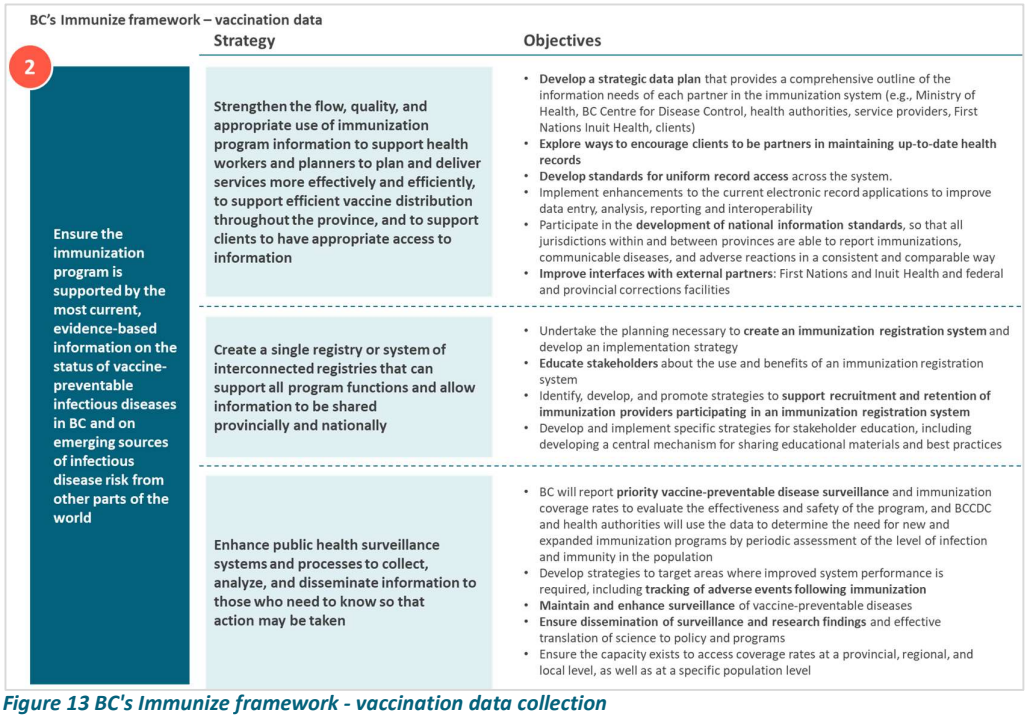


Figure 13 BC's Immunize framework - vaccination data collection

3.6. Increased accessibility based on broader utilisation of vaccinator capacity

Lowering barriers to vaccinate increases the reach and improves access to vaccination. Measures to lower barriers include offering vaccination in a more diverse range of settings where vaccination can be performed and enabling a broad number of HCPs to vaccinate (e.g. pharmacists). Adequately skilled immunisation workforce through promoting effective training is required. In addition, healthcare settings should be fully prepared for possible outbreaks. An interesting example can be found in Ireland where the HPV vaccination rate increased significantly as retail pharmacies started playing a significant role in the recommendation of HPV vaccination.

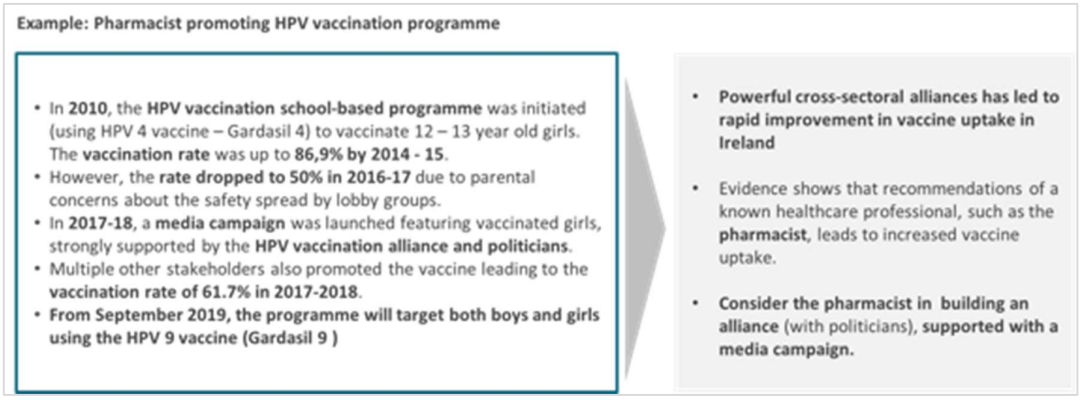


Figure 14 Pharmacist role in vaccination promotion in Ireland

3.7. Secure vaccine supply

Efficient and effective procurement through centralized procurement ensures a timely vaccine supply. In addition, to address the structural gap in late-stage vaccine manufacturing process development, a dedicated UK vaccines manufacturing innovation centre for clinical trials and for emergency preparedness was announced in December 2018. This second example can be found in annex.

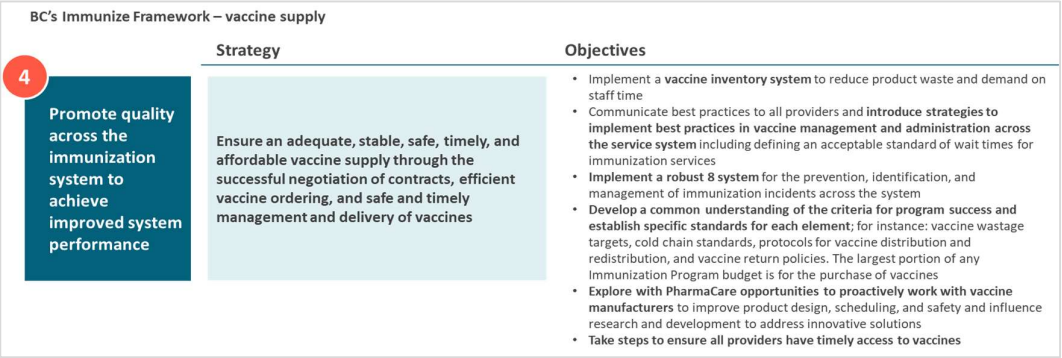


Figure 15 BC's Immunize Framework - vaccine supply

4. Policy recommendations

4.1. Belgian vaccine framework and plan

Based on the Belgian landscape analysis, performed on extensive interviews and international benchmarking, a Belgian vaccine framework has been formulated to articulate the strategic goals, priority actions and enablers. The priority actions outline the policy proposals and recommendations for Belgium to overcome the main shortcomings of the actual system in the near future.

The proposed framework articulates the strategic goals that are set to achieve the Belgian immunization mission. Priority actions are defined to drive and deliver each of the strategic goals. In addition, enablers have been defined, to support the execution and delivery of the priority actions.

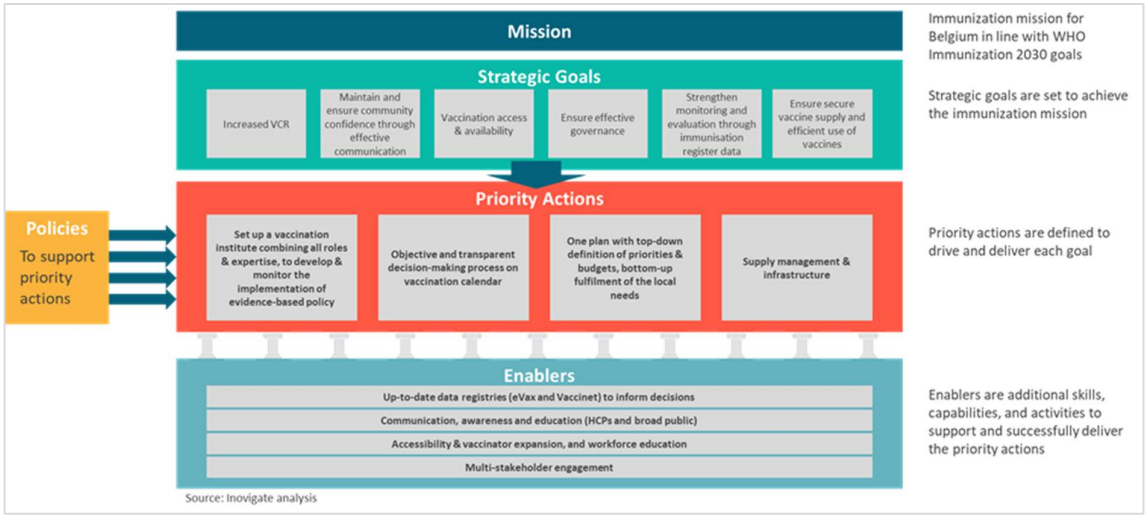


Figure 16 Belgian vaccine landscape framework with strategic goals, priority actions and enablers

For Belgium, the following vaccination strategic goals are proposed:

- Increased VCR
- Maintain and ensure community confidence through effective communication
- Vaccination access and availability
- Ensure effective governance
- Strengthen monitoring and evaluation through immunisation register data
- Ensure secure vaccine supply and efficient use of vaccines

To achieve these five goals, four priority actions together with four enablers have been formulated. Based on the interviews there are 4 main priority actions that need to be put in place to overcome the identified shortcomings in the actual system and providing the plan with concrete actions for a more performing system on the near term:

- Set up a vaccination institute combining all roles and expertise, to develop and monitor the implementation of evidence-based policy
- Objective and transparent decision-making process on vaccination calendar
- One plan with top-down definition of priorities and budgets, bottom-up fulfilment of the local needs
- Supply management and infrastructure.

