PERSPECTIVES ON VACCINATION

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List of Acronyms

AEFI - Adverse Event Following Immunisation
CGMP - Current Good Manufacturing Practices
CPME - Standing Committee of European Doctors
EASO - European Asylum Support Office
ECDC - European Centre for Disease Prevention and Control
EMA - European Medicines Agency
ETAGE - European Technical Advisory Group of Experts on Immunisation
EU - European Union
EVACO - European Vaccination Coverage Collection System
EVAP - European Vaccine Action Plan
EXPH - Expert Panel on Effective Ways of Investing in Health
GDP - Gross Domestic Product
HCP - Healthcare Professional
HPV - Human Papillomavirus
HTA - Health Technology Assessment
IFPMA - International Federation of Pharmaceutical Manufacturers & Associations
IIS - Immunisation Information System
IPROVE - Innovation Partnership for a Roadmap on Vaccines in Europe
MEAT - Most Economically Advantageous Tender
MMR - (refers to) Measles Vaccine
NIP - National Immunisation Programme
NITAG - National Immunisation Technical Advisory Group
PAC - Post-Approval Manufacturing and Quality Control Changes
R&D - Research & Development
SAGE - Strategic Advisory Group of Experts
TIP - Tailored-Immunisation Programme
VAERS - Vaccine Adverse Events Reporting System
VCR - Vaccination Coverage Rates
VPD - Vaccine-Preventable Disease
WHO - World Health Organisation

FOREWORD

WHY THIS BOOK ABOUT HEALTH POLICY AND VACCINES?

- Vaccines are a unique type of health product that are administered to individuals to prevent the spread of vaccine-preventable diseases (VPDs). In Europe, vaccines are usually provided as part of a publicly funded national immunisation programme. The fact that vaccines are considered a public health intervention, rather than an individual treatment option, means policy decisions are central to their success or failure.
- MSD has produced this book to offer science-based facts and analyses to policymakers on key factors influencing the success - or failure - of vaccination programmes and individual vaccines.

WHO SHOULD READ IT?

- The book is aimed at health policymakers and people who work with or advise them.

WHAT STORY DO THE ILLUSTRATIONS TELL?

- Vaccination is a complex topic that involves discussions around scientific discovery, research, development, manufacturing, distribution, and delivery. In addition, the vaccine ecosystem is composed of a diverse set of stakeholders. To help make this information easier to understand, a parallel series of cartoons tells the story of a group of organic gardeners trying to keep their plants healthy, providing a visual analogy of the different perspectives on vaccination.

HOW TO MAKE THE BEST USE OF THE BOOK?

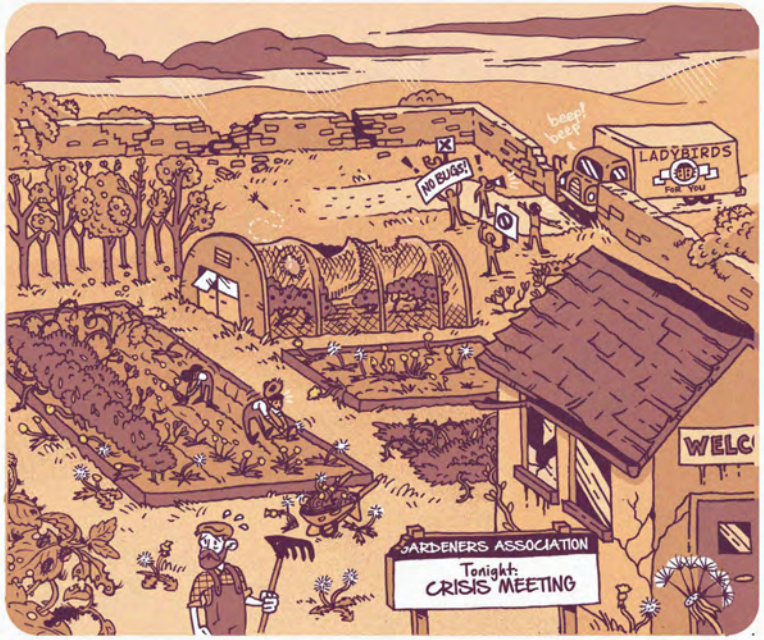
- This book contains 28 policy perspectives on vaccination, which have been organised into seven chapters covering the value of vaccination, the policy environment, vaccines and their complexities, vaccine confidence, access to vaccination, and programme implementation. The final chapter covers two perspectives of MSD's vision for vaccination.
- In addition to stating facts, providing analysis, and giving scientific references, each perspective contains an extract from the story about the organic gardeners, presenting some of the policy challenges as metaphors. This is because relying solely on scientific evidence to communicate health issues can be counterproductive with some audiences. People who do not have a scientific background—and this can include policymakers—have a tendency to 'tune out' if they feel the discussion is becoming overly technical. The story and the metaphors it contains are a tool to help communicate with different audiences.

FOREWORD

THE STORY BEHIND THE POLICY

Vaccination is one of the great public health success stories of the past 100 years. Infectious diseases that used to kill and affect many thousands of children and adults each year—smallpox, polio, diphtheria, measles—are now either eradicated or very rare in Europe.

It would appear to be a simple, happy picture of success. Everything in the garden is fine, and always will be.



However, vaccination is anything but simple. Not everything is fine in the garden. And if we choose to see only success, then we risk losing the gains we've made.

Infectious diseases that were major killers may now be under control in Europe, but only one disease (smallpox) has been eradicated worldwide. This means European countries need to keep vaccinating against diseases that are very rare on our continent, such as diphtheria. They also need to keep vaccinating every child against polio, despite Europe being polio-free.

Motivating people to invest time, money and effort in vaccination programmes to protect against diseases that have virtually disappeared is challenging. Policymakers may be tempted to ignore pathogens that do not seem to pose an immediate threat. Even more challenging is motivating countries and international partners to 'go the extra mile' needed to eliminate a disease from a continent (as Europe is trying to do with measles) or eradicate it world-wide (as the world is trying to do with polio).

FOREWORD

Old diseases, such as measles, diphtheria, and even polio, can quickly re-emerge in countries that let their vaccine coverage fall.

However, the case for investing in national immunisation programmes goes beyond just maintaining the status quo. Developing new vaccines, and using existing ones more effectively, could significantly improve health in Europe.

It would help the continent be better prepared to face future pandemics and new, emerging diseases. And it can even save health systems money, since preventing diseases is always cheaper than treating them.

Time and again, though, the case for action on vaccination comes up against the complexities of the vaccine ecosystem. Among these complexities are:

- Vaccines are most effective when given to a full segment of the population, rather than a few individuals
- Because of this, they are usually purchased in bulk by governments, sickness funds or other collective bodies
- The person receiving the vaccine has usually not been involved in buying it—and does not see any immediate benefit after being vaccinated.

Each vaccine is a complex biological product, which is usually given to a healthy person. Often, the person given the vaccine has not been involved in buying it. They are asked to trust that there is a benefit for them and their community. They also trust that the vaccine will not harm them or their loved ones. In an age when trust in public authorities is given less readily than it once was, this can be a lot to ask of some people.

Expanding the role of prevention in healthcare by widening the range of vaccines offered (and populations targeted) is an even bigger ask. Policymakers have access to all the data and can review the evidence on vaccine safety and effectiveness. Still, that does not make decisions easy, as they need to navigate pressures on health systems, demographic changes, and increasing public scepticism. On top of all this, decision makers have to contend with the time and complexity involved in manufacturing vaccines.

Despite the many complexities and frustrations of working in and with the vaccines ecosystem, there are people involved that passionately believe in the good that vaccines can do. They know that, after clean water and sanitation, vaccination continues to be the most effective tool for protecting and improving public health.

Perspectives on Vaccination provides evidence-based context, trends, and messages that aim to support vaccination policies in Europe. It presents 28 perspectives on vaccination policy. These are accompanied by 28 illustrations that are aimed to help explain this complex issue to all stakeholders.

Analogy for illustrative purposes only and not based on scientific data

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CHAPTER F - IMMUNISATION PROGRAMME IMPLEMENTATION

CHAPTER G - MSD'S VISION FOR VACCINATION

P1 | VACCINE-PREVENTABLE DISEASES: CONTROL FROM CONTAINMENT TO ERADICATION

Containment, elimination, and eradication are incremental targets of strategies for vaccine-preventable disease (VPD), prevention and control.[1]

- Containment is “the process of preventing spread of a transmissible infectious disease by vaccinating all contacts of every diagnosed case”.
- Elimination is “a situation where the infecting agent cannot sustain itself in the population”.
- Eradication is “ending all transmission of an infectious disease agent by bringing about the extermination of the disease agent”. Eradication is only technically possible when humans are the only host of the target pathogen.

OTHER RELATED TOPICS

- P9 | Vaccination Ecosystem
- P11 | Coalitions
- P17 | EU Regulatory Issues
- P19 | Role of Healthcare Professionals
- P22 | Immunisation Programmes
- P24 | Vaccine Surveillance
- P25 | Information Systems
- P28 | Future Vision for Vaccination

P1 | VACCINE-PREVENTABLE DISEASES: CONTROL FROM CONTAINMENT TO ERADICATION

KEY CONTEXT AND TRENDS

- Vaccination is one of the most effective public health tools. It has made a major contribution to the control of infectious diseases.[2]
- Due to vaccination, the world eradicated three viruses that caused human suffering: smallpox and wild poliovirus types 2 and 3 (two of the three virus types that cause poliomyelitis).[3-5]
  - Eradicating poliomyelitis is a more challenging goal than smallpox. There are three in full polioviruses and most infections are asymptomatic. Still, only 33 paralytic poliovirus type 1 infections occurred in 2018.[4]
- Europe has made eliminating measles and rubella a strategic goal[6]; however, measles and other vaccine-preventable diseases (VPDs) demonstrate the potential to re-emerge in countries where vaccination coverage drops.[7]
  - Under increasing vaccine hesitancy in Europe, measles cases tripled in 2018 compared to 2017: 47 of 53 European countries reported over 80 000 measles cases, with 61% hospitalised and 72 deaths.[8]
- For outbreaks of severe viral zoonotic diseases, like Ebola, vaccination proves to be an excellent strategy for containment and is a cornerstone of global preparedness efforts.[9]

KEY MESSAGES

- WHO EUROPE and member states aim for "a European Region free of vaccine-preventable diseases (VPDs), where all countries provide equitable access to high-quality, safe, affordable vaccines and immunisation services throughout the life course."[6]
- No country or region should still be experiencing outbreaks of VPDs. Each VPD outbreak represents a failure of prevention.
- Sustainable high vaccination coverage, allowing for herd protection, is essential for achieving elimination and eradication goals for VPDs.[10]
- When all stakeholders commit to acting together, regional elimination and eradication are possible.
- All stakeholders are encouraged to commit to integrating their vaccination strategies with a global post-2020 vaccination strategy.[7]

P1 | VACCINE-PREVENTABLE DISEASES: CONTROL FROM CONTAINMENT TO ERADICATION

Containment

To contain the growth of weeds such as dandelions on lawns and flower beds, organic gardeners must work continuously to detect the weeds early and respond quickly by pulling them out. This is hard work, as the roots of this weed grow deep, especially when detection is late.

Elimination

Once the garden is free of weeds, seeds from neighbouring gardens may still drift on the winds to settle again on the controlled lawns. To prevent this risk of re-emergence, gardeners on neighbouring allotments must agree on one approach. Thus, an entire continent may become weed-free.

Eradication

To remove the threat of seeds being imported from other continents, by trade or by the prevailing winds, a bold plan is needed to eradicate the weed from the planet. It will take massive, collaborative efforts and strong political will. However, when it works, the return on investment will be substantial for all.

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P2 | THE IMPORTANCE OF HIGH VACCINATION COVERAGE RATES

Vaccination directly protects individuals who are immunised. It can also indirectly protect those who are unvaccinated through herd protection. Herd protection requires sustainable and adequate vaccination coverage rates (VCR); there needs to be a high percentage of vaccinated individuals in the population to induce herd immunity. To achieve high VCR, European countries need publicly funded health services, awareness campaigns, a healthy delivery network for timely access to vaccination, and healthcare professionals who foster confidence and a positive attitude towards vaccination within the population.[1,2]

OTHER RELATED TOPICS

- P1 | VPD Control
- P3 | Outbreaks
- P4 | Life Course
- P9 | Vaccination Ecosystem
- P10 | EVAP
- P11 | Coalitions
- P17 | EU Regulatory Issues
- P18 | Vaccine Confidence
- P19 | Healthcare Professionals
- P21 | Vaccination Access and Equity
- P22 | Immunisation Programmes
- P24 | Vaccine Surveillance
- P25 | Information Systems
- P28 | Future Vision for Vaccination

P2 | THE IMPORTANCE OF HIGH VACCINATION COVERAGE RATES

KEY CONTEXT AND TRENDS

- A key performance indicator of an immunisation programme is the VCR. VCR reflects population protection against vaccine-preventable diseases (VPDs).
- The VCR needed for herd protection varies according to the communicability of the disease.[3]
- Recommended coverage thresholds vary:
  - 95% for measles vaccines (goal: elimination).[3]
  - 75% for influenza vaccines (goal: risk group protection).[4]
- Immunisation policies in Europe are fragmented, leading to a variance of VCR and lack of adequate monitoring.
- Some EU countries set target VCR for vaccination programmes. Ensuring that targets are met requires VCR monitoring systems to assess vaccination programme implementation.
- Large numbers of unvaccinated people have accumulated in Europe as VCRs dropped over the past decades. Many European countries are experiencing sizeable measles outbreaks. Measles cases rose by 300% in the first quarter of 2019.[6,7]

KEY MESSAGES

- Systems for monitoring VCR are needed for rapid insights into coverage gaps, trends, and vaccine effectiveness.[5]
- EU countries need to coordinate their systems for monitoring VCR to ensure a timely response when coverage rates start to decline.
- Achieving target VCR does not happen spontaneously. It requires coordinated, sustained, and programmatic efforts to communicate the benefits of vaccination and to facilitate access.[8]
- In diseases such as rubella, failure to reach the target VCR has been associated with increased health risks compared to not vaccinating at all.[8]
- VCR can vary substantially between demographic groups. Even countries with an overall VCR of 95% for measles may experience outbreaks in specific communities with low coverage rates.[9]
- Many adult measles cases in Europe have an unknown vaccination status. EU countries need life course[1] immunisation registers.[9]

P2 | THE IMPORTANCE OF HIGH VACCINATION COVERAGE RATES

Dry stone walls are among the oldest artificial barriers created to protect people and places from external danger. The distance between the individual stones needs to be close enough to allow the stones to interlock in such a way that they start acting together as one large stone under gravity. It looks easy, but this technique that predates the invention of the wheel takes a lot of skill and craftsmanship.

The strongest walls may have gaps and removing the odd small stone will not immediately affect its strength. This is actually similar to herd protection, where immunised individuals create a protective wall around the few sensitive individuals who, for some reason, cannot be vaccinated. But as you can imagine, we cannot keep taking stones out of the wall and still expect it to remain strong enough.

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P3 | ROLE OF VACCINES IN OUTBREAK RESPONSE

Vaccination plays a critical role in preventing and controlling an outbreak of a vaccine-preventable disease (VPD). During an outbreak, the goal of vaccination is to provide a rapid public health effect, which is usually coordinated by public sector institutions or international non-governmental organisations.

Maintaining high vaccination coverage rates, ensuring robust data systems to monitor vaccination coverage, and utilising good disease surveillance systems are the best ways to prevent and even identify the potential for outbreaks. Without these factors, outbreaks can be unpredictable and place a strain on the global supply of vaccines leading to challenges allocating vaccines between emergency and routine programmes.

OTHER RELATED TOPICS

- P1 | VPD Control
- P2 | Vaccination Coverage
- P5 | Healthcare Systems
- P8 | Procurement
- P9 | Vaccination Ecosystem
- P10 | EVAP
- P15 | Vaccine Supply
- P18 | Vaccine Confidence
- P23 | Stockpiles
- P26 | Vaccine Innovation

P3 | ROLE OF VACCINES IN OUTBREAK RESPONSE

KEY CONTEXT AND TRENDS

- Outbreaks of VPD occur globally following drops in vaccination coverage (eg measles[1]), waning immunity (eg pertussis[2]), or limited access to vaccination (eg Ebola[3]).
- Current guidelines for global health emergency response include vaccines as one of the first interventions required, often with a need for delivery within the first 72 hours of an emergency.[1,4,5]
- The Ebola epidemic in West Africa (2014-2016) changed thinking towards the acceleration of vaccine research and development (R&D), regulatory processes during emergencies, and contingency stockpiles.[1]
- Increased occurrence of VPD outbreaks often places strains on vaccine supply; shortages have highlighted challenges about how to allocate limited supplies during periods of high demand.[5]

KEY MESSAGES

- Efficient surveillance systems and detailed monitoring of vaccine coverage are vital to predict the risk of VPD outbreaks.[6]
- Vaccination can be a critical intervention to control a VPD outbreak, though the decision to utilise vaccination needs to be made on a case-by-case basis.[7]
- Vaccination during emergencies requires preparedness, including the ability to predict resource needs, increase vaccine availability during national or global shortages, and address regulatory barriers to delivering new products.[8]
- To facilitate the transfer of vaccines between EU countries in the event of shortages, vaccine manufacturing needs to be streamlined. This includes reducing the number of specific national/regional products, packaging, and labelling requirements.
- Stockpiling of vaccines at the European level may require significant effort on behalf of governments to harmonise regulatory requirements, as well as allocation of financial resources.
- The Ebola epidemic in West Africa (2014-2016) demonstrated that vaccine R&D and access to vaccination are vital for health security; this is a shared responsibility of governments and cannot be left to market forces.[9]

P3 | ROLE OF VACCINES IN OUTBREAK RESPONSE

Outbreak Support

Keeping a garden healthy takes continuous care. There is a plethora of biological threats to the population of plants and flowers that grow and flourish throughout the year's seasons. Take aphids, for example, a feared infestation. Fortunately, science has found ways to strengthen the forces that keep garden pests down. Ladybirds are the natural enemy of aphids and this particular gardener has calculated that investing in regular supplies of ladybirds not only keeps her garden healthy, it saves money that would otherwise be spent on replacing withered plants.

Supply Shortage

However, ladybirds are a biological product. They need to be cultivated and grown under high-quality circumstances. Each batch must be free of contaminants and other risks. In times of frequent aphid infestations, the supply of fresh ladybirds may stall. Gardeners may despair, yet suppliers explain that increasing production capacity requires time and investment. The Gardeners Association will start thinking about ladybird policies that address the needs of members and that can better predict the ladybird demand.

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P4 | LIFE COURSE IMMUNISATION

A life course approach to vaccination recognises that for optimal public health and societal impact, vaccine coverage needs to reach beyond childhood. For example, seasonal influenza has a major impact on sick leave.[1] Also, a recent study in adults with shingles (aged 50–65) found that two-thirds stopped working as a result of the infection.[2] Vaccines in development against common healthcare-associated infections may reduce mortality and shorten hospital stays among people of all ages, but particularly the elderly, by preventing these serious infections.[3,4] The World Health Organisation (WHO) advocates a life course approach to vaccination for the benefit of all individuals and healthcare systems.[5]

OTHER RELATED TOPICS

- P1 | VPD Control
- P2 | Vaccination Coverage
- P5 | Healthcare Systems
- P6 | Benefits and Growth
- P10 | EVAP
- P12 | Health Systems Pressures
- P13 | R&D
- P25 | Information Systems
- P26 | Vaccine Innovation
- P28 | Future Vision for Vaccination

P4 | LIFE COURSE IMMUNISATION

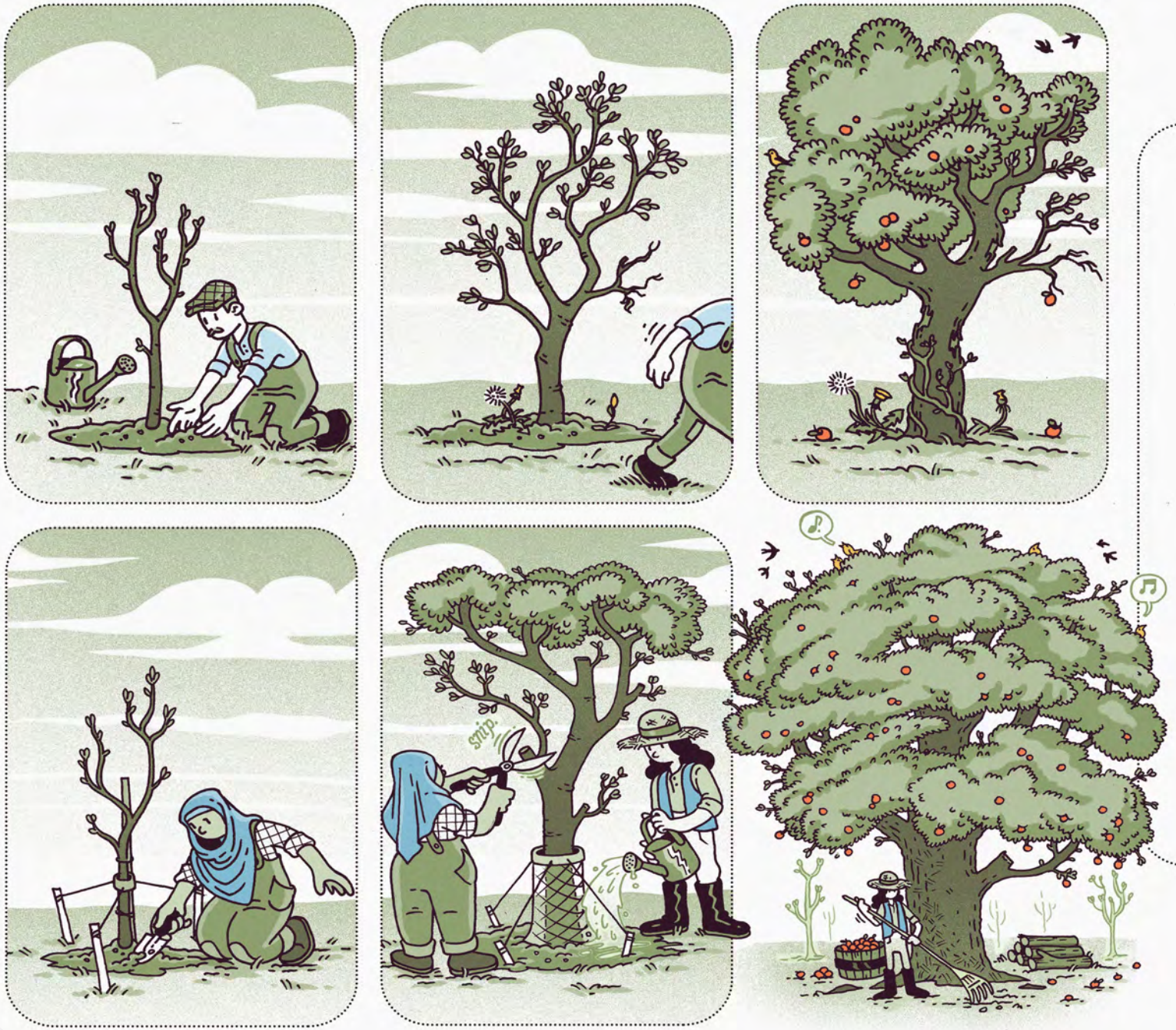
KEY CONTEXT AND TRENDS

- Missed vaccination opportunities and waning immunity are factors contributing to the proportion of adults unprotected against vaccine-preventable disease (VPD).[6] Lack of awareness and barriers to access also contribute to the lack of protection.
- The evidence-base shows that adult vaccination programmes constitute important strategies for improving health and quality of life across Europe.[7]
- Coverage data for adults is not collected routinely as seen with childhood vaccination. Limited data shows sub-optimal vaccination in target groups and in high-risk individuals.[6]
- The WHO views immunising older individuals as a priority intervention for promoting healthy ageing.[8]
- The EU Council invites member states to adopt a life course approach to vaccination.[9]
- Estimates for Western Europe show that protecting one individual against 15 pathogens over a lifetime costs a maximum €3,395.[10]

KEY MESSAGES

- Preventing disease in children, adults, and seniors reduces the transmission of disease, improves quality of life, reduces absenteeism, and contributes to economic growth.[11]
- Shifting demographics in Europe means that the ageing population will need to remain independent, contributing to society and the economy for a longer period of time.[12]
- Life course vaccination policies should maximise an individual's ability to maintain good health throughout their life. This will support the control of communicable diseases, co-morbidities, and pathogens in the population.[13]
- Integrating vaccination into non-healthcare settings (eg schools or workplaces) may encourage vaccination throughout all stages of life.[13]
- Member states are encouraged to conduct further research, to strengthen the evidence base for a life course approach to vaccination.[9]

P4 | LIFE COURSE IMMUNISATION



An orchard is so much more than a garden with fruit trees. When it is well managed, the orchard can be seen as a mini-economy. The farmer is responsible for ensuring that new generations of fruit trees are regularly planted so that, in time, they will replace the oldest ones.

When trees are young they are at their most vulnerable, and the farmer who spends time nurturing young trees will reap the rewards when the trees bear fruit. However, even adult trees need care, pruning and trimming, and will benefit from preventive measures to foster lifelong healthy growth.

In fact, most farmers know that investing in the care of trees throughout their life course makes them healthier and benefits orchard productivity. With vaccines, it is pretty much the same.

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P5 | CONTRIBUTION TO HEALTHCARE SYSTEMS AND SUSTAINABILITY

In the context of increasing pressure on healthcare budgets and an ageing population, vaccination contributes to the sustainability of healthcare systems by reducing the burden of infectious diseases and avoiding unnecessary use of financial and human resources, making them available for other medical interventions.[1] In addition, establishing vaccination programmes in countries may create the capacity for monitoring and surveillance as demonstrated by the Smallpox Eradication Programme.[2] The public health impact of vaccination strengthens and sustains health systems, directly and indirectly. Such strengthening is considered to be part of the socioeconomic impact.

OTHER RELATED TOPICS

- P3 | Outbreaks
- P4 | Life Course
- P10 | EVAP
- P12 | Health Systems Pressures
- P15 | Vaccine Supply
- P24 | Vaccine Surveillance

P5 | CONTRIBUTION TO HEALTHCARE SYSTEMS AND SUSTAINABILITY

KEY CONTEXT AND TRENDS

- Around the world, much of the capacity for monitoring and surveillance are a legacy of the Smallpox Eradication Programme. These sustainable capacities are used daily in various public health applications.[2]
- In Europe, the average budget allocated to healthcare represents 9% of the gross domestic product (GDP), with only 3% of that budget earmarked for prevention and an even smaller fraction (less than 1%) spent on vaccination.[3,4]
- Ageing populations will put increasing pressure on healthcare consumption in European countries, resulting in pressure on sustainability of budgets and resources.[5]
- Proper use of vaccines during the life course has the potential to reduce the healthcare spending for vaccine-preventable disease-related primary and secondary care, therefore contributing to healthcare system sustainability.[6]
- The EU Council calls on member states to develop and implement national and regional vaccination plans aimed at reaching the goals and targets of the World Health Organisation's European vaccine action plan by 2020.[7,8]

KEY MESSAGES

- Estimates show that 68% of varicella hospitalisations and 57% of varicella deaths in Italy could be prevented with a 90% uptake of varicella vaccination.[1]
- Human papillomavirus (HPV) vaccination of 12-year-old girls (70% uptake rate) is estimated to reduce HPV 16/18 cervical cancers in females by 86% compared with no vaccination, thereby reducing treatment costs, hospitalisation, and costs associated with HPV pre-cancerous conditions.[9]
- In France, it has been estimated that lifelong vaccination costs are four to 10 times lower than the costs of treatment for hypertension and six to 13 times smaller than the costs of antithrombotic medication for the prevention of recurrent stroke.[10]
- Vaccination programmes need investment in healthcare infrastructure and adequate staffing, which provides a potential legacy of system strengthening and sustainability.[6]
- National and regional vaccination plans should include provisions for sustainable financing and vaccine supply, a life course approach to vaccination, the capacity to respond to emergencies, and communication and advocacy activities.[7]

P5 | CONTRIBUTION TO HEALTHCARE SYSTEMS AND SUSTAINABILITY

A newly landscaped garden always looks fresh and healthy. As the years go by, plants and trees grow older, while weeds and infestations threaten the garden. Plants increase in value and beauty, yet also require continuous care. The sooner we invest in such care, the better it is for the plants. And if you think care and prevention are expensive, try paying the bill for restoring the damage from deferred maintenance. If we build our maintenance tools and infrastructure wisely, we will also benefit from additional advantages that come from dual-use. Basic preparedness and prevention infrastructure will allow the gardener to deal with threats that are bound to challenge the garden in the future. This is similar to prevention capacity in public health.

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P6 | SOCIETAL BENEFITS AND ECONOMIC GROWTH

Vaccines are one of the greatest public health success stories in history.[1] Vaccination helps to ensure health, education, and equity across all stages of life and allows important social and economic returns that go beyond the individual and family. The benefits of vaccination accrue without regard to race, gender, age, or geography.[2] Recognising this impact and making it more visible will support the adoption of innovative policies to create sustainable immunisation programmes.

OTHER RELATED TOPICS

- P4 | Life Course
- P7 | Health Technology Assessment
- P21 | Vaccination Access and Equity

P6 | SOCIETAL BENEFITS AND ECONOMIC GROWTH

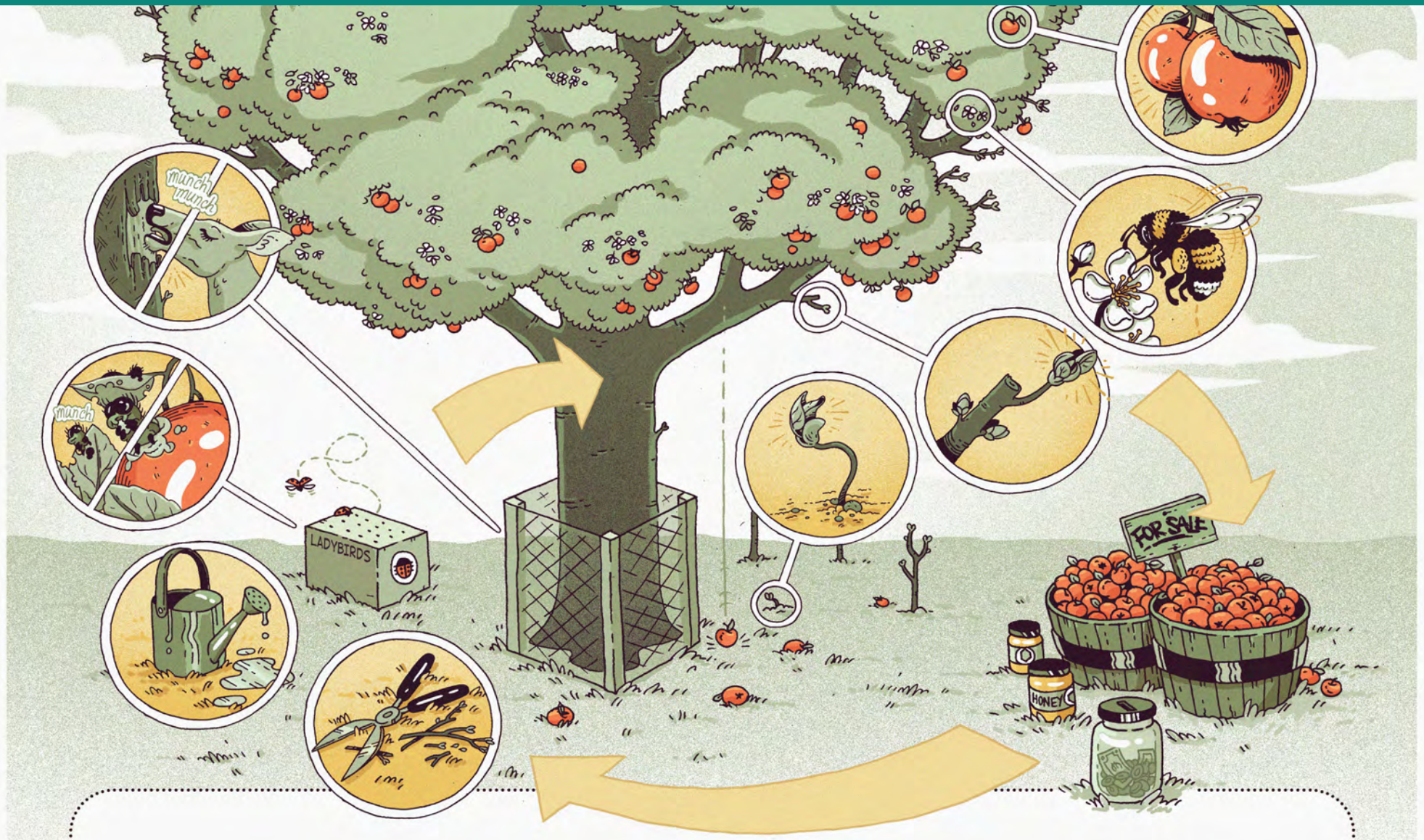
KEY CONTEXT AND TRENDS

- Vaccination is recognised as a high-value public health investment, not just in terms of reducing the burden of disease, but also as an economically and socially beneficial healthcare intervention.[3]
- Vaccination produces benefits that accrue across a lifetime, during which the full public health value of vaccination is often undervalued. Typically, regulatory and implementation policy discussions are limited to easily identifiable health gains and costs.[4,5]
- Vaccination contributes to economic and societal growth by keeping people healthy. Healthy people lead to improved educational outcomes, labour productivity, tax contributions, and health savings.[6]
- A five-year improvement in life expectancy is estimated to translate to a 0.3–0.5% faster annual growth of per capita income.[7]
- Gradually, governments are shifting how they view the value of vaccination from a narrow to a broad perspective of cost-effectiveness. Vaccination protects chronic patients, strengthens social inclusion, and contributes to social equity.[8,9]
- The EU Council of Health Ministers updated the EU's Europe 2020 economic growth strategy, recognising the importance of investment in health as a contributor to economic growth and highlighting preventive actions including vaccination.[3]

KEY MESSAGES

- Frameworks used to assess the value of vaccination should be expanded to include societal value and economic benefits of vaccination.[5]
- Maintaining a child's health through vaccination can improve their cognitive skills, physical strength, and performance in schools. This can also have a positive impact on parents' labour productivity, as well as giving children the best possible start in life.[6]
- Protecting adults against infectious diseases ensures that they can fully contribute to productivity and economic development by avoiding sick leave and helping them maintain their social capital.[6]
- Vaccination in older adults contributes to healthy ageing, enables them to assist with families, and decreases their functional decline—avoiding or delaying the associated negative health and welfare impacts.[6]
- In Italy, 20 years of universal hepatitis B vaccination led to €790 million in net societal savings and a 99% prevalence reduction.[10]
- A case study in the Netherlands shows that every €1 invested in adult vaccination starting at age 50 would yield €4.02 of future economic revenue for the government over the lifetime of the person.[11]
- Socio-ethical contributions of vaccination include effects on health equity, the public good of herd immunity, and inclusion of minority groups; these are neglected in cost-effectiveness analyses.[9]

P6 | SOCIETAL BENEFITS AND ECONOMIC GROWTH



In a well-kept garden, everything is connected. The gardener knows that protecting individual trees results in a healthier garden as a whole, not just a better fruit harvest. By timely investment in fences and ladybirds, a gardener can prevent loss of fruit production, and the cost of repairs or tree treatments. Healthy trees produce more and better seeds and fruit. They provide shade and retain water, thus creating a good climate for animals and other plants. For example, bees will flourish and produce honey, thus adding to the dividend of investing in prevention. Similarly, the effect of vaccination goes beyond the health of individuals.