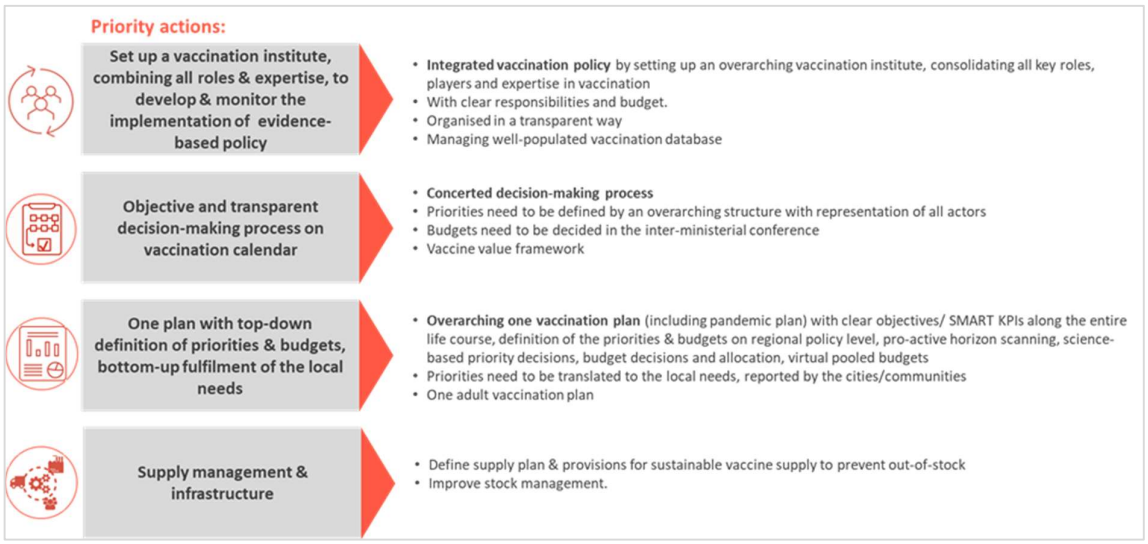


Figure 17 Four priority actions in the Belgian vaccine landscape framework

The 4 priority actions should be supported by four enablers:

- Up-to-date data registries (eVax and Vaccinnet) to inform decisions
- Communication, awareness and education (HCPs and broad public)
- Accessibility and vaccinator expansion, and workforce education
- Multi-stakeholder engagement.

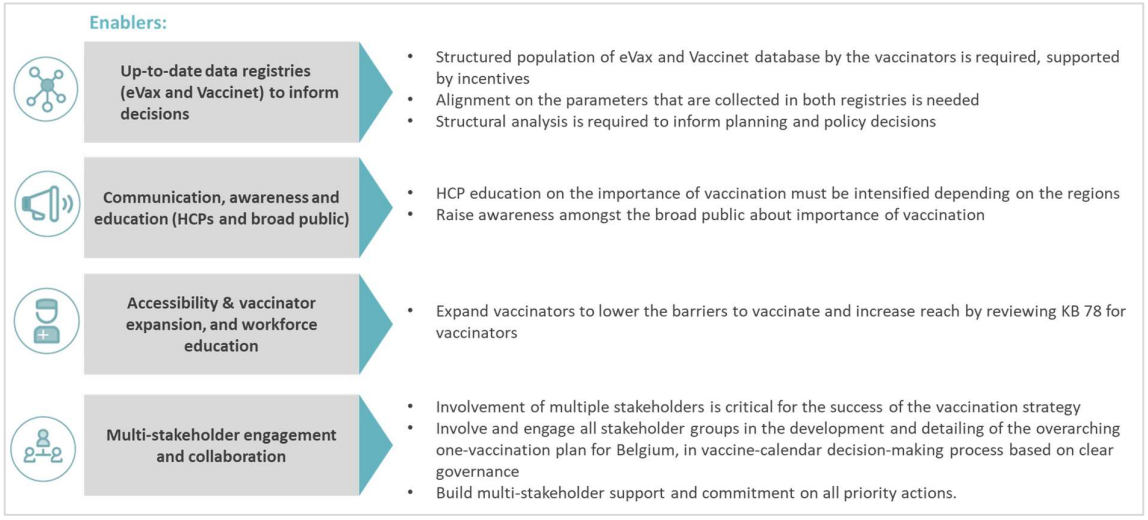


Figure 18 Four enablers in the Belgian vaccine landscape framework

4.2. Policy proposals and recommendations include the minimum "must haves"

Based on the interviews and the international benchmarking, 10 minimum "must have" elements for an optimal vaccine landscape were identified. These "must haves" are also included in the policy proposals. The minimum "must haves" are listed in the table below:

	Minimum must have	Description
1	Clear vision and/or mission	A well-defined vision or mission as a basis for immunization goals
2	Specific goals for immunization	VCR objectives / KPI-target setting including universal mass vaccination (UMV) outcomes reporting and systematic surveillance
3	Stakeholder map within roles and responsibilities	Identification of all relevant stakeholders (including the public) and how they must work together
4	Access	Accelerate availability of vaccines and use innovation to increase access and vaccination rates
5	Standardized assessment frameworks	Including horizon scanning, publication of decision-rationale, priorities and budget allocation
6	Life course immunization schedule	An immunization schedule that covers children, adolescents, adults, and at-risk populations
7	Communications strategy	For all stakeholder, that covers both traditional (e.g. press) and new (e.g. social media) channels
8	Workforce education and capacity	Educated HCPs to take advantage of any patient contact, and enough capacity to meet objectives
9	Centralized registry	Centralised registry, e-vaccination records (Vaccinnet, e-Vax) to support insights, priority setting and KPI setting
10	Provisions for sustainable vaccine supply	Centralised stock management and oversight

The mapping of the policy recommendations with the minimum “must haves” is outlined in the table below:

Priority actions	1) Clear vision/mission	2) Specific goals for immunization	3) Stakeholder map with roles and responsibilities	4) Access	5) Standardized assessment frameworks	6) Life course immunization schedule	7) Communications strategy	8) Workforce education and capacity	9) Centralized registry	10) Provisions for sustainable vaccine supply
Vaccination institute	✓	✓	✓		✓	✓	✓		✓	✓
Objective and transparent decision-making process on vaccination calendar				✓	✓					
One plan with top-down definition of priorities and budgets, bottom-up fulfilment of the local needs		✓				✓				
Supply management and infrastructure				✓						✓
Enablers										
Up-to-date data registries (eVax and Vaccinnet) to inform decisions									✓	
Communication, awareness and education (HCPs and broad public)							✓	✓		
Accessibility and vaccinator expansion, and workforce education				✓						
Multi-stakeholder engagement			✓							

4.3. Alignment with the WHO Immunization 2030 strategy

The strategic goals, priority actions and enablers are aligned with the strategic priorities of WHO Immunization 2030. WHO Immunization 2030 defines 7 strategic priorities with objectives, listed in the table below.

Strategic priorities	Objectives
Immunization for primary health care and universal health coverage	To build effective, efficient and resilient immunization programmes that deliver high-quality immunization services as a part of national primary healthcare systems aimed at achieving universal health coverage
Equity and access	To ensure that everyone has equitable access to vaccines, irrespective of their geographical location, gender, socioeconomic status or any other factor, that might prejudice their access to services
Ownership and accountability	To ensure that everyone, everywhere values immunization and seeks out immunization services, by positioning immunization as an undeniable human right, building community ownership, and strengthening accountability at all levels
Outbreaks and emergencies	To maintain and strengthen capacity to prepare for, prevent and respond to vaccine-preventable disease outbreaks, and ensure that those affected by conflict, political instability and other emergencies continue to receive essential immunization services
Life course and integration	To realize the full benefits and impact of immunization by establishing and strengthening people-centred platforms to deliver vaccines and additional interventions along the life course, by collaborating with other health programmes and sectors, and by utilising all available opportunities to provide catch-up vaccination
Research and innovation	To encourage and intensify the development and adoption of new vaccines and vaccine administration technologies, novel vaccine manufacturing platforms, and programmatic innovations to enhance equitable access to immunization, taking account of ever-changing infectious disease epidemiology and emerging infectious disease threats
Availability and sustainability	To ensure a reliable global supply of affordable vaccines of assured quality, as well as a clear pathway for countries to programmatic and financial self-sustainability of their immunization programmes, taking account of global vaccine shortages and transitions out of global support programmes
Economic advantages*	Immunization can deliver economic benefits: maintain a healthy and productive workforce; reduce poverty, through avoidance of healthcare costs, lost wages, and lost productivity to illness

* highlighted in the WHO report as one of the benefits of immunization but has a very important societal impact and is therefore explicitly mentioned in this list.