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P7 | HEALTH TECHNOLOGY ASSESSMENT (HTA) AND NATIONAL IMMUNISATION TECHNICAL ADVISORY GROUPS (NITAGS)

When making decisions on vaccination policy, most governments use an objective evidence-based approach to establish efficient, equitable, sustainable, and high-quality vaccination programmes. National Immunisation Technical Advisory Groups (NITAGs) are responsible for advising national governments on decisions regarding vaccine and immunisation policy. Some NITAGs use the process of Health Technology Assessment (HTA) to provide an objective evidence base.[1]

OTHER RELATED TOPICS

- P6 | Benefits and Growth
- P9 | Vaccination Ecosystem
- P12 | Health Systems Pressures
- P15 | Vaccine Supply
- P16 | Vaccine Safety
- P17 | EU Regulatory Issues
- P21 | Vaccination Access and Equity

P7 | HEALTH TECHNOLOGY ASSESSMENT (HTA) AND NATIONAL IMMUNISATION TECHNICAL ADVISORY GROUPS (NITAGS)

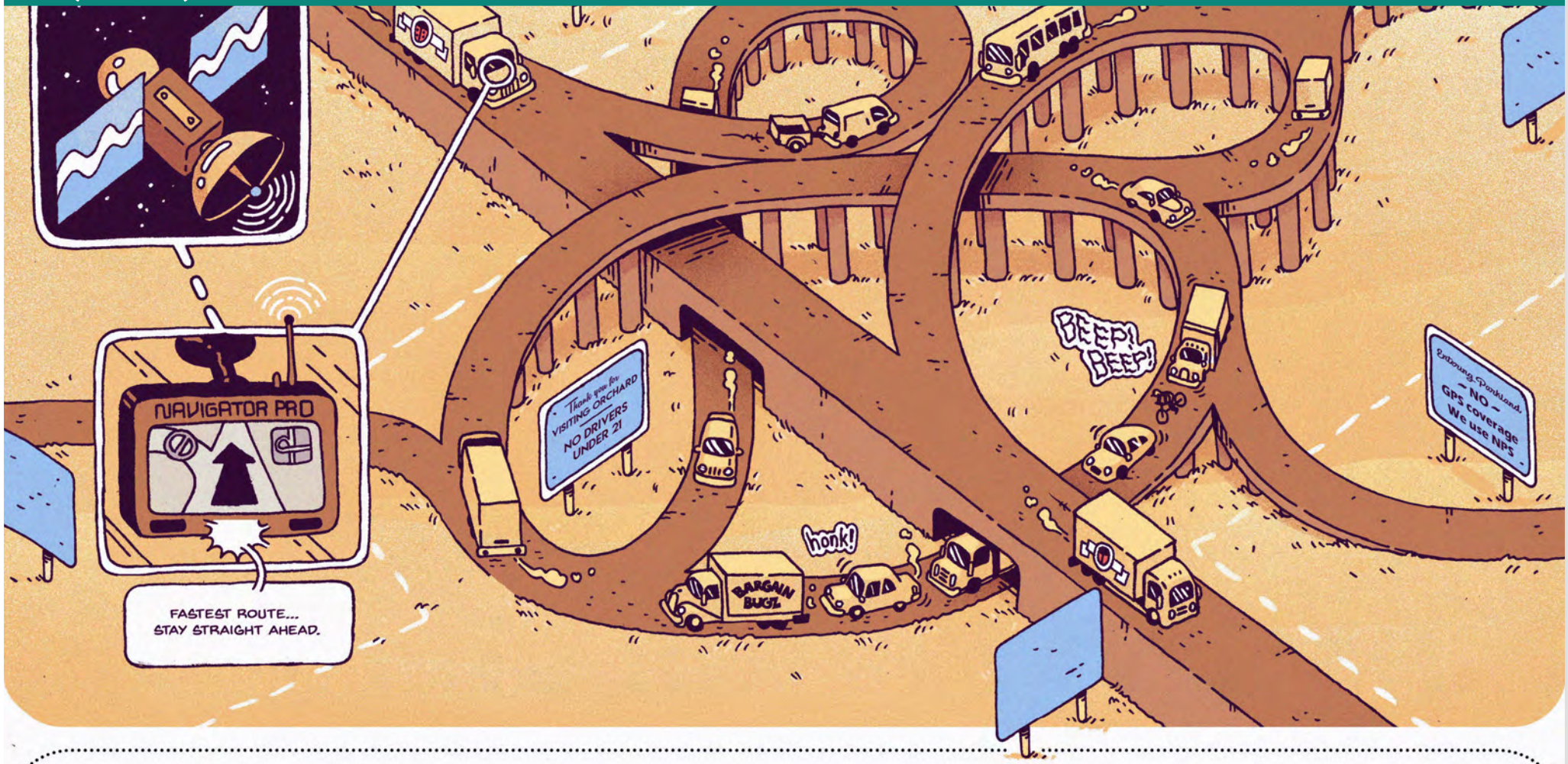
KEY CONTEXT AND TRENDS

- Economic, demographic, and societal challenges create pressure on healthcare demand and lead to more stringent assessment procedures for medicinal products.[2]
- Though classified as medicinal products, vaccines require different assessment methods. The benefits impact multiple sectors over the long term, so more is needed to determine the full value of vaccination besides traditional medical HTA.[2]
- In Europe, the time from registration of new vaccines to population access is unpredictable and often considerable (approximately 6 years compared with a range of 2 to 3 years for drugs/treatment).[3,4]
- HTAs are undertaken nationally and do not share a common European process. Duplication of vaccine assessments occurs across public health payers and NITAG's/HTA bodies at the national and regional level resulting in delayed public health impact on the European population.[5]
- The role of NITAGs in the policy-making process varies between countries, due to differences in legal basis, committee membership, scope of work, role of Ministry of Health, and conflict of interest policies.[6]
- The European Commission asks member states to work together on building HTA frameworks for vaccination.[7]

KEY MESSAGES

- NITAGs play a critical role in the recommendation and funding process of vaccination programmes, in a context that considers local differences in national budgets, disease epidemiology, and health priorities.[6]
- The broader economic evaluation of vaccines should take into account[8]:
  - Use of clinically-defined outcomes in addition to etiologically-defined outcomes.
  - Wider societal benefits; reduced health disparities; medical innovations; reduced pressure on healthcare services; and synergies in economic benefits with non-vaccine interventions.
- Member states and the European Parliament should work together on a common framework for the assessment of vaccines, with a common methodology for evaluating vaccines, removing duplication, and shorter time to access.[2]
- NITAGs in member states should meet at least six Basic NITAG Process Indicators defined by WHO as minimum criteria of functionality.[9]
- The European Commission should fund and strengthen the power of the NITAGs network to issue national vaccination recommendations resulting in a framework for assessment and development of economic models.[1]

P7 | HEALTH TECHNOLOGY ASSESSMENT (HTA) AND NATIONAL IMMUNISATION TECHNICAL ADVISORY GROUPS (NITAGS)



When it comes to ladybirds-supply to all gardens, we face a bit of a problem in our story. Gardens and parks in different countries follow different rules and legislation. The supply routes use different systems to navigate, and even traffic rules have slight, yet impactful differences. Of course, each country wants its own connection to the supply highway. When ladybirds are produced on different continents, gardeners everywhere expect a reliable supply, on time, and of the best quality available.

Fragmentation of navigation systems and variability in local traffic rules are the main reasons for the inefficient and costly supply of ladybirds. Though the region agreed on a common navigation system 'Copernicus', some countries insist on using their own National Positioning Systems (NPS). Drivers frequently get lost, and their live cargo of ladybirds suffers. Other countries have different age limits for drivers or drive on a different side of the road.

Similarly, vaccine assessment methods of European countries are not part of a common, coordinated process, resulting in duplication of effort and delays. Building the roads to a reliable, faster, and more efficient joint vaccine assessment process should ultimately benefit the health of all.

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P8 | PROCUREMENT AND ACCESS TO VACCINES

Countries purchase vaccines in different ways. In some countries, vaccines are purchased by the government at the national or sub-national level under the national immunisation programme. In other countries, vaccines may be purchased by insurers, healthcare providers, or even individuals. Vaccine procurement is the process by which vaccines are acquired using specific procedures. It is a highly specialised activity and differs in the process for drugs and other pharmaceutical products.[1]

OTHER RELATED TOPICS

- P3 | Outbreaks
- P13 | R&D
- P14 | Vaccine Manufacturing
- P15 | Vaccine Supply
- P19 | Role of Healthcare Professionals
- P22 | Immunisation Programmes
- P26 | Vaccine Innovation

P8 | PROCUREMENT AND ACCESS TO VACCINES

KEY CONTEXT AND TRENDS

- The number of vaccine manufacturers is small. Some types of vaccine only have a few suppliers, and others may have limited interchangeability.[1]
- Current vaccine procurement systems in Europe are rigid, and provide manufacturers with alternative models. The EU Directive has argued that value-based acquisition should replace cost-based purchasing.[1,2]
- The tender process provides economy of scale, value for money, and security of a stable vaccine supply. Besides these advantages for governments, it is too rigid to allow rapid supply increases for emergency response. Also, a 'lowest price strategy' risks a disincentive to continue production and to invest in R&D for new vaccines.[3]
- The European Commission adopted the Joint Procurement Agreement for pandemic f u vaccines in 2014 covering 447.8 million of the 508.2 million EU citizens.[4,5]
- The European Commission created a Joint Procurement Agreement to purchase medical countermeasures such as medicines, medical devices, vaccines, antivirals, and services to prepare for an outbreak of a serious, cross-border threat to health.[6]

KEY MESSAGES

- The acquisition of vaccines should be driven by health outcomes and benefits for the population, rather than by cost containment objectives.[1]
- Appropriate tender duration and conditions related to time of order to delivery are key attributes to appropriate demand forecasting.
- Sufficient vaccination coverage requires a sustainable, timely supply of vaccines. This includes vaccination programmes (predictable), as well as emergency vaccinations (unpredictable) during outbreaks.
- Price-led procurement practices that do not consider the unique vaccine properties, as well as sustainability and timeliness of supply, may stifle future research innovation.
- Longer lead times and contract duration may enable better manufacturing planning and ensure continuity of supply.[7]
- Tender specifications and procurement-awarding criteria should systematically take into account the concept of Most Economically Advantageous Tender (MEAT) criteria.[8]

P8 | PROCUREMENT AND ACCESS TO VACCINES

Our Gardeners Association values fair and transparent decision-making when it comes to important decisions like buying bulk supplies to prevent plant diseases. Naturally, they only consider products that are proven to be optimally safe and effective. But what if several products have similar safety and effectiveness profiles? Some members argue for the product with the lowest price. Others remember that in the past, such choice not always proved the best. Once, their supplier decided to leave the market, while all other suppliers had waiting lists for new clients. On another occasion, they had a large outbreak of aphids, and their supplier could not deliver extra supplies in time. So now the association is aware that 'the product' they want to procure is not the ladybird; it is the 'reliable supply of ladybirds' that matches their need, even in infestation emergencies. In the same sense, 'vaccine procurement' should not only be about buying vaccines, but ensuring sustainable access to vaccination.

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P9 | THE VACCINATION ECOSYSTEM

Europe is fragmented when it comes to healthcare systems, policies, and stakeholders. This creates important challenges to ensure timely access to vaccines across the region. The vaccination ecosystem is shaped by a landscape of stakeholders, policies processes, programmes, and public health effects. Also, it directly affects the processes of supply, health technology assessments, programmes, funding, and procurement.[1]

OTHER RELATED TOPICS

- P2 | Vaccination Coverage
- P3 | Outbreaks
- P7 | Health Technology Assessment
- P8 | Procurement
- P13 | R&D
- P14 | Vaccine Manufacturing
- P15 | Vaccine Supply
- P18 | Vaccine Confidence
- P21 | Vaccination Access and Equity
- P22 | Immunisation Programmes
- P24 | Vaccine Surveillance
- P26 | Vaccine Innovation

P9 | THE VACCINATION ECOSYSTEM

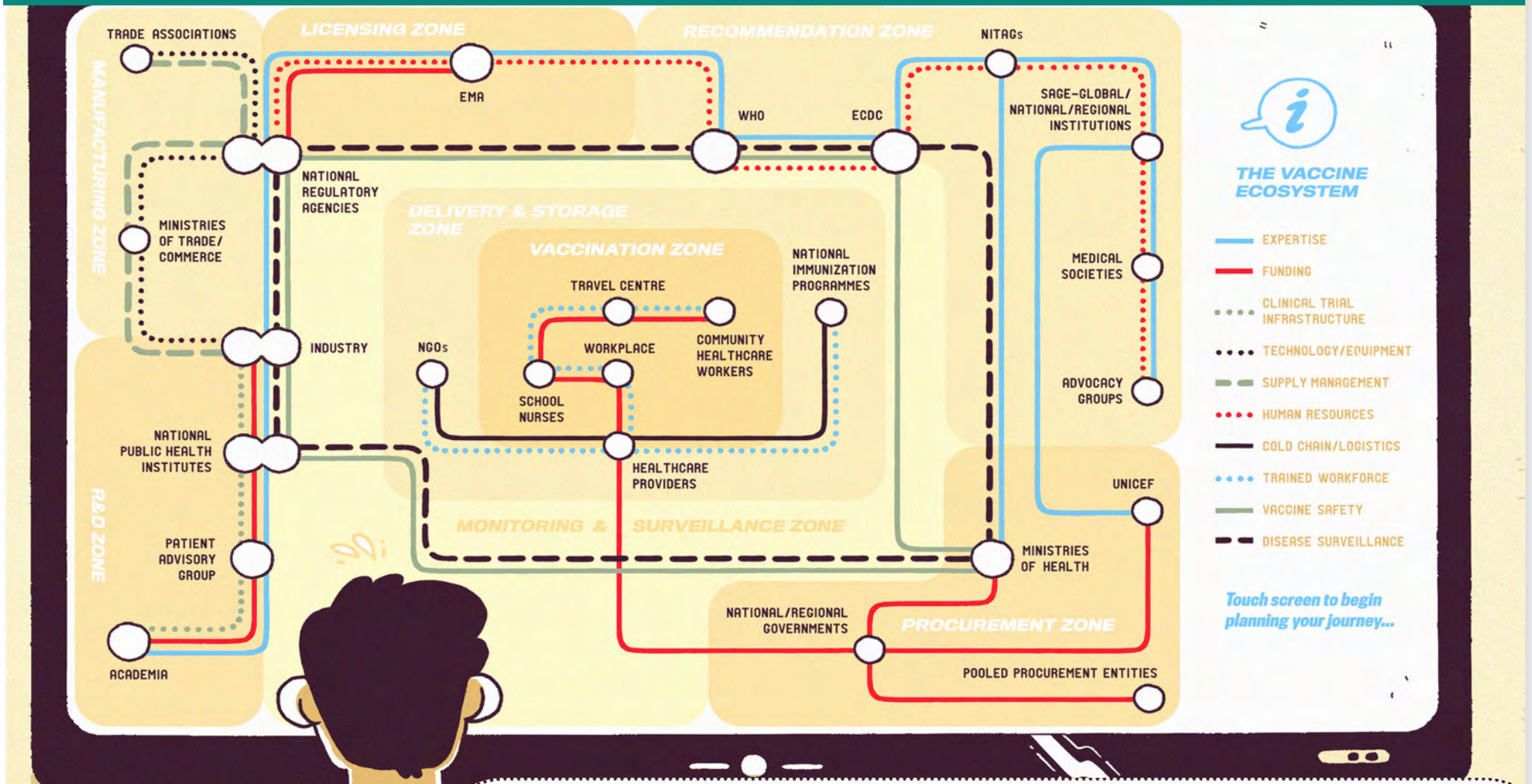
KEY CONTEXT AND TRENDS

- Factors threatening to weaken the vaccination ecosystem in Europe include[2]:
  - A small and decreasing number of suppliers.
  - The paucity of research-driven companies.
  - Regulatory pressures.
  - Market uncertainties.
  - Reductions of prevention budgets.
  - Political prioritisation.
  - Anti-vaccine movements.
  - Complacency.
- Europe faces a decrease in vaccination coverage, which has led to the re-emergence of diseases, and an inability of most member states to track the performance of their vaccination programmes.[3]
- The journey from research and development (R&D) to delivery lacks a harmonised approach among European countries and involves duplicated work.
- Processes such as vaccine recommendation, decision-making, vaccination calendars, and access vary between member states.
- Surveillance data provide a crucial evidence base for recommendations on vaccination. Much has been achieved by the WHO and the European Centre for Disease Prevention and Control (ECDC) in the harmonisation of vaccine-preventable disease (VPD) surveillance in Europe. However, there is still variation between countries in assessing completeness, representativeness, and timeliness of systems.[4]

KEY MESSAGES

- Drivers that may help to ensure the sustainability of vaccine's ecosystem include:
  - Recognising the value of vaccination by all stakeholders from research to delivery.[2,3]
  - Ensuring presence of multiple effective suppliers to reduce monopolies and secure supply.[2]
  - Creating awareness on the need for political support.[2]
  - Strengthening European surveillance capabilities to support National Immunisation Strategies and Programmes.[3]
  - Harmonising regulatory requirements to improve access to markets and shorten disruption periods.[2,3]
  - Tackling vaccine hesitancy and improving confidence in vaccination.[3]
  - Establishing predictable vaccine supply and demand.[3]
  - Setting up a R&D framework (including financing) to develop future vaccines.[3]

P9 | THE VACCINATION ECOSYSTEM



The landscape of all stakeholders and players in the European ecosystem of vaccination is complex. Some stakeholders are linked to only one particular activity, such as licensing or making recommendations on vaccination. Others have a diversity of tasks. Some groups of stakeholders are connected through networks of experts only, or through the funding of activities. Some need to work closely together to establish a sustainable supply of vaccines or to share data for surveillance and monitoring. Still, they all need to work in concert, in order to ensure a healthy ecosystem that achieves common strategic goals in protecting the population.

Navigating in this landscape requires either many years of experience or a good map. Unfortunately, the diversity of systems in the EU means that such maps (if they exist at all) are very different between countries.

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P10 | EUROPEAN VACCINE ACTION PLAN (EVAP) 2015–2020

Developed under the leadership of the WHO Regional Office for Europe, the European Vaccine Action Plan (EVAP) 2015–2020 sets a regional vision of "a European Region free of vaccine-preventable diseases (VPDs), where all countries provide equitable access to high-quality, safe, affordable vaccines and immunisation services throughout the life course", and outlines goals, objectives, indicators, and strategies to achieve this vision. The EVAP directly influences national and subnational vaccination policies in Europe and has a vital influence on regional public health. It also shapes the context around health technology assessments, procurement, and the entire supply chain of vaccines.[1]

OTHER RELATED TOPICS

- P1 | VPD Control
- P2 | Vaccination Coverage
- P3 | Outbreaks
- P4 | Life Course
- P5 | Healthcare Systems
- P11 | Coalitions
- P12 | Health System Pressures
- P17 | EU Regulatory Issues
- P18 | Vaccine Confidence
- P21 | Vaccination Access and Equity

P10 | EUROPEAN VACCINE ACTION PLAN (EVAP) 2015–2020

KEY CONTEXT AND TRENDS

- The WHO Regional Office for Europe helps member states with technical assistance, research, and recommendations to address high-impact health issues, including vaccine-preventable diseases (VPDs).[2]
- Health 2020 is a unified framework and vision developed by the WHO Regional Office in Europe and member states to improve health, reduce health inequalities, and improve participatory governance for health.[2]
- The EVAP should complement, regionally interpret, and adapt the Global Vaccine Action Plan in harmony with Health 2020 and other key regional health strategies and policies.[1]
- One of the EVAP goals is eliminating measles and rubella.[1] While some European countries have made progress, declining vaccine coverage and hesitancy create challenges.[3]

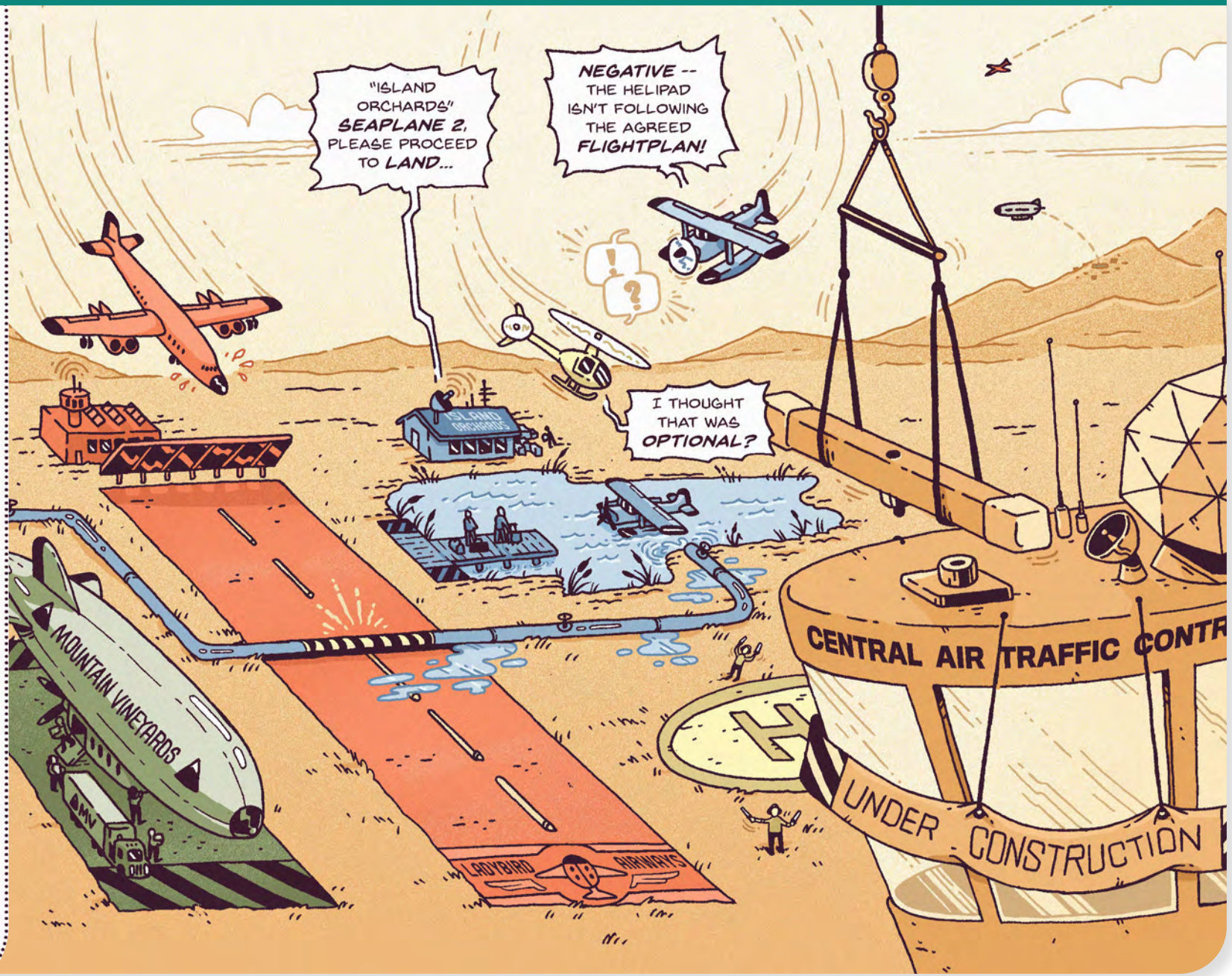
KEY MESSAGES

- Despite some success, measles and other childhood diseases have the potential to re-emerge when vaccination rates drop, as seen recently across Europe.[4,5]
- Stakeholders should work together to achieve EVAP objectives, including equitable access to vaccination, advocating for the sustainability of programmes, and promoting well-functioning health systems.
- The needs, gaps, and strengths across Europe are diverse and support is needed from industry associations (eg Vaccines Europe) at a national and regional level to help achieve the EVAP goals.
- Ensured, sustainable market access to vaccines across Europe is crucial in achieving EVAP goal 1 (sustain polio-free status), EVAP goal 2 (eliminate measles and rubella), and EVAP goal 3 (control hepatitis b infection).[1] A collaborative approach between governments and industry facilitates this.
- In the context of the ongoing epidemiologic transition and changing demographic structure, there must be a greater focus on a life course approach to vaccination.[6]

P10 | EUROPEAN VACCINE ACTION PLAN (EVAP) 2015-2020

Mountain Vineyards and Island Orchards, together with Nordic and Mediterranean Gardeners Associations, have decided on a joint strategy for keeping gardens healthy: the Regional Ladybird Action Plan (RLAP). This plan sets priorities and agrees on the commitment to eliminate the top five garden pests from the region. Therefore, each group has set up contracts with producers of biological garden support to supply effective and high-tech products, such as Ladybird colonies and Dandelion Seed Detectors. And each garden association uses its national airline for the fastest and safest delivery possible. The problem is, though they agree on the strategic plan, there is no agreement on coordination of operations.

Therefore, they soon decide to construct a Central Air Traffic Control to ensure that all operational plans work together with a minimum of friction. For operational vaccine delivery, there is also a wide variation in regulations, policies, and infrastructure. Would it not be useful to have European coordination or standards for that as well?



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P11 | EUROPEAN INSTITUTIONS AND COALITIONS

Public health policies in the European Union (EU) continue to be shaped by treaties, regulations, agencies, networks, and coalitions, many of which influence implementation of effective vaccination programmes. Coalitions and networks may effectively help to strengthen health programmes, influencing policy, and mobilising political will. Coalition members can share resources and workload in joint advocacy campaigns or in shared research, and seek to establish collective demands.[1] Networks and coalitions are an important part of the vaccination ecosystem.

OTHER RELATED TOPICS

- P2 | Vaccination Coverage
- P8 | Procurement
- P9 | Vaccination Ecosystem
- P10 | EVAP
- P15 | Vaccine Supply
- P16 | Vaccine Safety
- P17 | EU Regulatory Issues
- P18 | Vaccine Confidence
- P24 | Vaccine Surveillance

P11 | EUROPEAN INSTITUTIONS AND COALITIONS

KEY CONTEXT AND TRENDS

- The European Centre for Disease Prevention and Control (ECDC) fosters the exchange of best practices and information pertaining to vaccination programmes. Also, the ECDC coordinates surveillance at EU level, including vaccination strategies.[2,3]
- The European Medicines Agency (EMA) is a regulatory authority mandated to promote and protect public health. EMA authorises the use of safe and effective vaccines and assesses their benefit and risk profile following the granting of market authorisation.[4]
- The European Council acknowledges that outside of existing EU legislation, the WHO European Vaccination Action Plan, and the work of ECDC and EMA, cooperation and improved synergies in the vaccination network are needed.[5]
- With the resolution on vaccine hesitancy of April 2018, the European Parliament called for intensified cooperation between the EU Commission and member states to counter the drop in vaccination coverage rates in Europe.[6]
- I-MOVE is a public health coalition platform for sharing methodology and data to estimate influenza vaccine effectiveness. The experience and methods can be adapted to monitor surveillance of the effectiveness of other vaccines.[7]

KEY MESSAGES

- EU-level cooperation, policy frameworks, and exchange of ideas can be a catalyst for more effective public health action in European countries.
- Even though national or regional governments make spending decisions on vaccines, EU-level public health policy is part of the ecosystem that helps inform and shape those decisions.
- The December 2018 Council Recommendation on strengthening EU cooperation against vaccine-preventable diseases (VPDs) calls for stakeholders to[6]:
  - Encourage and cooperate with higher education institutions and relevant stakeholders to consider including and strengthening training on vaccine-preventable diseases (VPDs), vaccinology, and immunisation in national medical curricula.
  - Strengthen the key role of healthcare workers in aiming for higher vaccination coverage rates.
  - Consider possibilities for improving EU manufacturing capacity, ensuring continuity of supply and ensuring diversity of suppliers.
- Scientific public health coalition initiatives, such as I-MOVE, deserve continued support from the Commission, Parliament, and member states.

P11 | EUROPEAN INSTITUTIONS AND COALITIONS

It takes more than just dedication and competence to manage a garden. It also depends on external conditions. For example, the orchard in this community cannot always be reached by ladybird suppliers because of the brook that often floods. Interrupting the flow of the brook is not an option, because it provides clean water to the town and is protected by environmental regulations. Besides, Major Sylvie Wilson's Town Council plans to transform the orchard area into a modern shopping centre. The Orchard Association is small and has no power to change policy plans. It will need coalitions with other groups to create a momentum for change.

Coalitions are also important for changing vaccination policies. For example, to remove unnecessary duplication of regulatory requirements, to promote investment in innovation, or to expand the national programme.

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P12 | DEMOGRAPHIC AND ECONOMIC PRESSURE ON HEALTH SYSTEMS

Changes in health systems influence the introduction, access, uptake, and sustainability of vaccination programmes. Though some policymakers may consider vaccination as an intervention for children only, evidence demonstrates that demographic developments, including ageing and migration, require a life course approach to vaccination. Understanding how demographic and economic pressures on health systems relate to the public health impact of vaccination programmes is critical in developing policy.