The mapping of the proposed priority actions for Belgium against the WHO Immunization 2030 strategic goals is represented in the table below:

	Immunization for primary health care and universal health coverage	Equity and Access	Ownership and Accountability	Outbreaks and emergencies	Life course and integration	Research and innovation	Availability and sustainability
Priority actions							
Vaccination Institute	✓	✓	✓	✓	✓	✓	✓
Objective and transparent decision-making process on vaccination calendar		✓	✓		✓		✓
One plan with top-down definition of priorities and budgets, bottom-up fulfilment of the local needs	✓	✓	✓	✓	✓	✓	✓
Supply management and infrastructure			✓	✓			✓
Enablers							
Up-to-date data registries (eVax and Vaccinnet) to inform decisions		✓	✓		✓	✓	✓
Communication, awareness and education (HCPs and broad public)			✓		✓	✓	
Accessibility and vaccinator expansion, and workforce education		✓	✓		✓		
Multi-stakeholder engagement		✓	✓				✓

4.4. Recommendations and policy proposals

A plan with four priority actions has been proposed for a performing vaccine system in Belgium in the near term. Each of the priority actions are further detailed below and formulated as concrete policy proposals, addressing the shortcomings and providing the plan with concrete actions for a more performing vaccine system.

4.4.1. Policy proposal 1: Set up of a vaccination institute

Integrated vaccination policy in Belgium by setting up an overarching vaccination institute to improve vaccination policy in the future.

This vaccination institute with clear responsibilities, consolidates on a permanent basis all the key roles, players and expertise in vaccination, including federal and regional policy makers, health authorities and health insurance funds, academics and manufacturers.

The Institute develops and oversees the implementation of an evidence-based vaccination vision and policy. This includes defining priorities and timelines, the vaccination calendar and proactive horizon scanning. In addition, the institute has its own budget, bringing together existing scattered vaccination budgets, to make budget decisions and allocation.

To this end, (1) the Institute has to have access to an accurate vaccination database, (2) it ensures alignment on the parameters of data collection and its structural analysis, as a basis for the development of the best available evidence supporting policy, and (3) it is organised according to the most modern principles of transparency regarding everyone's role and responsibility, evidence-based decisions are made public, and the Institute develops a code of good management of potential conflicts of interest.

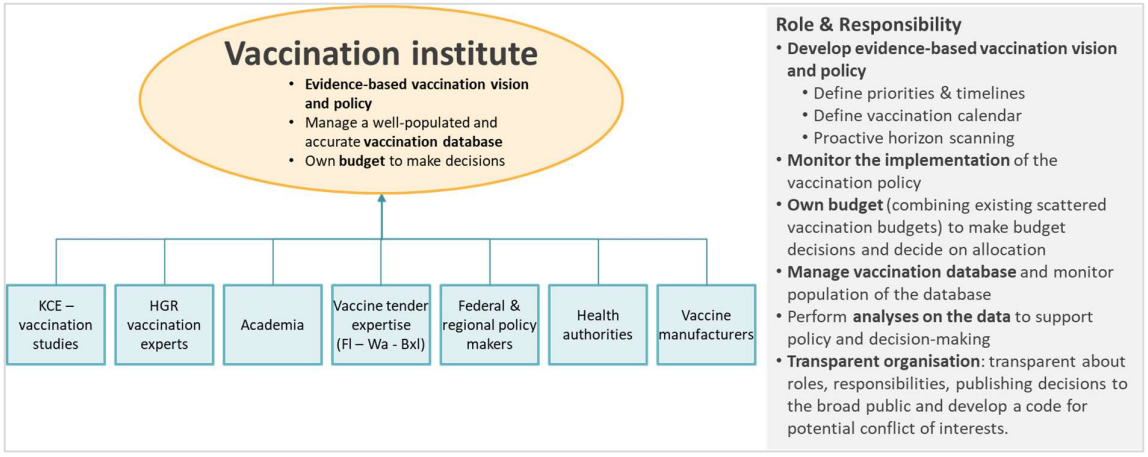


Figure 19 Vaccination institute

4.4.2. Policy proposal 2: Objective and transparent decision-making process on vaccination calendar

The decision-making process, for a new vaccine to be included in a vaccination programme, has to be objective and transparent, based on:

- Priorities defined by an overarching structure with representation of all actors
- Publication of decision-rationale, priorities and budget allocation, to increase transparency.
- Budgets need to be decided in the inter-ministerial conference, in a transparent manner
- Concerted decision-making process for new vaccines to be included in a vaccination programme
- A common standardized vaccine value framework supporting objective evaluation
- A standard 'core outcome sets' for prevention (cfr. in other disease areas)
- A common standardised overarching vaccine value framework reflecting a ROI for prevention that goes beyond financial. This includes economical, societal, other values and benefits to demonstrate larger and more transversal value add. Good public health promotes both economic growth and social and well-being of a country.
- Horizon scanning required for improved decision-making on the longer-term.

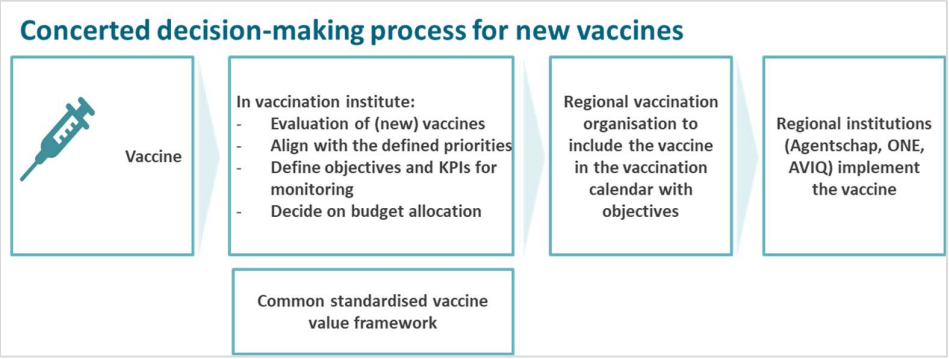


Figure 20 The decision-making process for a (new) vaccine to be included in a vaccination programme

A vaccine value framework integrates the strategic health goals of a life course immunisation plan and effective preparedness of pandemic outbreaks. This framework should include vaccination and coverage needs, "unmet medical" needs in the field and the pipeline of vaccines in development (horizon scanning), to plan and prepare budgets on long term. The value framework should be the reference basis for decision-making based on objective and transparent demographic and health criteria.

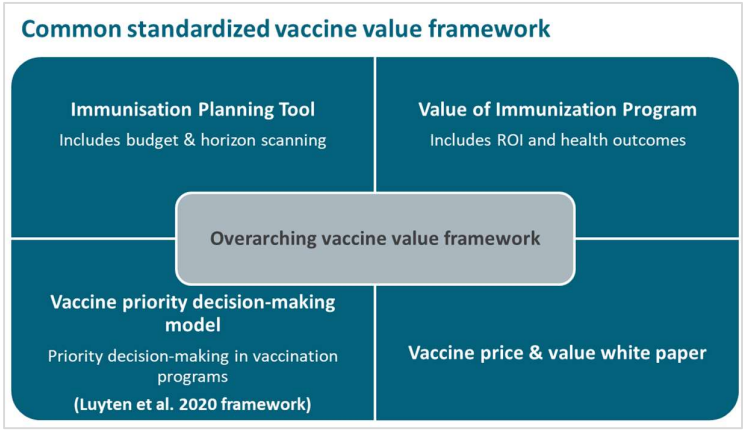


Figure 21 Common standardized vaccine value framework

4.4.3. Policy proposal 3: One plan with top-down definition of priorities and budgets, bottom-up fulfilment of the local needs

An overarching one vaccination plan (including pandemic plan) for life course vaccination, will support engagement and collaboration of all system stakeholders. This overarching vaccination plan is outlined as a framework to detail core functions, with aligned resources to the strategic priorities and enablers and should combine:

- Well-defined vision, mission and strategic priorities (in line with WHO immunization 2030 goals)
- Clear objectives, defined as SMART KPIs, along the entire life course
- Virtually pooled budgets, translated into priorities and budgets on regional policy level, and to the local needs, reported by the cities/communities
- Pro-active horizon scanning to plan on the long-term for life course vaccination
- Science-based priority decisions (including based on registry data analysis), budget decisions and allocation

An overarching life course vaccination plan based on a well-defined vision is required as a basis for achieving the immunization goals (in line with WHO immunization 2030 goals). Defined strategic priorities and SMART objectives, are key to accelerate the availability of vaccines and use innovation to increase access and vaccination rates. These SMART objectives should be based on clear VCR objectives, KPI-target setting (including universal mass vaccination outcomes reporting) and systematic surveillance. Resources should be aligned to the priorities, as well as a clear governance should be defined with clear roles and responsibilities of all relevant stakeholders involved, including the public. The use of a framework to detail core functions, strategic priorities and enablers supports the involvement and collaboration with all system stakeholders.

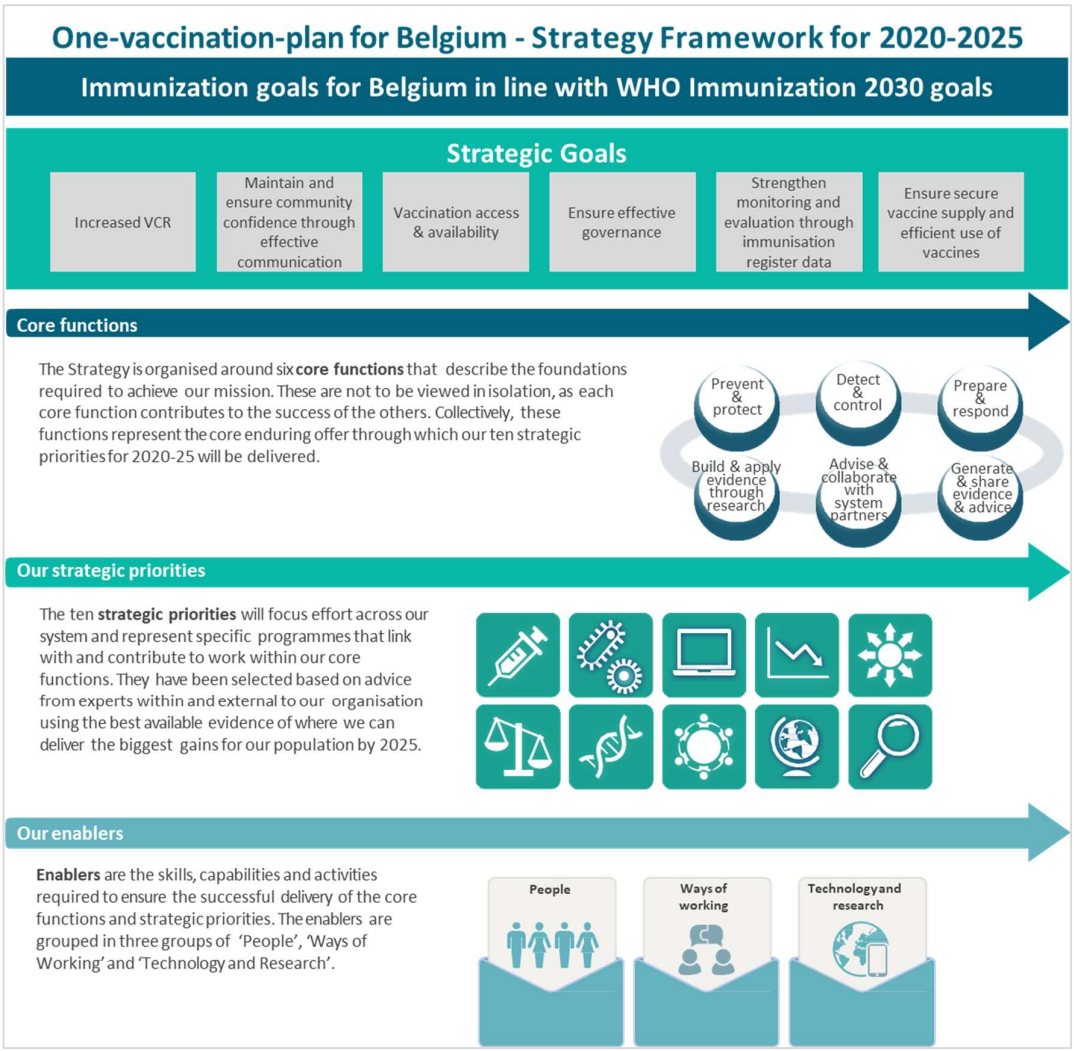


Figure 22 Overall one-national-vaccination plan for Belgium

A continuously updated immunization programme is required, covering whole life course immunization (for children, adolescents and adults) and incorporating new, more effective, cost-effective vaccines. Furthermore, additional recommendations for specific populations, organisation of catch-up programmes is key. Moreover, new uses for existing vaccines across the life course increases the benefits for the population immunisation.

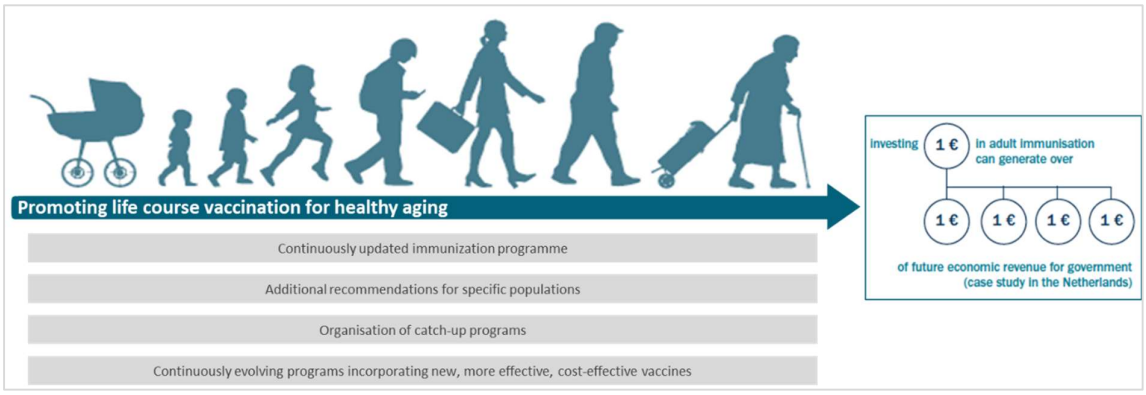


Figure 23 One-adult-vaccination plan for life-course vaccination

Furthermore, a centralised registry and e-vaccination records (Vaccinnet, e-VAX) to support insights, priority setting, and KPI setting are required. Whole life immunisation registry is key and should be systematically and accurately populated to support and inform policy decisions. In addition, systematic surveillance through rigorous case investigation of suspected cases, should be facilitated by an overarching surveillance network with an active monitoring system that enables real-time tracking of outbreaks and vaccine adverse events. Finally, an evaluation framework and cycle is required to assess programme delivery effectiveness.

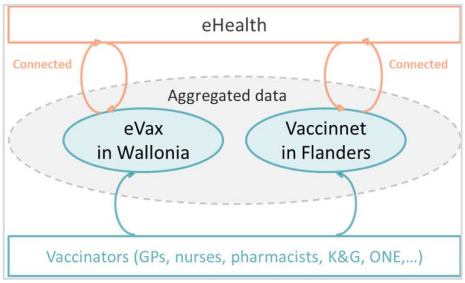


Figure 24 Centralised accurate whole-of-life-course vaccination

4.4.4. Policy proposal 4: Supply management and infrastructure

Occurrence of out-of-stock of vaccines, also at the pharmacists, requires improved planning and forecasting.
To achieve this "one vaccines supply plan" and solve out-of-stock-issues, collaboration between authorities and responsible actors will be crucial. In addition, centralised stock management and oversight through the implementation of a vaccine inventory system will reduce out-of-stock situations and improve forecasting demand and supply, by reducing product waste and demanding on staff time. Efficient and effective procurement through centralised procurement will also be needed to ensure an adequate, stable, safe, timely, and affordable vaccine supply. The centralised procurement enables the successful negotiation of contracts, efficient vaccine ordering, and safe and timely management and delivery of vaccines.