OTHER RELATED TOPICS

- P4 | Life Course
- P5 | Healthcare Systems
- P7 | Health Technology Assessment
- P10 | EVAP
- P21 | Vaccination Access and Equity
- P22 | Immunisation Programmes

P12 | DEMOGRAPHIC AND ECONOMIC PRESSURE ON HEALTH SYSTEMS

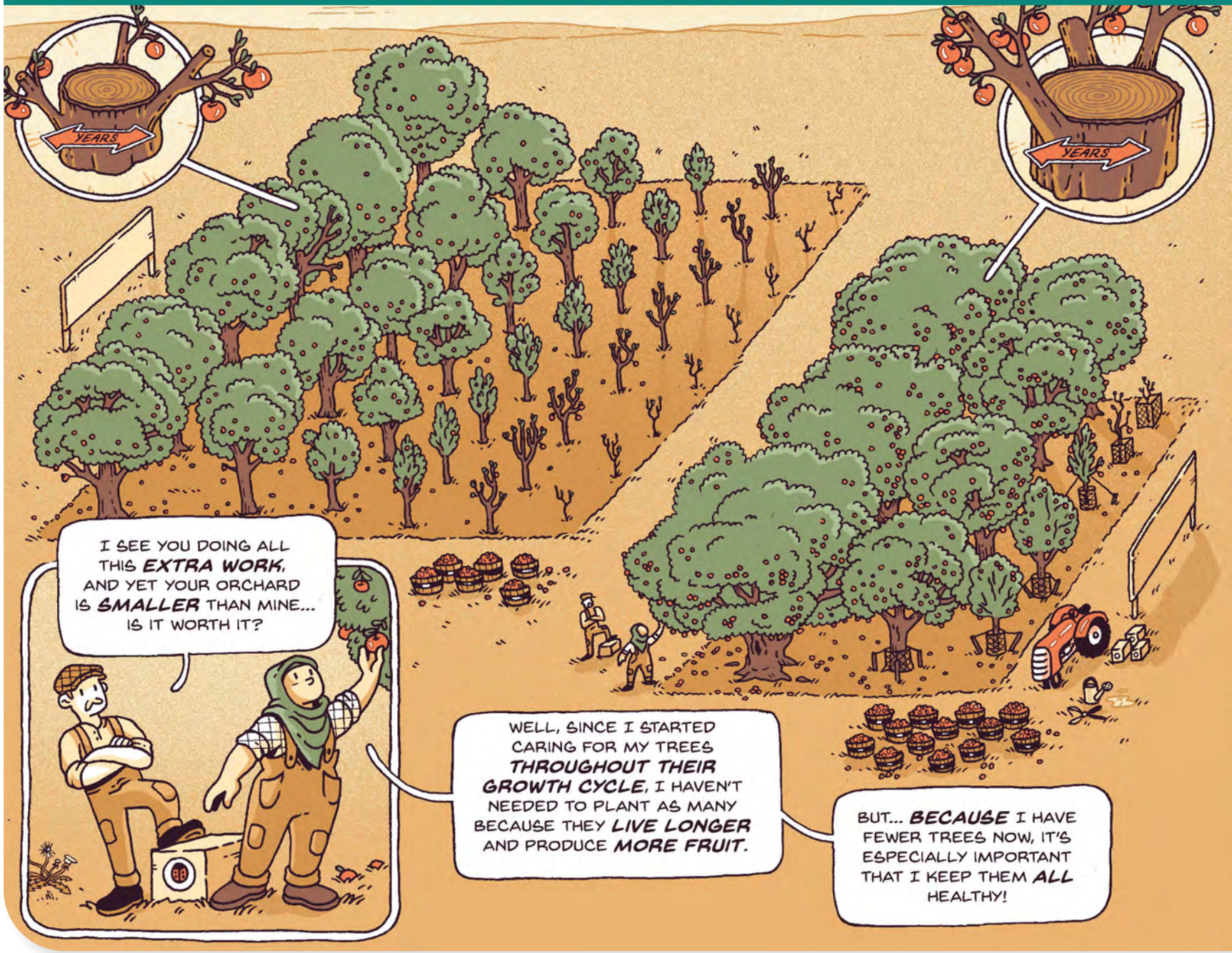
KEY CONTEXT AND TRENDS

- The 2008 economic crisis led to budget restrictions, from which some European healthcare systems still have yet to recover.[1]
- Ageing increases healthcare expenditure, adding further pressure on budgets. By the year 2060, the number of people in the European Union aged over 65 years will nearly double, and those aged over 80 years will triple.[1]
- Between 2008 and 2015, prevention spending per capita decreased in most European countries.[2]
- Human movement is playing an increasing role in the spread of communicable disease. Measles resurgence can be triggered by only a handful of infected arrivals in countries with low vaccination coverage.[3,4]
- International tourism is expected to grow 3-4% per year globally.[4] It is expected that 1.5 million people will immigrate to the EU annually through 2036. This increases vulnerabilities of the region to the spread of infectious diseases.[5]
- National policies to assess the vaccination status of immigrants (and offer appropriate catch-up vaccination) mostly focus on children under five years, while adolescent and adult migrants are often excluded from initiatives.[6]
- European guidance states that immigrants should be vaccinated without unnecessary delay according to the schedule of the country in which they intend to stay for more than a week, with priority given to measles, mumps, rubella, and polio vaccines.[7]

KEY MESSAGES

- Prevention and vaccination are among the best and most cost-effective investments to address changing demographics and pressures on health systems.[8]
- Infectious diseases account for one-third of all deaths in people over 65 years.[9]
- Successful adult vaccination programmes will prevent a significant health burden and lead to a considerable reduction in healthcare costs.[10]
- All European member states should have specific directives on the vaccination of immigrants in their national programmes, which is currently the case in only a few countries.[6]
- Immigrants should not be excluded from catch-up vaccination, although almost one-third of member states report that they charge undocumented immigrants for vaccinations while they have no entitlement to health services.[6]
- The trend of decreasing prevention budgets may need to be reversed to address the increasing need for life course vaccination and catch-up vaccination programmes for all newcomers.

P12 | DEMOGRAPHIC AND ECONOMIC PRESSURE ON HEALTH SYSTEMS



Our gardeners have to deal with many pressures. New generations of trees grow old, which put them at increased risk of infestation. In addition, due to budget reductions, there are fewer garden staff around to nurse diseased trees back to health. This gardener, however, made a fine discovery: by investing in life-long ladybird coverage, the older trees will also benefit from this prevention, reducing the frequency of disease. As a result, they develop better, bear more fruit, and require less nursing time. Hence with less staff, the orchard produces more fruit than ever. The same can be said for vaccinating people: "it is a great and cost-effective investment to address changing demographics and pressures on health systems.

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P13 | VACCINE RESEARCH AND DEVELOPMENT

Research and development (R&D) is the cornerstone of developing new or enhanced vaccines to address current public health threats and to respond to future threats. The process of developing a vaccine can take decades, starting from candidate discovery to pre-clinical and clinical development, to regulatory review. R&D continues well after a vaccine is approved and includes ongoing monitoring and evaluation of its safety, effectiveness, and value.[1]

OTHER RELATED TOPICS

- P3 | Outbreaks
- P4 | Life-Course
- P9 | Vaccination Ecosystem
- P14 | Vaccine Manufacturing
- P17 | EU Regulatory Issues
- P21 | Vaccination Access and Equity
- P26 | Vaccine Innovation

P13 | VACCINE RESEARCH AND DEVELOPMENT

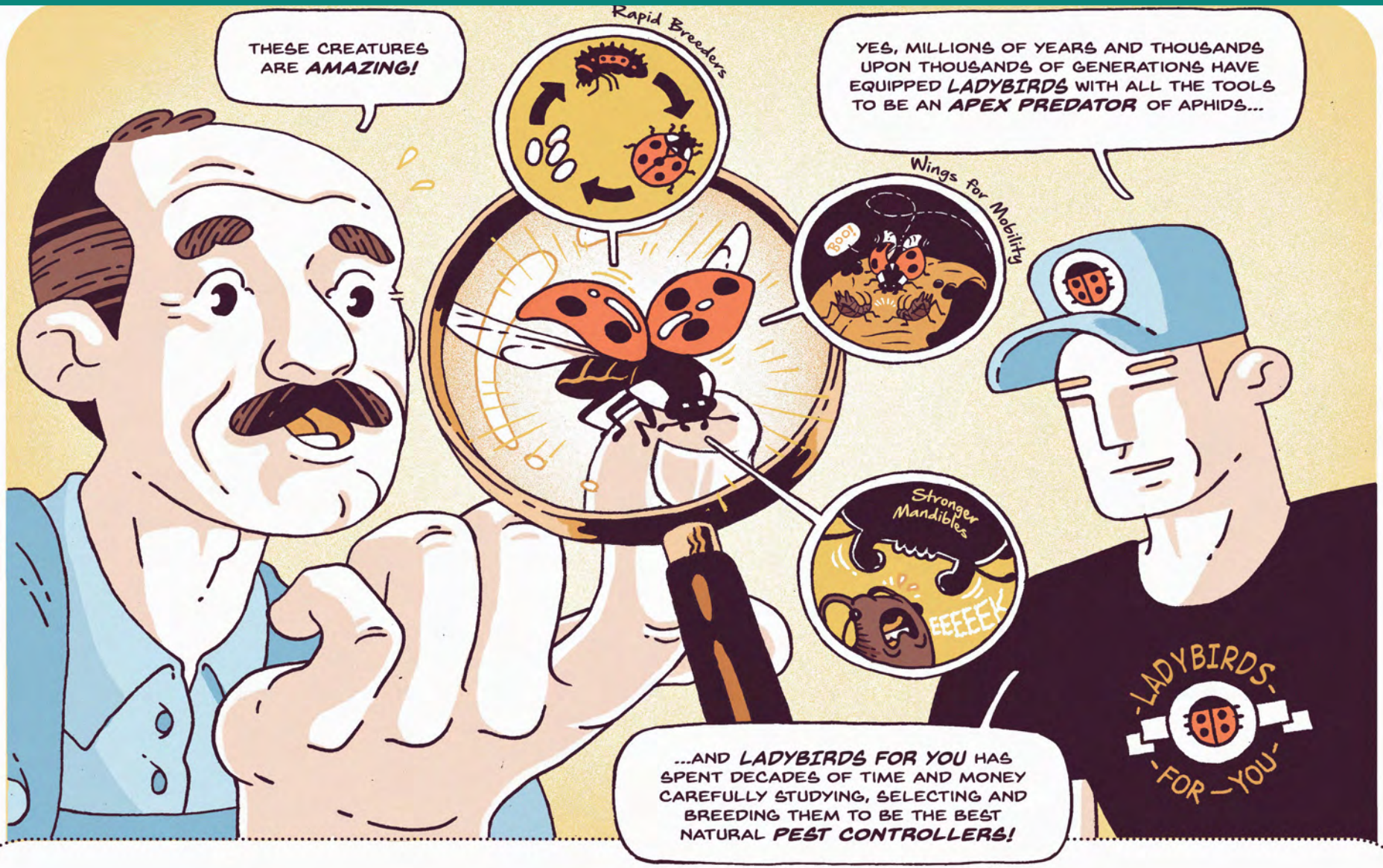
KEY CONTEXT AND TRENDS

- Vaccine R&D is a long, complex, and costly process to ensure safety and efficacy. Developing a vaccine may take 15-20 years and can cost between €200-800 million.[2,3]
- Although 80% of vaccines from the major research manufacturers are currently produced in Europe[4]:
  - Europe does not have an integrated vaccines R&D agenda.
  - The number of R&D projects in Europe has plateaued.
- Governments in emerging countries are investing heavily in domestic vaccine R&D and production to secure access to vaccines.[4]
- In March 2016, the Innovation Partnership for a Roadmap on Vaccines in Europe (IPROVE) presented its strategic vision for vaccine research and innovation in Europe.[4]
- Currently, close to 30 infectious diseases are vaccine-preventable, but there are still gaps that need to be addressed. For example[3]:
  - Healthcare-associated infections.
  - Novel technologies to improve the efficacy of existing vaccines (eg influenza, tuberculosis).
  - Specific populations that could be better protected (eg those with chronic disease, the elderly and immunocompromised).

KEY MESSAGES

- European vaccine manufacturers and the public sector are continuously investing in R&D for new and improved vaccines.
- However, the vaccine R&D process in the European Union is challenged by pressures from increasing regulatory requirements and public health budget constraints; it is developing slower than emerging economies.[4]
- To ensure sustainable R&D in the EU, open, multi-stakeholder collaboration is needed to[3]:
  - Define vaccine research priorities more clearly.
  - Implement policies that reward innovation.
  - Ensure vaccines are appropriately valued.
- Stakeholders (in particular the European Medicines Agency, National Immunisation Technical Advisory Groups, and Health Technology Assessment groups) should explore barriers to the discovery and development of the next generation of vaccines capable of addressing unmet medical needs that span across the life course.[3]
- The IPROVE roadmap could provide the basis for selecting priority areas for funding future EU research projects and the funding model.[3]
- New vaccines could play a critical role in preventing infection with healthcare-associated and multi-drug resistant bacteria, such as S. aureus and extra-intestinal pathogenic E.coli.[3]

P13 | VACCINE RESEARCH AND DEVELOPMENT



Nature never sleeps. We may now have effective control of garden pests, but we can expect the pests to evolve and find an escape from ladybirds. Gardeners associations do not want to wait for that to happen. They benefit from innovation to anticipate future threats. Here, the manufacturer demonstrates a new, innovative type of ladybird that can deal with evolved garden pests. Research and Development is the cornerstone for responding to future threats. That R&D process can take decades before an effective new ladybird is ready for release. Most gardeners understand this. They know all too well that most things in nature need a lot of time to grow and develop. This is very similar to vaccine R&D: it takes time, foresight, sustainable investment in new technology, and a stable vaccination ecosystem.

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P14 | VACCINE MANUFACTURING

Ensuring access to human vaccines on a global scale requires the use of sophisticated manufacturing methods, strict quality control, and distribution channels that guaranteed products are safe and effective at the point of use.[1,2] Manufacturing is the first step in the supply pathway of vaccines from delivery to sustainable population access. Safety is a critical priority along every step of this journey, as is regulatory compliance.

OTHER RELATED TOPICS

- P8 | Procurement
- P9 | Vaccination Ecosystem
- P14 | Vaccine Manufacturing
- P15 | Vaccine Supply
- P16 | Vaccine Safety
- P17 | EU Regulatory Issues
- P26 | Vaccine Innovation

P14 | VACCINE MANUFACTURING

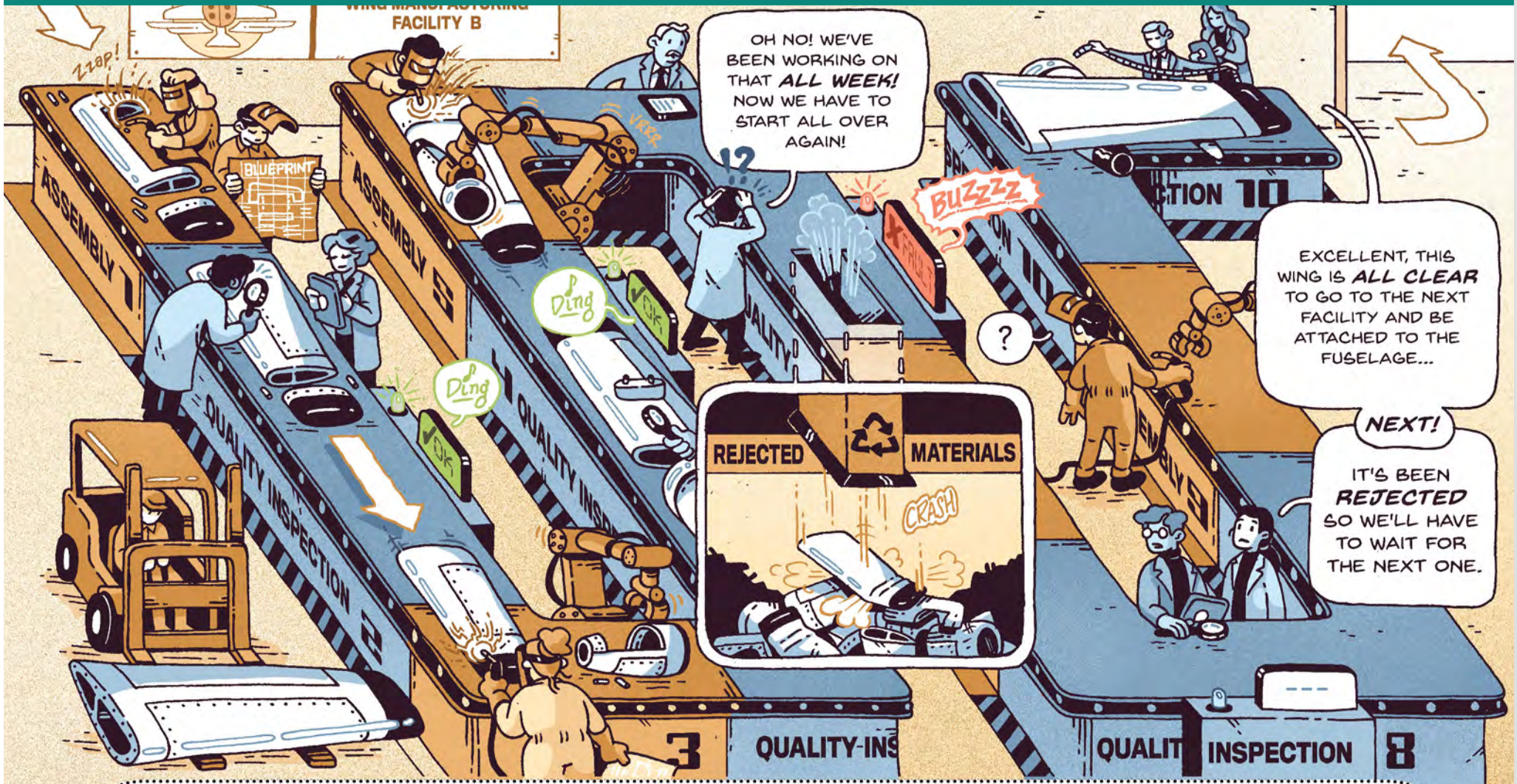
KEY CONTEXT AND TRENDS

- Vaccines are biopharmaceutical products; a subset of pharmaceuticals, inherently biological in nature, and manufactured using biotechnology.
- Biopharmaceutical products are derived from living organisms such as bacteria or mammalian cells.
- All vaccine production processes have to comply with standards defined by the relevant regulatory authorities for Current Good Manufacturing Practices (CGMP).[3]
- For most vaccines, vaccine manufacturing can take between six and 26 months; quality control processes represent 70% of the manufacturing time.[4,5]
- Post-approval manufacturing and quality control changes (PACs) are introduced routinely worldwide.
- Regulatory requirements for submitting and reviewing PACs in multiple markets are becoming more complex.
- For global manufacturers, a single PAC may have to be submitted to more than 100 regulatory agencies worldwide.
- A vaccine company with a large portfolio typically submits an average of 6,000 to 8,000 PAC variations per year around the world.