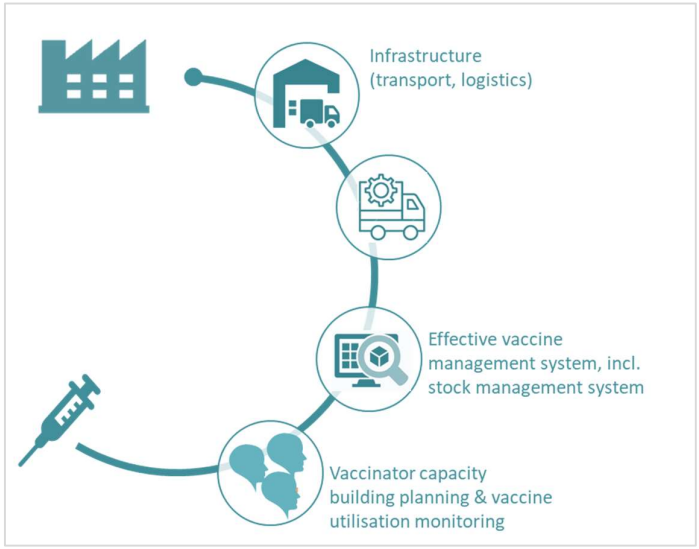


Figure 25 Supply management system

Furthermore, several supporting measures should be implemented. Communicating best practices to all providers and introducing strategies to implement best practices in vaccine management and administration across the service system (including defining an acceptable standard of wait times for immunization services) will be needed. Also, implementation of a robust system for the prevention, identification, and management of immunization incidents across the system, is required. And finally, the development of a common understanding of the criteria for programme success have to be developed and specific standards established for

each element. Several examples are vaccine wastage targets, cold chain standards, protocols for vaccine distribution and redistribution, and vaccine return policies. The largest portion of any immunization programme budget is for the purchase of vaccines. Steps to ensure all providers have timely access to vaccines, have to be defined.

Opportunities to proactively work with vaccine manufacturers have to be explored, to improve product design, scheduling, vaccine safety and influence research and development to address innovative solutions. Moreover, a dedicated vaccines Manufacturing Innovation Centre for clinical trials and for emergency preparedness will be required.

4.4.5. Enablers for the priority actions:

Enabler 1: Up-to-date registries (eVax and Vaccinnet) to inform decisions

A centralised registry, e-vaccination records (vaccinnet, e-VAX), to support insights, priority setting, and KPI setting are required. Data registries are key and should be accurately populated to support and inform policy decisions. Structured population of eVax and Vaccinnet database by the vaccinators is required, supported by incentives. Moreover, coupling of the databases of Vaccinnet in Flanders and eVax in Wallonia is recommended by certain stakeholders.

In addition, alignment is needed on the parameters that are collected in both registries to allow for population-wide and structural analysis required to inform planning and policy decisions.

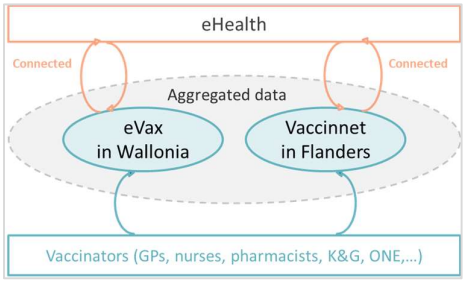


Figure 26 Centralised accurate whole-of-life-course vaccination

Furthermore, the following elements are needed to monitor the vaccination coverage rate: whole life immunization register, surveillance through rigorous case investigation of suspected cases, overarching surveillance network with an active monitoring system enabling real-time tracking of outbreaks and vaccine adverse events. Finally, an evaluation framework and cycle to assess vaccine programme delivery effectiveness is required.

Enabler 2: Communication, awareness and education (HCPs and broad public)

Communication, awareness campaigns and education for all stakeholders, covering both traditional (e.g. press) and new channels (e.g. social media marketing tools/technology) remain imperative. Increasing community awareness through timely, complete and appropriate communication is key to successful and sustainable vaccine introduction. Each target group calls for multifaceted communications strategies. For HCPs, education on the importance of vaccination has to be intensified especially in Wallonia. For the broad public, increasing knowledge and awareness amongst the broad public about availability of vaccinations and the vital importance of vaccinations is key.

Figure 27 Strategic communications through multiple channels

Current attitudes, knowledge and beliefs regarding immunization across all target populations should be determined, in order to further tailor information and maximise the positive impact of the communication. Tailored information will facilitate the development of attitudes and behaviours at the broad public that reflect an informed understanding of the vital importance of immunization, to sustain individual and population health. In addition, impact can be further maximised by engaging the public to comprehend the immunization value and seeking to be vaccinated, with an emphasis on high-priority populations (e.g. hard-to-reach, under-immunized groups). Finally, promotion, advocacy, and communication should be an integral component of the immunization programme.

Enabler 3: Accessibility and vaccinator expansion, and workforce education

Expand vaccinators to lower the barriers to vaccinate, increase reach and improve access to immunization services. Sufficient, qualified providers is key to meet current and future immunization programme demands in an inter-disciplinary service system. This can be enabled through 1) investigating opportunities to expand the range of health care professionals providing immunization (e.g. active involvement of community pharmacists as zero-line access, with broad reach and low barrier to access); and 2) reviewing Royal Decree (RD) 78 for vaccinators. In addition, the development and implementation of a strategy to increase the range of settings in which immunizations are provided beyond public health clinics, physicians' offices and school services is key to improve access and lower barriers. The consistent delivery of immunization by all providers (e.g., primary care, public health, and private physicians, pharmacists, etc.) should also be promoted and ensured. This can be enabled by a clearly defined interdisciplinary model of staffing with clear criteria. Finally, ways should be explored to address the barriers to increased physician participation (especially for adult and
elderly vaccination).

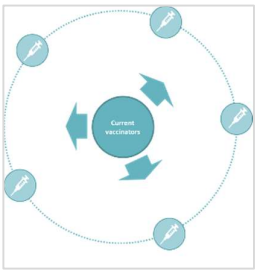


Figure 28 Vaccinator expansion

Enabler 4: Multi-stakeholder engagement and collaboration

Involvement of multiple stakeholders is imperative for the success of the vaccination plan. All stakeholder groups (incl. industry) should be involved and engaged in the development and detailing of the One-vaccination plan for Belgium, governance and vaccine-calendar decision-making process. Hence, multi-stakeholder support and commitment on all priority actions can be built.

Successful delivery of the Belgian Vaccination mission is only possible through mutually beneficial partnerships within a robust and effective health protection system at the local level, regional and federal level. A strategic forum for stakeholders should also be provided to facilitate health sector preparedness and planning for emergencies. Moreover, this strategic forum can facilitate manufacturers to discuss their vaccine pipeline to support long-term planning.

To deliver this combination of public health protection duties and services, close partnership working is required between federal and regional government, agencies, industry and the public.

Figure 29 Multi-stakeholder engagement is key

5. Conclusions

The ambition of this report is to deeply understand the prevention and complex vaccination landscape in Belgium and identify opportunities for improvement. With this report, we provided a plan based on four priority actions supported by four enablers for a top performing vaccine system, meeting the WHO Immunization 2030 requirements.

Finally, the four priority actions that have been defined need multi-stakeholder harmonization:

- **Set up a vaccination institute, combining all roles and expertise, to develop and monitor the implementation of evidence-based policy:**
  A Vaccination Institute should facilitate an integrated vaccination policy. This vaccination institute with clear responsibilities and own budget, consolidates on a permanent basis all the key roles, players and expertise in vaccination, including federal and regional policy makers, health authorities and health insurance funds, academics and manufacturers. The Institute develops and oversees the implementation of an evidence-based vaccination vision and policy.

- **Objective and transparent decision-making process and vaccination value framework on vaccination calendar**:
  The decision-making process for a new vaccine to be included in a vaccination program, has to be objective and transparent. This has to be decided in a concerted decision-making process for new vaccines, based on a common standardized vaccine value framework, as well as horizon scanning (to support long-term planning).

- **One plan with top-down definition of priorities and budgets, bottom-up fulfilment of the local needs**:
  An overarching one vaccination plan (including pandemic plan) should be outlined as a framework to detail core functions with aligned resources to the strategic priorities and enablers. This will support engagement and collaboration of all system stakeholders. The plan should be complemented with a continuously updated immunization program and a centralised accurate whole-of-life immunisation registry (e-vaccination records).

- **Supply management and infrastructure**:
  Ensure reliable and secure vaccine supply, based on an improved planning and forecasting. An “one vaccines supply plan” needs to be defined where collaboration between authorities and responsible actors is key to solve out-of-stock issues. Furthermore, centralised stock management and oversight through the implementation of a vaccine inventory system, will reduce out-of-stock situations and improve forecasting demand and supply. A centralised procurement and pro-actively collaborating with vaccine companies also supports continuous supply of essential vaccines for Belgium. Furthermore, a dedicated vaccines Manufacturing Innovation Centre for clinical trials and emergency preparedness will be required.

We hope this report will inspire and facilitate multi-stakeholder discussions to further detail the four priority actions of the vaccination plan for Belgium and build consensus to put them in practice.

We would like to encourage all readers of this report to contact us to contribute to the multi-stakeholder dialogue.

Annex

International benchmarking – Additional country examples

Several additional examples and best practices from other countries are worthwhile mentioning. Additional information on good examples are listed below on:

- Long-term strategy (UK, British Columbia in Canada, Australia)
- Continuously updated immunization programme (Australia, UK)
- Increase awareness at the public and the HCPs (Australia, British Columbia in Canada)
- Updated data system and continuous surveillance (UK, Australia)
- Increased accessibility and vaccinator capacity (British Columbia in Canada)
- Sufficient supply (UK).

Long-term strategy

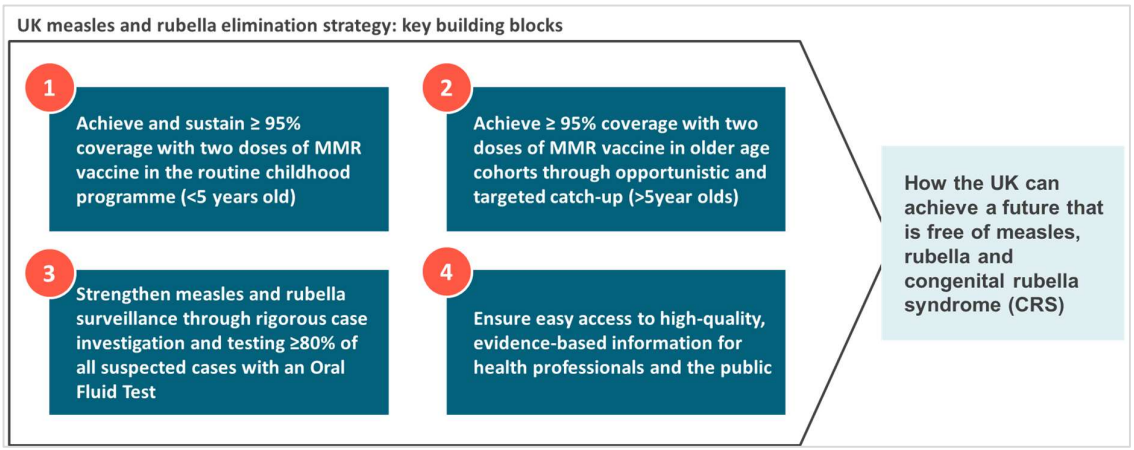


Figure 30 UK Measles and Rubella elimination strategy

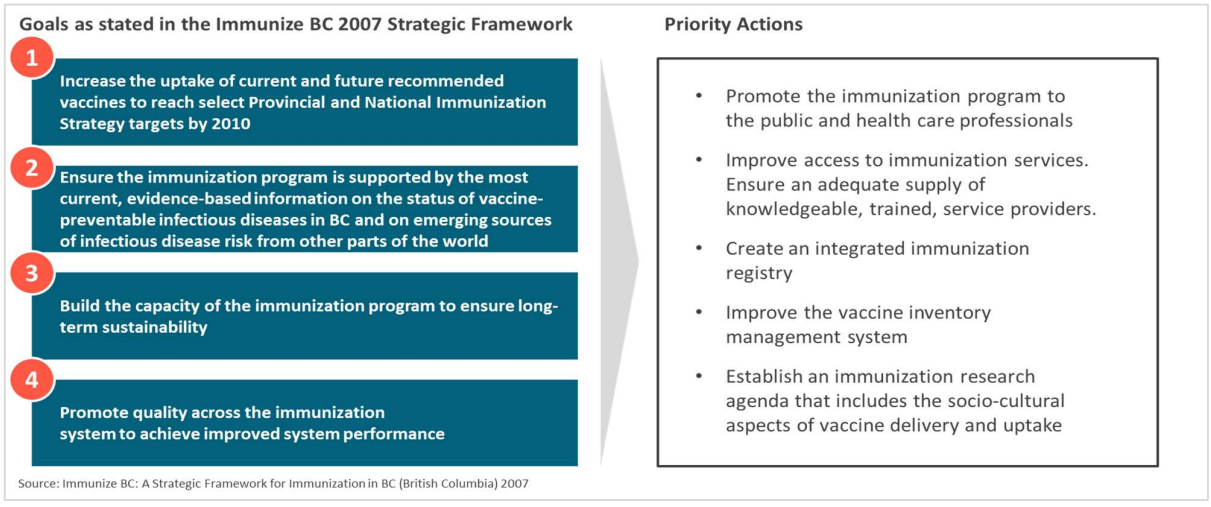


Figure 31 Immunize British Columbia - 2007 strategy

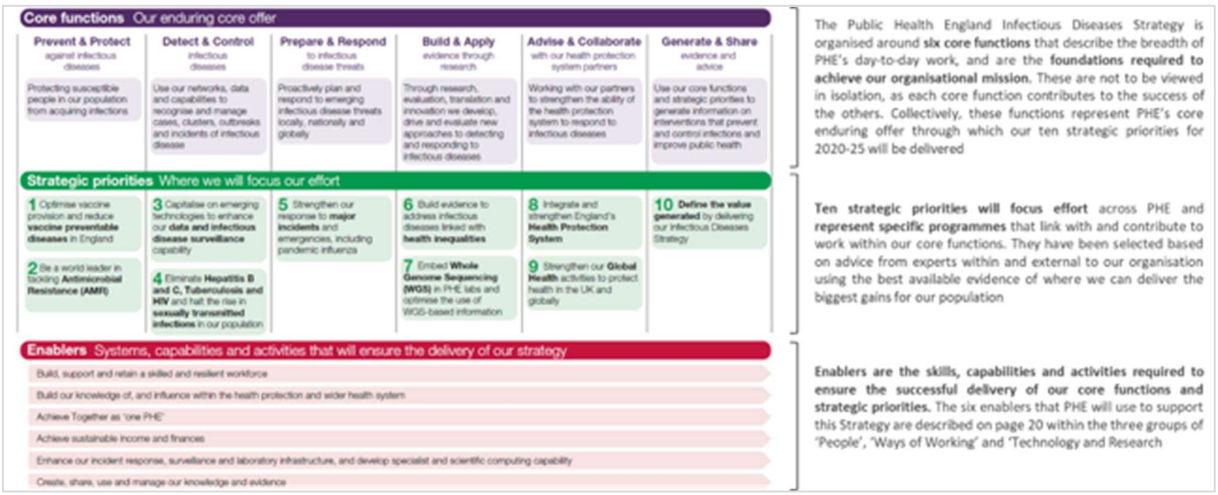


Figure 32 UK's PHE's infectious disease strategy – framework in detail

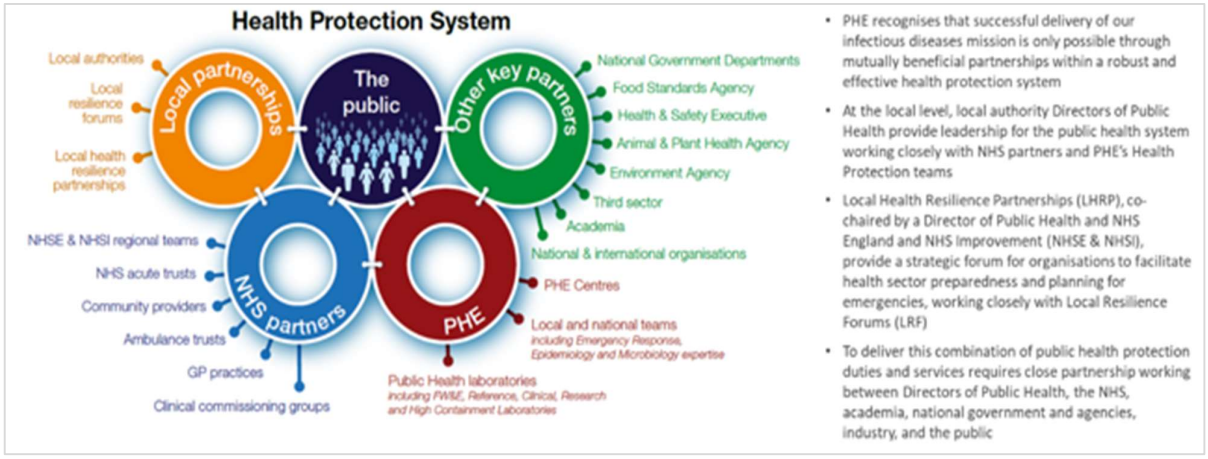


Figure 33 UK's PHE's infectious disease strategy - stakeholder involvement

Continuously updated immunization programme

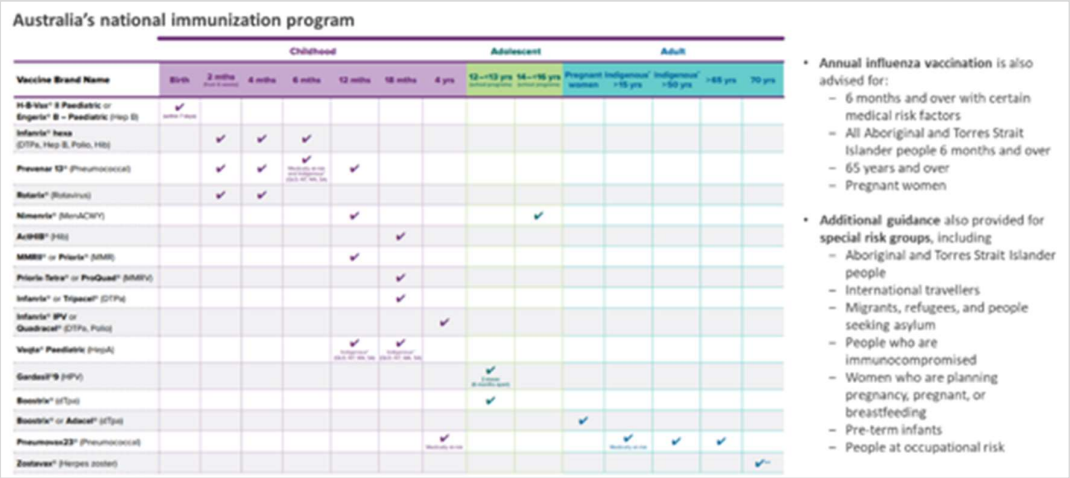


Figure 34 Australia's national immunization programme schedule

Additional guidance is also provided on other populations in the UK Immunisation Schedule – updated August 2019