KEY MESSAGES

- Vaccines are biological products that require a long and complex manufacturing process, and require high levels of expertise and investment compared to other pharmaceutical products.[6]
- Vaccine development is costly, with a diminishing number of global manufacturers able to invest.
- Considering the stringent CGMP requirements, vaccines are considered one of the safest and most powerful disease prevention tools available when they are released for use.[7]
- Globally, Europe still leads much of vaccine development and production.[5]
- European regulatory procedures need to be streamlined to facilitate access.[8]

P14 | VACCINE MANUFACTURING



Ladybirds are sensitive creatures. The transport to deliver them safely to their gardens of destination needs to meet the highest quality control standards. Given the time and resources it takes to cultivate a supply of ladybirds for one country, can you imagine the loss when a train or aeroplane carrying such a precious cargo crashes? Even a delay of several hours could jeopardise the quality of the shipment. So, these trains and aeroplanes need to meet the highest of safety standards. In this factory, every single part of the aeroplane is checked and double-checked before, during, and after assembly. In fact, the quality control steps are so strict and abundant they take up 70% of the total production time of the aeroplane. But what do you want, if it has to be as safe as possible? And any part that fails the quality check is immediately recycled, and production starts again. This is very similar to the rigorous quality control processes of vaccine manufacturing. Because, as with trains and aeroplanes, we want them to be as safe as possible.

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P15 | VACCINE SUPPLY

Building a vaccination programme with long-term supply contracts and consistently high vaccine coverage rates may help to reduce the risk of outbreaks of vaccine-preventable diseases (VPDs). Manufacturing processes and regulatory conditions also directly impact vaccine supply. Understanding the barriers and facilitators to stable vaccine supply can help health officials and policymakers develop effective vaccination programmes and policies.

OTHER RELATED TOPICS

- P3 | Outbreaks
- P5 | Healthcare Systems
- P7 | Health Technology Assessment
- P8 | Procurement
- P9 | Vaccination Ecosystem
- P14 | Vaccine Manufacturing
- P22 | Immunisation Programmes
- P23 | Stockpiles

P15 | VACCINE SUPPLY

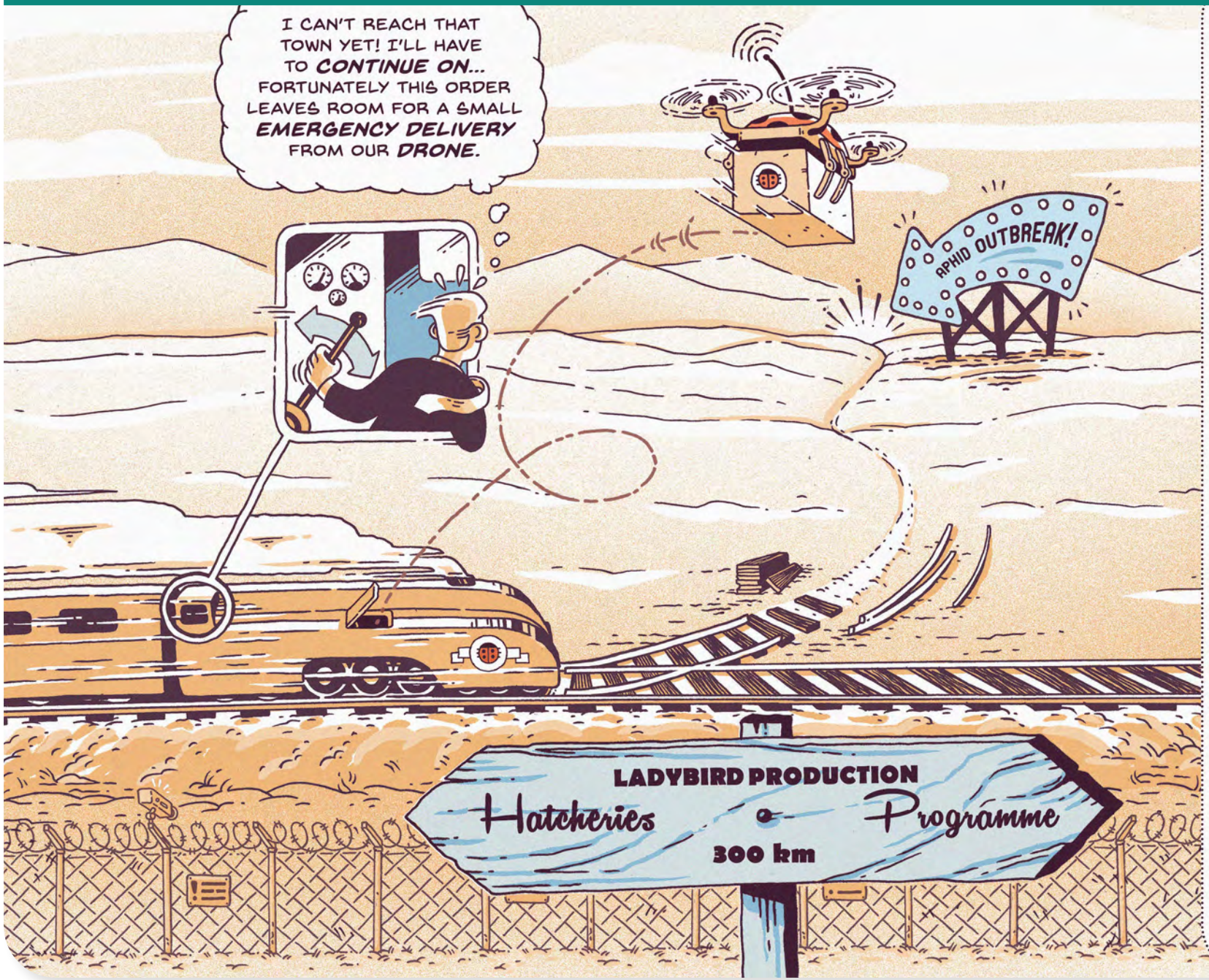
KEY CONTEXT AND TRENDS

- Manufacturing times range from several months to three years for most vaccines.[1] If one quality control point fails, the process starts all over again.
- External events such as outbreaks or manufacturers leaving the market can result in critical supply interruptions.[2]
- The European Medicines Agency has regulatory responsibility for ensuring the quality of vaccines and manufacturing facilities. Each manufacturer providing vaccines in the European Union must meet Current Good Manufacturing Practice (CGMP) standards.[3]
- During the past 50 years, the number of pharmaceutical companies making vaccines has decreased dramatically.[4]
- Supply for one country or region is not necessarily transferable to another, given the variety of local regulations and packaging specifications.[5]
- Since 2019, vaccine manufacturers are obligated to place two safety features on vaccine packaging in the EU, which is the 'serialisation requirement' by Commission Delegated Regulation.[6]

KEY MESSAGES

- Vaccines are complex, highly-regulated biological products that require long lead times to manufacture and supply. This means that sudden increases in demand cannot be immediately met since building new or additional supply capacity takes time.
- Advanced forecasting is foundational to a reliable supply of quality vaccines.[2] Predictable demand allows a reduction in barriers to planning, manufacturing, and distributing vaccines, given the long manufacturing time.
- A two to three year demand forecast, including an adapted procurement mechanism, is optimal for vaccine manufacturers to produce supply to meet demand. This also supports upstream vendors who need to prepare sensitive raw materials for manufacturing and testing processes (eg eggs, animal-derived serums).
- Changes in vaccination calendars (programme expansion) and procurement decisions should be communicated to manufacturers early on and take into account their input to ensure a sustainable supply.
- Simplified European regulatory procedures, including an adaptation of serialisation requirements in emergencies, would reduce barriers to vaccine supply in member states.[7]

P15 | VACCINE SUPPLY



Imagine the supply of ladybirds from production to delivery in the garden, as a long, complex chain of safe and secure transport. Timing is important because ladybirds do not live forever. As soon as they arrive by plane at the airport, they are stowed on trains to take them to the Ladybird Programme in all regions of the country.

But what to do if one of the regions suddenly needs a much bigger supply of ladybirds, because of an outbreak of garden pests, for example? Can we divert the delivery?

Perhaps there is not yet a railroad track to that region. But even if we do have transport available to reach it, will we have enough ladybirds? If we dip into our current shipment, will the programme at our destination have enough?

The same challenges exist around vaccine supplies. It requires planning ahead.

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P16 | VACCINE SAFETY

Vaccine safety is carefully monitored and analysed throughout the life cycle of a vaccine. Understanding vaccine safety is critical to successful, sustainable vaccination programmes. Because vaccines are given to healthy individuals to prevent disease, the general public may expect higher safety standards than for other pharmaceuticals.[1] Many stakeholders are involved in evaluating and monitoring vaccine safety, including EU regulatory bodies, scientific institutions, national governments, and industry.[1]

OTHER RELATED TOPICS

- P7 | Health Technology Assessment
- P11 | Coalitions
- P14 | Vaccine Manufacturing
- P17 | EU Regulatory Issues
- P19 | Role of Healthcare Professionals
- P22 | Immunisation Programmes
- P24 | Vaccine Surveillance
- P25 | Information Systems

P16 | VACCINE SAFETY

KEY CONTEXT AND TRENDS

- Quality procedures for vaccines are among the strictest in the industry to ensure that vaccines that come to market have a good safety profile. They are monitored for safety throughout their lifecycle.[2]
- As vaccines are biological products, rare adverse reactions may occur. However, very serious adverse events following immunization are extremely rare. [2]
- For example, the risk of inflammation of the brain (encephalitis) due to measles vaccine is between one per 100,000 doses and one in a million.[2] In comparison, this risk is 500-5,000 times higher after a natural measles infection.
- Global, regional, and national organisations are involved in assessing, monitoring, and investigating safety across the vaccine lifecycle. This includes government regulatory authorities, health ministries, national public health institutions, National Immunisation Technical Advisory Groups (NITAGs), and vaccine manufacturers.[3]
- The EU regulatory process requires evidence of vaccine safety, quality, and efficacy before marketing authorisation.[4] In addition, the European Centre for Disease Prevention and Control (ECDC) undertakes an ongoing assessment of vaccine safety following programme implementation.[5,6]

KEY MESSAGES

- An adverse event following immunisation (AEFI) is defined as "any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine".[7]
- Vaccines are highly regulated and considered to have a good safety profile.[2]
- In case of AEFIs, there are pharmacovigilance procedures that are closely monitored in the EU.[6]
- The role of regulatory and scientific agencies (eg EMA, ECDC, NITAGs) is critical in helping ensure reliable and safe vaccines access.
- NITAGs are essential for developing evidence-based recommendations on the safe use of vaccines in national immunisation programmes.[7,8] They also play a crucial a crucial role in responding to safety concerns.

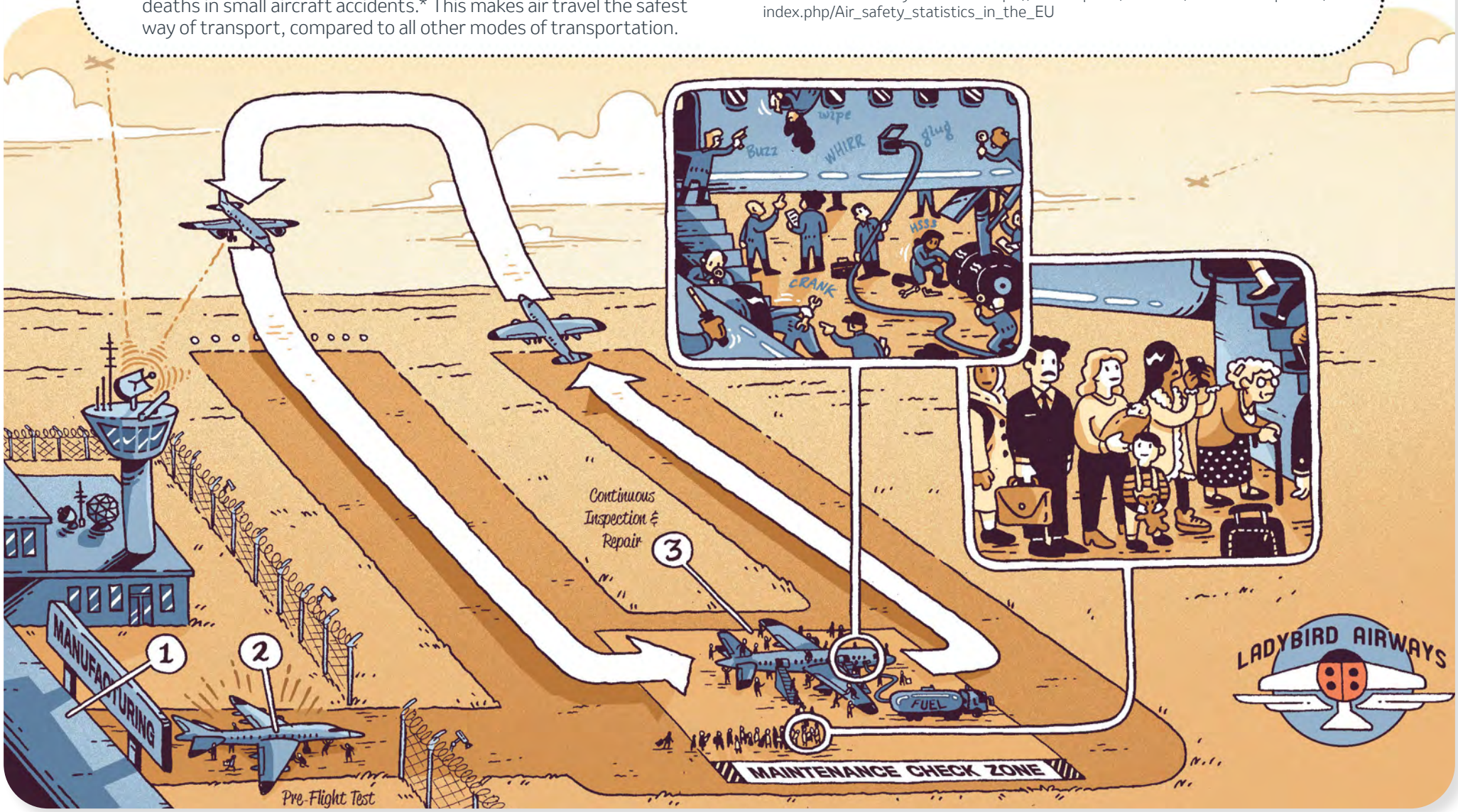
P16 | VACCINE SAFETY

In 2017, people in Europe made more than one billion air travel journeys. In addition to that, more than three million tons of freight was transported by air within the EU that year.* Quality control in air traffic is of paramount importance. Thanks to these precautions, the safety profiles of aeroplanes are extremely high: in 2017, five deaths occurred among passengers on commercial flights, and 166 deaths in small aircraft accidents.* This makes air travel the safest way of transport, compared to all other modes of transportation.

The industry is committed to maintaining the highest quality assurance standards to maintain this safety record.