Population/Group	Guidance
Individuals with unknown or incomplete immunisation status	Where an individual born in the UK presents with an inadequate immunisation history, every effort should be made to clarify what immunisations they may have had. Anyone who has not completed the routine immunisation programme as appropriate for their age should have the outstanding doses as described in the relevant chapters. If children and adults coming to the UK do not have a documented or reliable verbal history of immunisation, they should be assumed to be unimmunised and a full course of required immunisations should be planned.
Premature infants	It is important that premature infants have their immunisations at the appropriate chronological age (counted from their date of birth), in accordance with the national routine immunisation schedule. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed
Children and adults at particular risk	There are a number of selective immunisation programmes that target children and adults at particular risk of serious infections, such as hepatitis B, hepatitis A, influenza, Hib, meningococcal and pneumococcal infection. Other vaccines, including BCG, HPV, hepatitis B and hepatitis A, are also recommended for individuals at higher risk of exposure to infection, due to lifestyle factors, close contact or recent outbreaks in their community
Pregnant women	In 2010, routine influenza immunisation of individuals was extended to include all pregnant women. This was based on evidence of the increased risk from influenza to the mother and to infants in the first few months of life

Figure 35 UK's recommendations on immunisation for specific populations

Schedule for the UK's routine immunisation programme (excluding catch-up campaigns) – updated August 2019

Age Due	Vaccine Given
8 weeks old	Diphtheria, tetanus, pertussis, polio, Hib and hepatitis B (DTaP/IPV/Hib/HepB) Pneumococcal conjugate vaccine (PCV) Meningococcal B (MenB) Rotavirus
12 weeks old	Diphtheria, tetanus, pertussis, polio, Hib and hepatitis B (DTaP/IPV/Hib/HepB) Rotavirus
16 weeks old	Diphtheria, tetanus, pertussis, polio, Hib and hepatitis B (DTaP/IPV/Hib/HepB) Meningococcal B (MenB) Pneumococcal conjugate vaccine (PCV)
One year old (on or after the child's first birthday)	Hib/MenC booster Pneumococcal conjugate vaccine (PCV) booster Meningococcal B (MenB) booster Measles, mumps and rubella (MMR)
Eligible paediatric age groups annually	Live attenuated influenza vaccine (LAIV)

Age Due	Vaccine Given
Three years four months old or soon after	Diphtheria, tetanus, pertussis and polio (DTaP/IPV or dTaP/IPV) Measles, mumps and rubella (MMR)
Twelve to thirteen years old	Human papillomavirus (HPV)
Fourteen years old (school year 9)	Tetanus, diphtheria and polio (Td/IPV) Meningococcal ACWY conjugate (MenACWY)
65 years old	Pneumococcal polysaccharide vaccine (PPV)
65 years of age and older	Inactivated influenza vaccine
70 years old	Shingles (herpes zoster)

Figure 36 UK's immunisation programme covering the whole life course

Increase awareness at the public and the HCPs

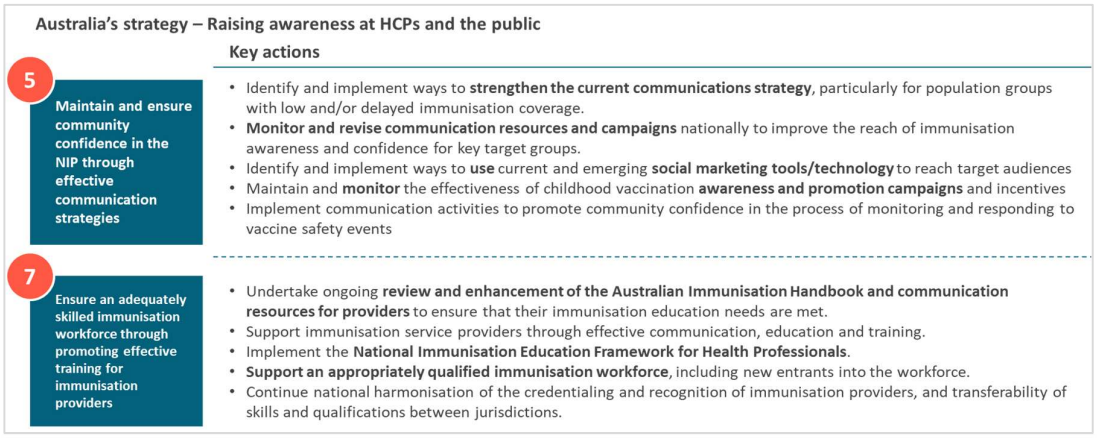


Figure 37 Australia's strategy - raising awareness at HCPs and public

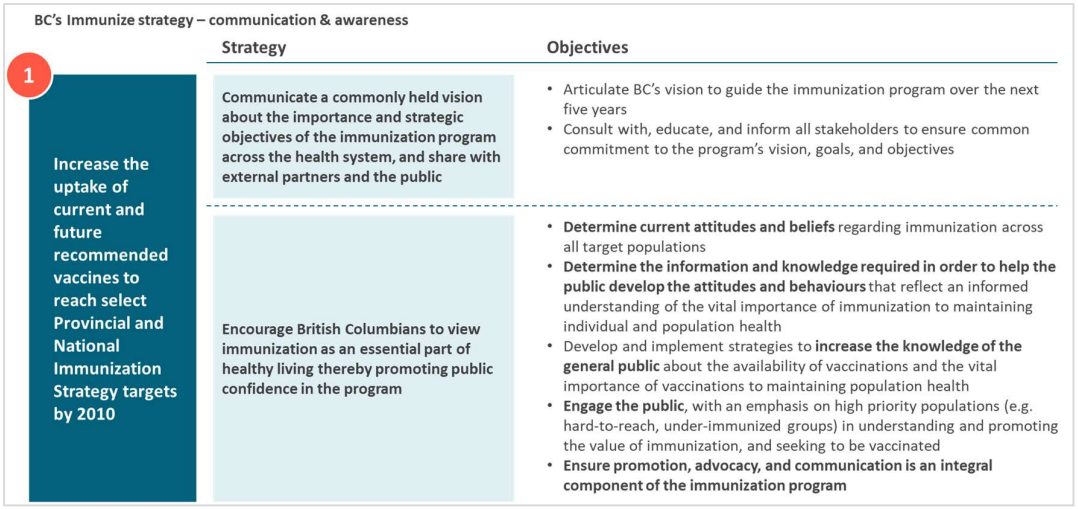


Figure 38 BC's Immunize strategy - Communication and awareness

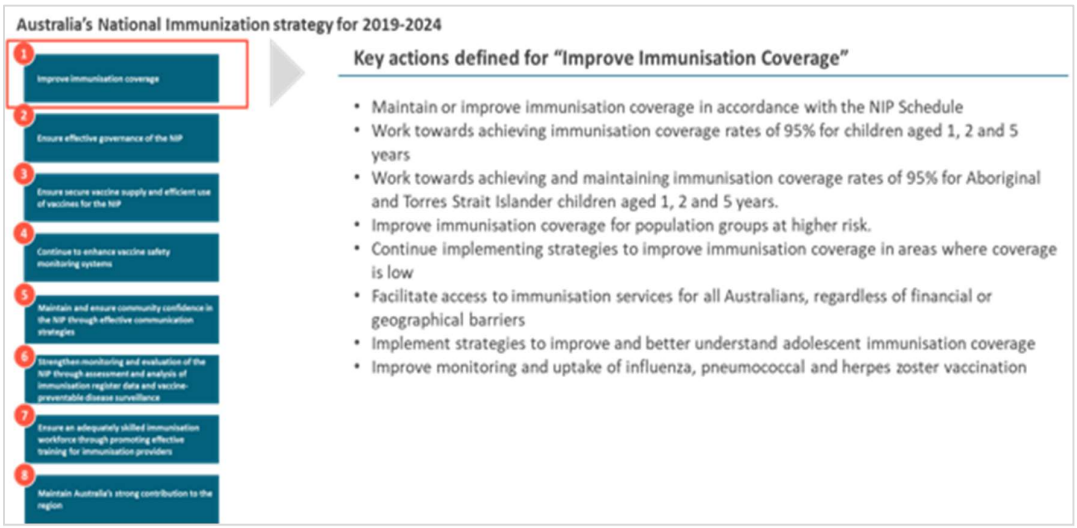


Figure 39 Australia's National Immunization strategy - key actions to improve coverage

Updated data system and continuous surveillance

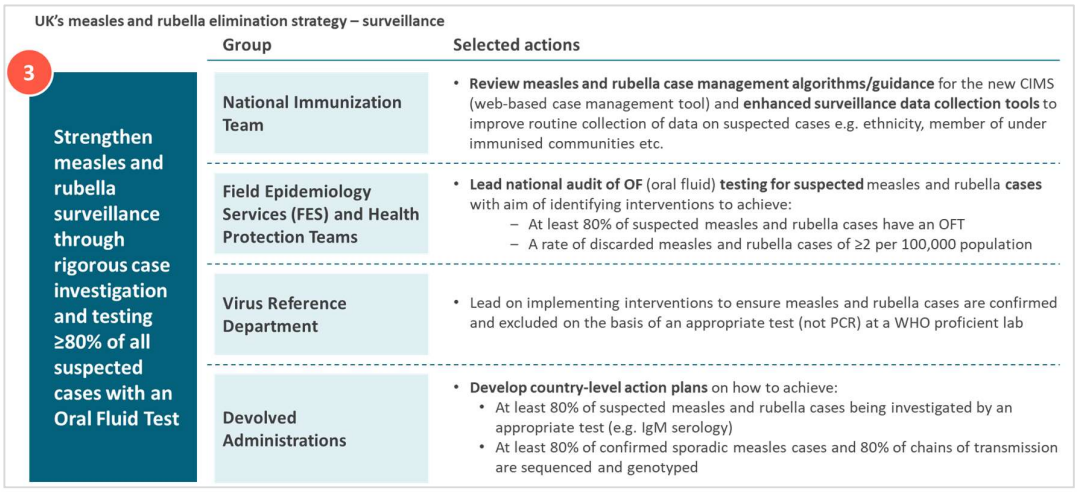


Figure 40 UK's measles and rubella elimination strategy - surveillance

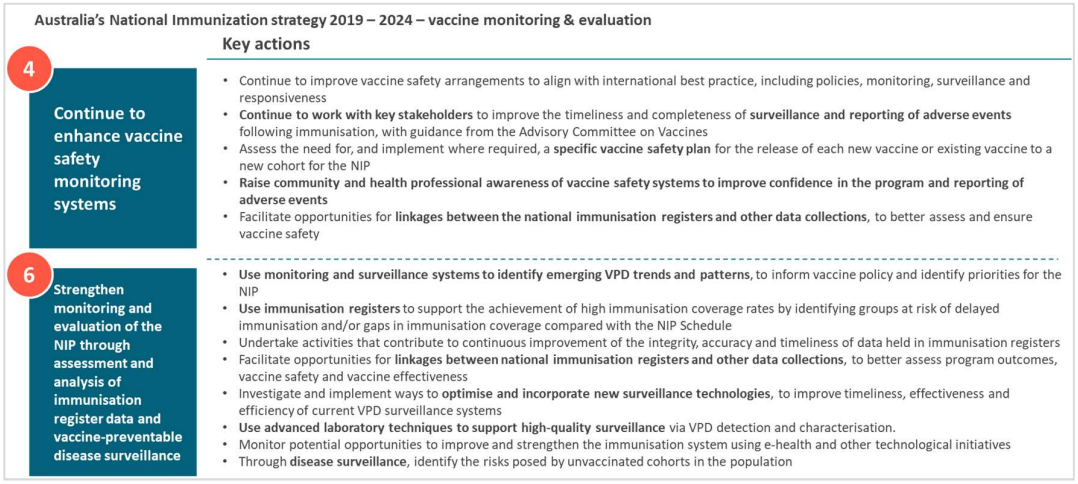


Figure 41 Australia's National Immunisation strategy 2019 - 2024 - Vaccine monitoring and evaluation

Increased accessibility and vaccinator capacity

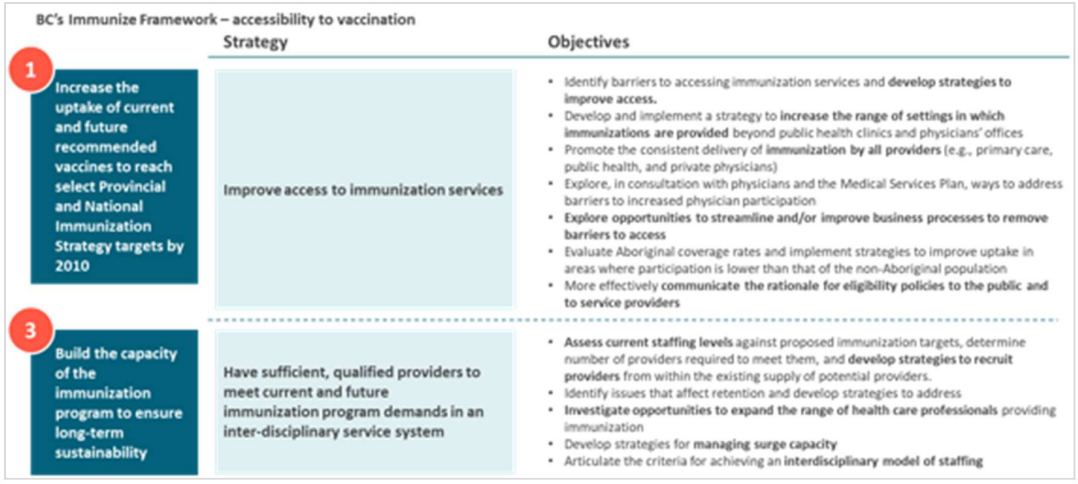


Figure 42 BC's Immunize Framework - accessibility to vaccination

Sufficient supply

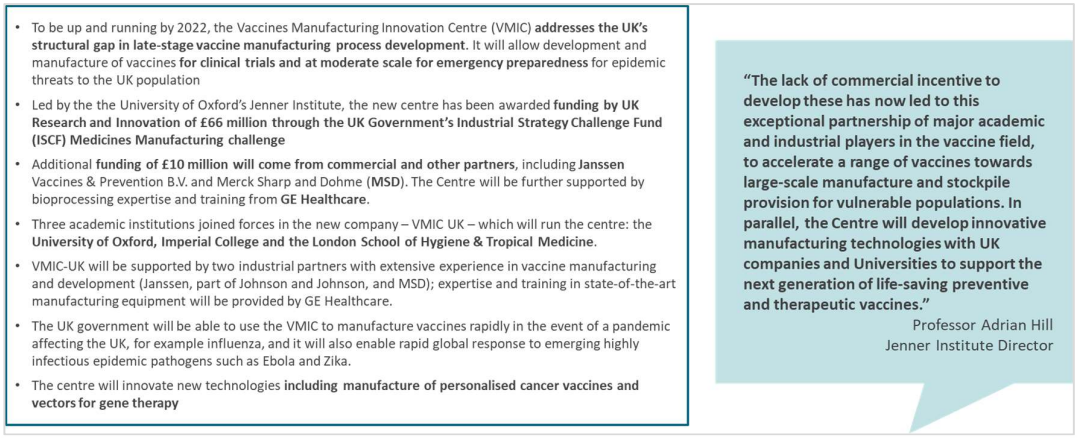


Figure 43 Dedicated UK Vaccines Manufacturing Innovation Centre

Abbreviations list

AVIQ	Agence pour une vie de qualité
BC	British Columbia, Canada
CCIV	Comité de concertation intersectorial vaccination
CLB	Centrum voor leerlingenbegeleiding
CPMS	Centres Psycho-médico-sociaux
CSF	Critical Success Factors
CSS	Conseil Supérieur de la Santé
GIEV	Groupe interuniversitaire d'experts en vaccinologie
GP	General Practitioner
HCP	Health Care Professional
HGR	Hoge Gezondheidsraad
KPI	Key Performance Indicators
LOGO	Lokaal Gezondheidsoverleg
MD	Medical doctor
OBGYN	Obstetrics and gynaecology
PSE	Services de promotion de la santé à l'école
RIZIV-INAMI	Rijksinstituut voor ziekte- en invaliditeitsverzekering – Institut national d'assurance maladie-invalidité
ROI	Return on Investment
SHC	Superior Health Council
SMART	Specific, Measurable, Achievable, Relevant, Timely
STD	Sexually Transmitted Disease
UMV	Universal Mass Vaccination
VCR	Vaccination coverage rate
WHO	World Health Organization

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