It's the same for vaccinations: the industry and public sector prioritise safety above all. And though extremely rare risks can never be excluded, one thing is clear: the risks of not vaccinating are much higher.[9]

*EUROSTAT Air Safety Statistics https://ec.europa.eu/eurostat/statistics-explained/index.php/Air_safety_statistics_in_the_EU



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P17 | EU REGULATORY AND ACCESS PATHWAY

The European Union is characterised by a diversity of national systems for recommendations and funding of vaccines. This diversity delays market access to new and innovative vaccines. There is an opportunity to adapt current decision-making pathways for regulatory approval/marketing authorisation, recommendations, reimbursement, and pricing to improve access.[1]

OTHER RELATED TOPICS

- P2 | Vaccination Coverage
- P3 | Outbreaks
- P7 | Health Technology Assessment
- P9 | Vaccination Ecosystem
- P10 | EVAP
- P11 | Coalitions
- P13 | R&D
- P14 | Vaccine Manufacturing
- P15 | Vaccine Supply
- P16 | Vaccine Safety
- P21 | Vaccination Access and Equity
- P26 | Vaccine Innovation

P17 | EU REGULATORY AND ACCESS PATHWAY

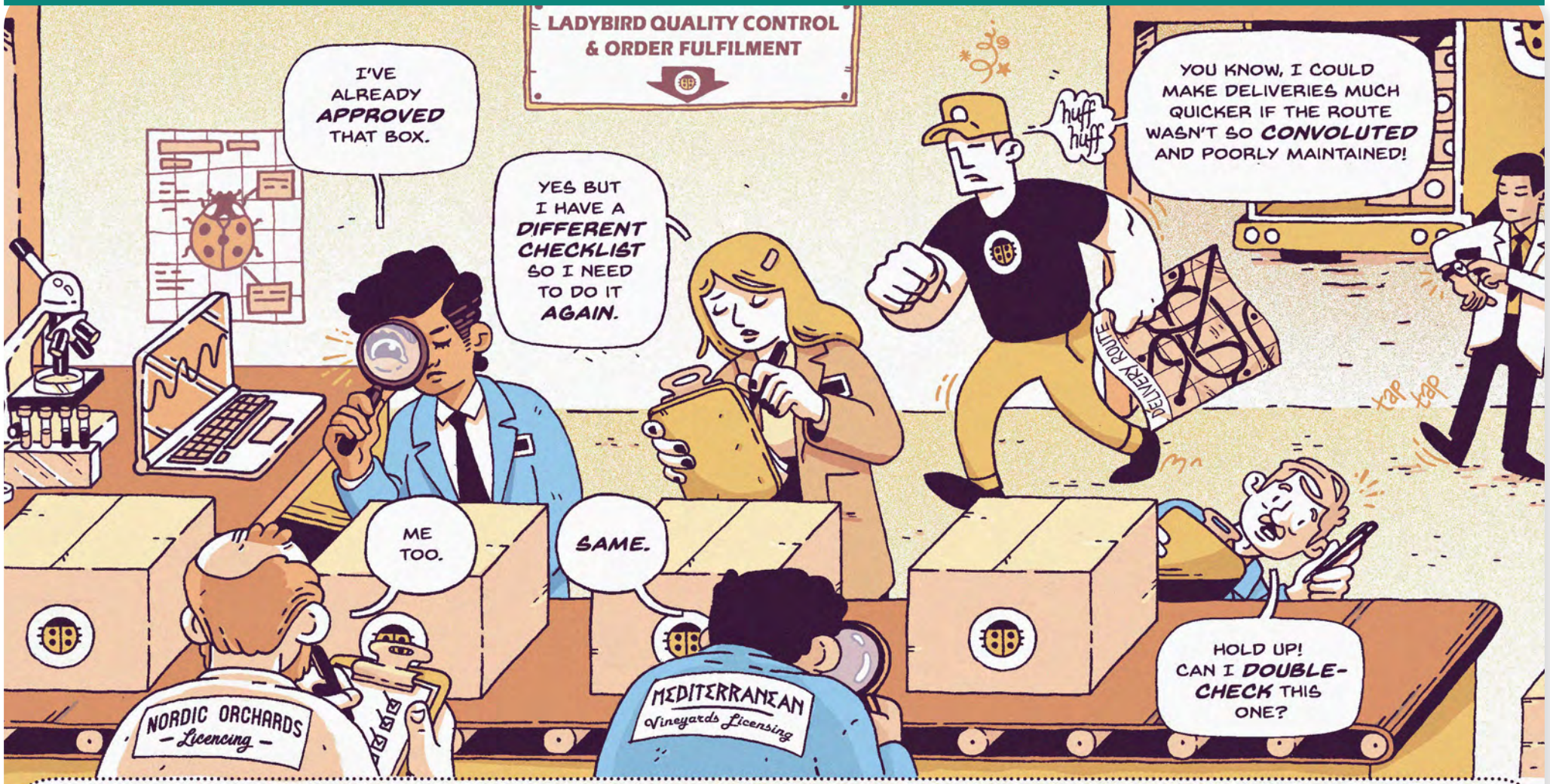
KEY CONTEXT AND TRENDS

- Key organisations involved in the decision-making process are:
  - The European Medicines Agency (EMA) or national regulatory authorities.
  - Ministry of Health or regional authorities.
  - National or regional regulatory authorities.
  - National Immunisation Technical Advisory Groups (NITAGs).
  - Health Technology Assessment (HTA) agencies.
- Decision-making for vaccine programmes differ across Europe, providing the opportunity to streamline assessments used by public health (eg NITAGs), payer, and regulatory bodies at European, national, and regional levels.[2]
- The median lag time between marketing authorisation to implementation of a vaccine programme in Europe is 6.4 years. The national assessment processes absorbs most of this time.[3,4]
- Reasons for access delays include:
  - Unnecessary duplication of decision-making.[2,4]
  - Lack of coordination across decision-makers and NITAGs.[2,4]
  - Inconsistencies in or lack of support for generating the necessary data for regulatory approval, recommendations, pricing, and reimbursement.[2]
- As new and innovative vaccines come to market, regulatory requirements are increasing further. This drives up the cost and time required to authorise new vaccines.[1]

KEY MESSAGES

- The regulatory and decision-making landscape for vaccines in Europe is complex and diverse. Streamlining these pathways could reduce the lag time between market authorisation and implementation.[2]
- Among decision makers in 27 EU countries, 93% saw potential for a collaboration/resource sharing between NITAGs to streamline the process of developing vaccine recommendations.[5]
- The Commission's proposal for an EU regulation on reinforcing cooperation between member states on HTAs gives the European Parliament and Council the opportunity to streamline the current HTA system. This could significantly speed up access to new vaccines.[6]
- Vaccines Europe calls on EU decision-makers to[7]:
  - Foster early-stage dialogue across regulatory, public health, payer, and industry bodies to facilitate the assessment of new and innovative vaccines.
  - Develop guidance for member states to implement timelines for decision-making for new and innovative vaccines.
  - Promote cooperation on vaccine-specific HTAs to identify good practice in evaluating preventative interventions.

P17 | EU REGULATORY AND ACCESS PATHWAY



The Ladybird Programme is a success. Its effectiveness was proven in several studies, and Gardeners Associations all around Europe want to order ladybirds to keep gardens safe. However, each association has its own rules and regulations on importing and using this biological pest control. This includes documentation and labelling in the national language, and each association uses its own licensing checklist. Though they share many items on these lists in common, some variations exist between associations.

This means lots of duplication of double-checks in the factory, during transport, and at delivery. And the driver is getting impatient. He knows that it also takes time to reach all corners of the country. He thinks: "Wouldn't it be good if these guys from the different Gardeners Associations could get together and agree on a single checklist?" Well, we can understand that thought… similarly this would be a great idea for the vaccine regulatory pathways.

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P18 | VACCINE CONFIDENCE AND PUBLIC HEALTH IMPACT

Vaccination programmes are successful when there is confidence among public, providers, and policymakers in the safety and efficacy of a vaccine, and in the full system – the people and systems that deliver and administer vaccines, and who make the decisions to procure, fund, and recommend vaccines. A loss of trust in one of these elements may result in declining vaccination coverage and increasing outbreaks of vaccine-preventable diseases (VPDs).

OTHER RELATED TOPICS

- P1 | VPD Control
- P2 | Vaccination Coverage
- P3 | Outbreaks
- P9 | Vaccination Ecosystem
- P10 | EVAP
- P11 | Coalitions
- P18 | Vaccine Confidence
- P19 | Role of Healthcare Professionals
- P20 | Vaccine Literacy
- P21 | Vaccination Access and Equity
- P22 | Immunisation Programmes
- P24 | Vaccine Surveillance

P18 | VACCINE CONFIDENCE AND PUBLIC HEALTH IMPACT

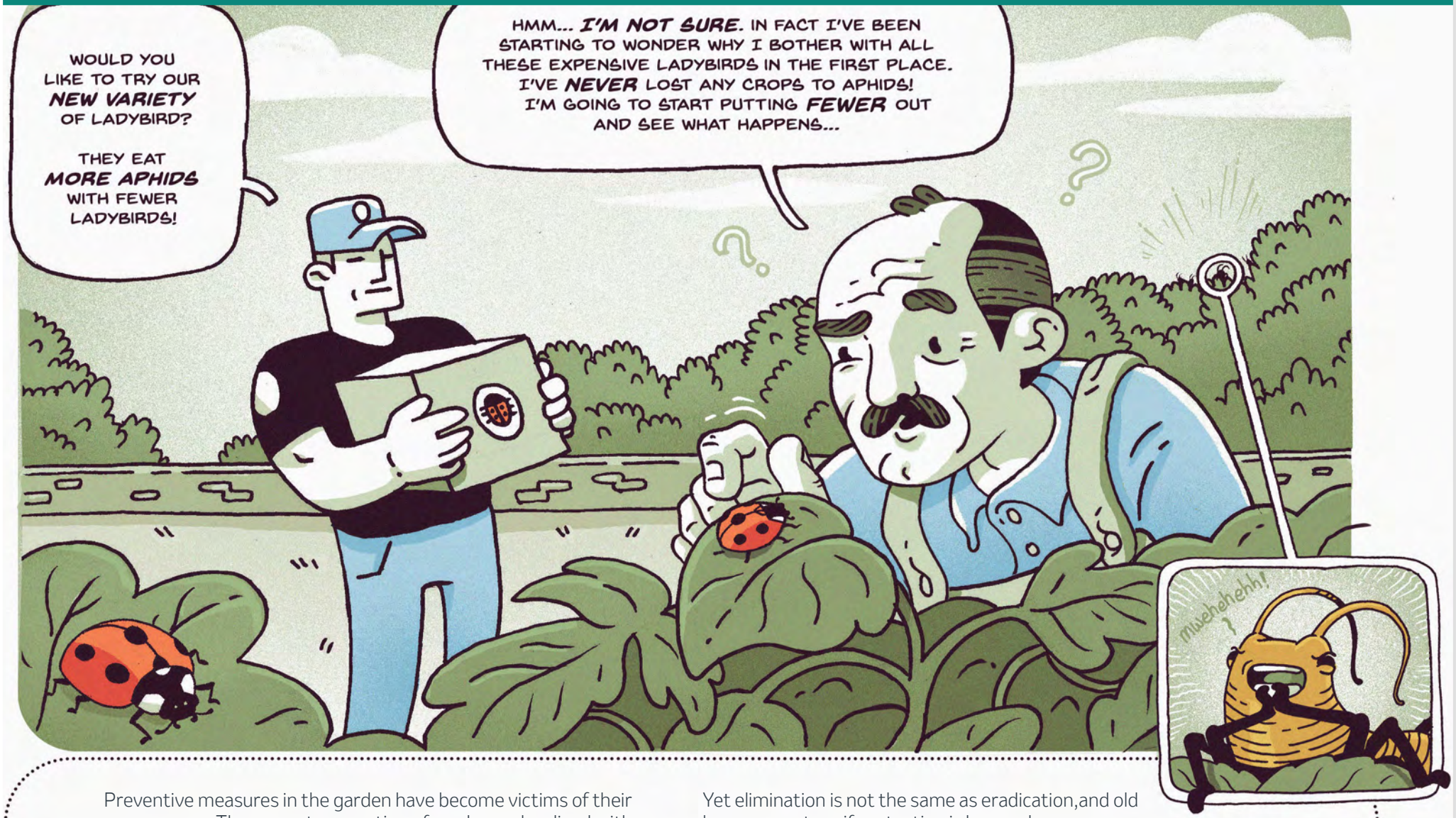
KEY CONTEXT AND TRENDS

- Vaccine confidence is relevant for all vaccines and is part of a spectrum of attitudes.
  - Around 5% or less are 'active resisters'.[1]
  - The 'hesitant', have concerns about perceived safety issues or are unsure about needs, procedures, and timings for immunisations.[2]
  - The 'unconcerned' are complacent and give low priority to vaccines.[2]
  - The poorly reached' have limited access to services, related to social exclusion, poverty, or factors related to convenience.[2]
- When the proportion of vaccine-hesitant parents increases, it negatively impacts vaccine uptake.[1,2]
- Increased measles morbidity and mortality are attributed to eroding vaccines confidence, growing complacency, as well as missed opportunities to vaccinate.[3]
- Eroding vaccine confidence has led to dramatic decreases in human papillomavirus (HPV) vaccination coverage in some countries.[4]
- Trends influencing confidence in vaccination include:
  - Few parents and doctors remember the severity of polio, measles, or diphtheria therefore underestimate the value of vaccination.[1]
  - Social norms related to how people make decisions about healthcare have shifted from expert-guided to self-informed.[5]
  - Social media has increased rapid access to information—not just facts, but also misinformation and rumours.[5]
  - Vaccination is, increasingly, a political issue.[6]

KEY MESSAGES

- In 2019, WHO ranked Vaccine Hesitancy as a "top 10 global public health threat".[3] WHO Europe developed the Tailoring Immunisation Programme (TIP) method in 2013 to address hesitant populations and subgroups.[2]
- Hesitancy must be addressed to maintain high vaccination coverage.[2]
- Stakeholders must work together to identify evidence-based strategies to address vaccine hesitancy:
  - Dialogue-based interventions are effective, eg motivational interviews.[5,7,8]
  - Focus dialogue on the benefits of getting protected.[7,9]
  - Make access to vaccination easier and more convenient.[7,9]
- Health workers remain the most trusted influencers of vaccination decisions. They need support to provide credible information on vaccines to target groups.[7]
- A resilient vaccine system can withstand major shocks, quickly adapt to changes, and maintain high vaccine acceptance over time.[10] Additionally:
  - Individuals and communities play a critical role. Widely-shared personal stories can trigger a surge in demand for health services, including vaccination.[10]
  - Trust in the vaccination system is a prerequisite for vaccine confidence. Healthcare professionals, vaccine supply chains, system financing, and data systems all contribute to improving confidence and convenience.[10,11]
- Coordination among and between these groups can create resilient systems, critical for generating high levels of vaccine confidence and driving vaccination uptake.[10]

P18 | VACCINE CONFIDENCE AND PUBLIC HEALTH IMPACT



Preventive measures in the garden have become victims of their own success. The current generation of gardeners has lived with the absence of threats, thanks to effective prevention. They've forgotten about the severity of eliminated pestilence. They have become unconcerned, and investing time and money in prevention has become inconvenient.

Yet elimination is not the same as eradication,and old bugs may return if protection is lowered.

This is the same with vaccination; it is important to remain aware that the threat that serious diseases may return should we lower the coverage rates of vaccination.

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P19 | THE ROLE OF HEALTHCARE PROFESSIONALS IN VACCINATION

Parents and patients view healthcare professionals (HCPs) as a trustworthy source of information making them strong influencers in vaccine decision-making pathway. They play a critical role in recommending vaccination, communicating about safety and effectiveness, and addressing individuals' questions or concerns. However, some HCPs feel ill-equipped to answer questions or engage in difficult conversations with those who are reluctant to be vaccinated. Such lack of confidence is a potential threat to vaccination programme implementation across Europe.[1,2]

OTHER RELATED TOPICS

- P1 | VPD Control
- P2 | Vaccination Coverage
- P16 | Vaccine Safety
- P18 | Vaccine Confidence
- P20 | Vaccine Literacy
- P21 | Vaccination Access and Equity
- P22 | Immunisation Programmes

P19 | THE ROLE OF HEALTHCARE PROFESSIONALS IN VACCINATION

KEY CONTEXT AND TRENDS

- The European Centre for Disease Prevention and Control (ECDC) confirms that vaccine hesitancy exists among HCPs. Concerns are country-specific and relate to the risks of vaccination, or lack of trust in health authorities.[1]
- Research shows that HCPs are more likely to recommend vaccination if they were vaccinated themselves.[3]
- The level of vaccine-specific knowledge of the HCP influences the parents' decisions.[3]
- Among Italian paediatricians, only 88% knew that measles vaccination was recommended and only 35% knew the vaccination calendar.[4] Among French doctors, 16–43% did not routinely recommend vaccines for their patients.[5]
- The European Parliament has called on EU member states to ensure sufficient vaccination of HCPs and to take steps against misinformation.[6]
- Parents expect HCPs to have current knowledge, to tell stories, to share scientific facts about vaccination, and take time to listen to concerns about possible side effects and risks.[7] However, few primary care physicians have the time, skills, and incentives to deliver ongoing, systematic prevention messages.[8]

KEY MESSAGES

- HCPs need to be active advocates for vaccine importance and safety.[9]
- HCPs are in a position to influence a parent's decision to vaccinate their children, including parents who believe that vaccinations are unsafe.[10]
- Transparent information on vaccines, delivered by well-trained HCPs, is vital to help improve vaccine coverage and minimise vaccine hesitancy.[1]
- Governments must support and enable HCPs to remain confident in the safety of vaccines and to communicate these messages to their patients.[5]
- Medical curricula targeting HCPs should include training on vaccine safety and efficacy, vaccination schedules, vaccination benefits, awareness of vaccine-preventable diseases (VPDs), and how to communicate with parents.[5]
- To accept HCP recommendations for vaccination, parents expect HCPs to be vaccinated themselves.[7]
- A comprehensive programme considers populations and individuals. Closer cooperation and better integration of public health and primary care services are needed.[11]

P19 | THE ROLE OF HEALTHCARE PROFESSIONALS IN VACCINATION

Gardeners consider the responsibility of care for crops, flowers and fruit as a serious matter. Of course, they benefit from advice received from peers and older generations. But how to keep up with scientific developments and improved protection for your garden? It's complex! And often it feels as if the whole world wants to sell you something 'that is vital for your garden'. Can you trust every expert that advises you? In this case, the expert is a botanist who has known this gardener for a long time. She is committed to providing reliable information and takes time for a dialogue to explain. She acknowledges his concerns, empathises and provides fact-based information, with transparent examples when needed.

A similar approach by healthcare workers could make a world of difference when attempting to strengthen parents' confidence in vaccination.

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P20 | VACCINE LITERACY

Decision-making around vaccination requires a high level of vaccine literacy. Vaccine literacy looks at health literacy from the perspectives of vaccine attitudes and hesitancy to better define and understand the main determinants of vaccine uptake.[1] Increased vaccine literacy enables individuals to make informed decisions about vaccination and motivates them to implement those decisions.[2]

OTHER RELATED TOPICS

- P18 | Vaccine Confidence
- P19 | Role of Healthcare Professionals
- P22 | Immunisation Programmes

P20 | VACCINE LITERACY

KEY CONTEXT AND TRENDS

- Scientifically accurate information about vaccines tends to be complex. Comprehending this information requires specific literacy and numeracy skills, which is why communicating information to patients can be a challenge.[1]
- Vaccination schedules are increasingly complex. Even parents who are motivated can easily forget.[3]
- Vaccine advocacy is difficult, as healthcare professionals' fears of potential adverse events and liability oppose their desire to advocate for vaccination.[4]
- Vaccine literacy is more than knowledge about vaccines, it is also about developing a system with decreased complexity to communicate and offer vaccines as indispensable for a functioning health system.[1]
- A knowledge gap exists regarding effective interventions for improving vaccine literacy.[5]

KEY MESSAGES

- Children and young people should be taught about how vaccines work, the diseases they prevent, and their value for society.[4]
- Learning opportunities also exist during non-vaccination experiences, to reinforce in families and recipients the public health benefits of vaccination.[4]
- To improve vaccine literacy, it is essential that HCPs are well trained and supported with appropriate information to help individuals to understand the disease, the risks of the disease, and the risks of vaccination.
- To create conditions of better health for all, and consequently promote vaccinations, people may need to receive support for their decisions. Community action should be reinforced to create empowerment and health services may need to be reoriented to bring them closer to citizens.[1]
- Further research is needed about the effectiveness of interventions to improve vaccine literacy.

P20 | VACCINE LITERACY

It has always been a challenge for gardeners to keep up with developments that determine the health of their gardens. Volumes of books, with experience from all corners of the globe, create a daunting challenge. The challenge not only consists of staying ahead of all that is written but also distinguishing fact from fiction. In modern times, the arrival of digital technologies only enhances this challenge.

Fortunately, the Gardeners Association has recognised this and has invested resources in improving 'garden-health literacy'. This includes practical digests of new scientific insights and technologies. And most helpful is the 'Seal of Approval' that indicates the reliability of information sources.

For vaccines, the same challenges exist. The World Health Organisation established 'Vaccine Safety Net', a global network of websites providing reliable information about vaccine safety.

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P21 | IMPROVING ACCESS AND EQUITY

Equitable access to vaccination is a core component of the human right to health. Despite increasing vaccination coverage globally, inequalities between and within countries persist and in some cases are widening.[1] Inequity impacts the protection of the population. Access to vaccination may differ due to differences in vulnerability of groups within a population, the existence of poorly-reached populations, or due to differences in vaccination programmes between countries. Vaccinating the poorly-reached is ethical, highly cost-effective, and has a substantial positive public health impact.[2]

OTHER RELATED TOPICS

- P1 | VPD Control
- P2 | Vaccination Coverage
- P3 | Outbreaks
- P6 | Benefits and Growth
- P7 | Health Technology Assessment
- P9 | Vaccination Ecosystem
- P10 | EVAP
- P12 | Health Systems Pressures
- P13 | R&D
- P17 | EU Regulatory Issues
- P18 | Vaccine Confidence
- P19 | Role of Healthcare Professionals
- P21 | Vaccination Access and Equity
- P22 | Immunisation Programmes
- P24 | Vaccine Surveillance
- P25 | Information Systems

P21 | IMPROVING VACCINATION ACCESS AND EQUITY

KEY CONTEXT AND TRENDS

- While disease knows no borders, access to vaccines across member states varies between neighbouring countries, as strongly demonstrated by varicella.[3]
- Vulnerable groups differ by country and are context-dependent. From an EU perspective, vulnerable groups include refugees, asylum seekers, and minority ethnic groups, such as the Roma and Traveller communities.[4]
- WHO Europe states: "Every individual in the society should be eligible to receive all appropriate vaccines, irrespective of their geographical location, age, gender, educational level, socioeconomic status, ethnicity, nationality, or religious or philosophical affiliation."[5]
- The vaccination journey that Europeans have to take varies among countries. For example, for measles vaccination[4]:
  - In the Netherlands, measles vaccine (or MMR) is administered at Child Health Centres, which is where all parents take their children for regular health check-ups.
  - In France, self-employed paediatricians mostly administer the measles vaccine, which is first prescribed, then parents go to a pharmacy, pick it up, and store it at home before returning to their paediatrician for vaccination.
- WHO Europe developed *The Guide to Tailoring Immunisation Programmes* to help identify susceptible populations, access barriers, and vaccination strategies tailored for poorly-reached populations.[6]

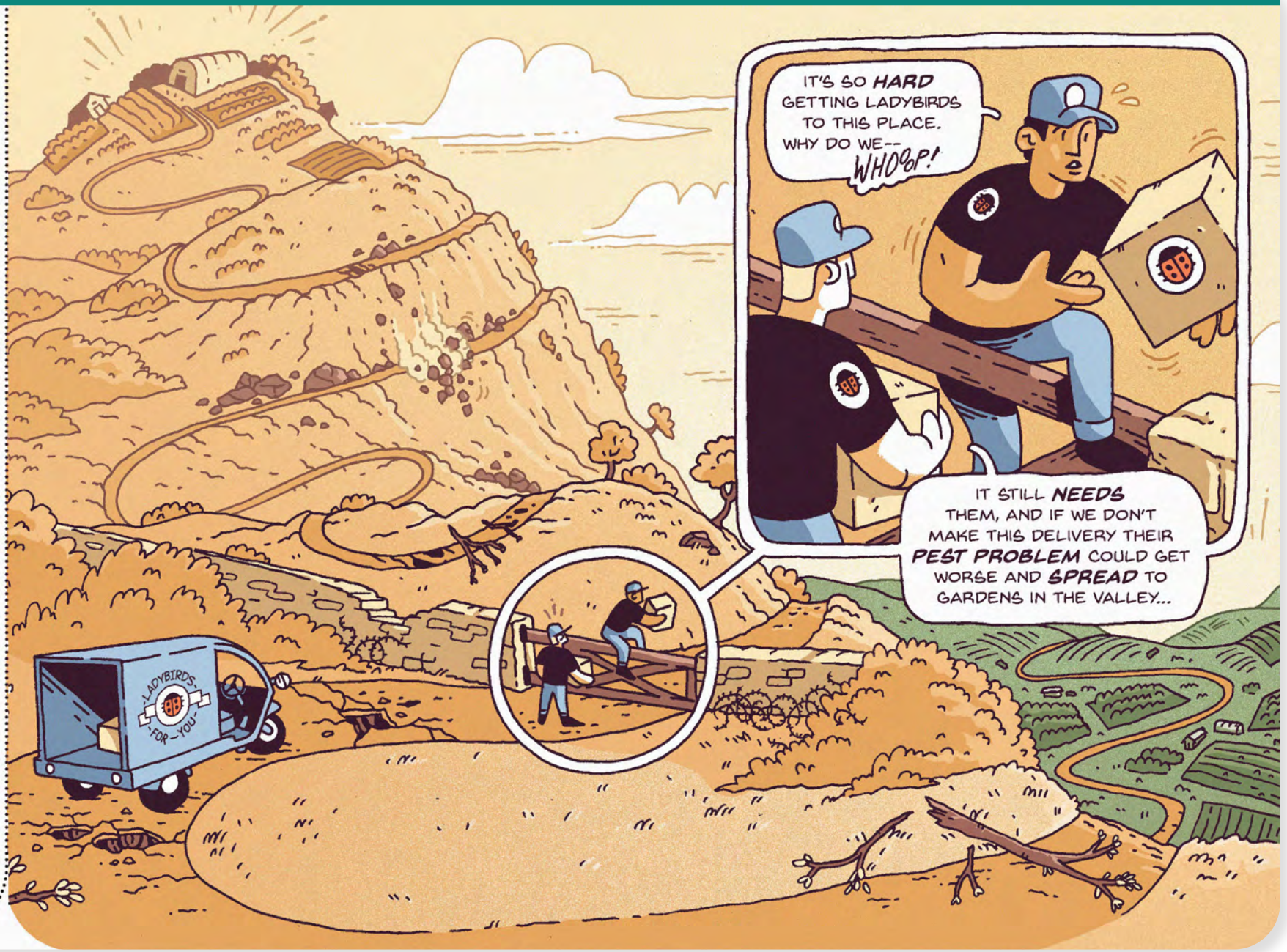
KEY MESSAGES

- Reaching high coverage in individual countries is not enough; achieving high coverage equitably across the European region is key.[1,7]
- Strengthening relationships between healthcare services and families with low socioeconomic status is vital to improve vaccination coverage.[8]
- Evidence-based, context-specific strategies need to be developed to facilitate equitable vaccination access across the lifecycle and across the EU.[1]
- Several approaches can be utilised to improve access to vaccines:
  - Policies that expand where vaccines are delivered and by whom (eg school-based, mobile, or outreach clinics).[7]
  - Training for healthcare professionals to interact with individuals and communities.[7]
  - Reduce out-of-pocket payments for vaccination.
  - Strengthen data systems to identify poorly-reached populations and reduce missed opportunities.[7]
  - Develop easy to understand vaccination schedules.[7]
  - Integrate vaccination campaigns in existing outreach programmes to vulnerable populations.[9]

P21 | IMPROVING VACCINATION ACCESS AND EQUITY

In this district, gardens are protected by the Ladybird programme. There are a small number of gardens growing unique fruit at the top of a remote mountain with a beautiful climate. However, the Ladybird Programme hasn't yet reached them. The district Gardeners Association liberated funds to reach out to that remote mountain top. Some gardeners disagree: "Let those mountain gardeners travel down and pick up the ladybirds themselves!" But the association believes that ease of access and equity in the Ladybird Programme is the key to keeping all gardens in the district healthy.

Similarly, with vaccination, we cannot afford to leave any part of society out. Pathogens do not discriminate, so vaccination policies shouldn't either. After all, it is for the benefit of all.



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P22 | ADHERENCE TO NATIONAL IMMUNISATION PROGRAMMES

National Immunisation Programmes (NIPs) provide recommendations on who should be vaccinated and the optimal vaccination schedule. When adherence to NIPs is not achieved, communities are vulnerable to outbreaks of vaccine-preventable diseases (VPDs), placing strain on the healthcare system and economic stability.

OTHER RELATED TOPICS

- P3 | Outbreaks
- P15 | Vaccine Supply
- P16 | Vaccine Safety
- P18 | Vaccine Confidence
- P19 | Role of Healthcare Professionals
- P20 | Vaccine Literacy
- P21 | Vaccination Access and Equity
- P23 | Stockpiles
- P24 | Vaccine Surveillance
- P25 | Information Systems

P22 | ADHERENCE TO NATIONAL IMMUNISATION PROGRAMMES

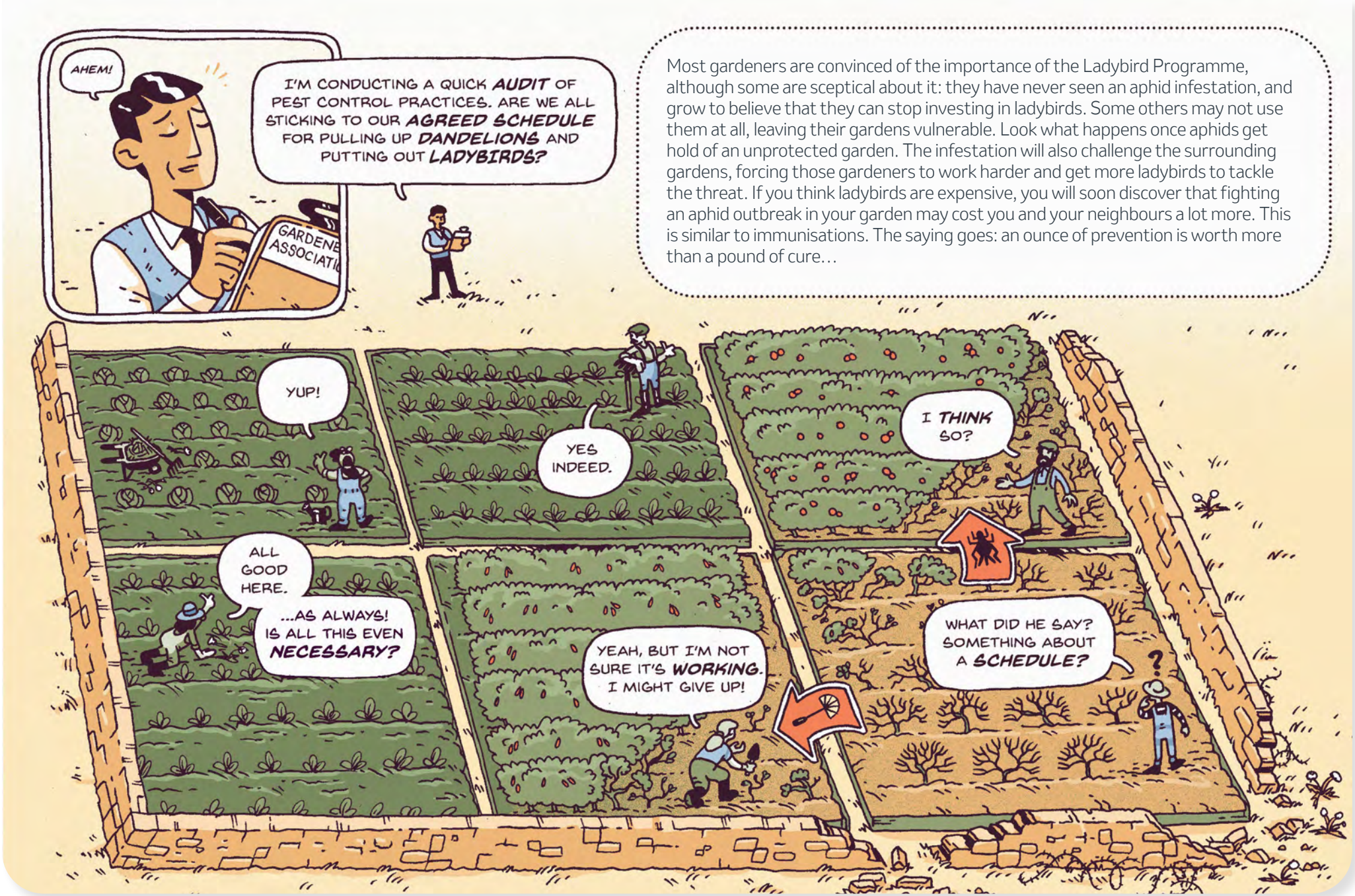
KEY CONTEXT AND TRENDS

- Lack of adherence to a NIP means there is a delay or absence of vaccination or an uncomplete vaccination scheme.
- There are many factors influencing adherence to a NIP, including[1,2]:
  - Lack of awareness of the importance of vaccines.
  - Fear of vaccines and possible side effects.
  - Missed appointments.
  - Poor access to healthcare providers.
  - Inconvenient times for clinics/appointments.
  - Poor communication between healthcare professionals and parents.
  - Lack of adequate financing.
  - High user charges or co-payments.
- Some European Union member states have mandatory childhood vaccinations, though the distinction with voluntary vaccination is not always clear.
- There is substantial disparity in vaccination policies between member states and in the way immunisation programmes are implemented.
  - Some member states impose mandatory vaccination programmes in childhood or for certain groups of adults.
  - Some organise school-based programmes for adolescents, and others expand access to adult vaccination via pharmacies.[2]

KEY MESSAGES

- Several approaches can be used to increase adherence to NIPs and help ensure individuals are vaccinated according to the national schedule:
  - Utilise Immunisation Information Systems (IIS) to inform timely and appropriate vaccine administration by providers, such as reminder systems.
  - Increase access to vaccination in non-healthcare settings such as school-based programmes or at workplaces.[2]
  - Enlarge access to vaccination within the healthcare community by expanding the role of nurses and pharmacists.
  - Ensure that healthcare professionals and the public have confidence in vaccines through communication that is clear, coherent, and research-based.
- At the country level, as well as at the EU level, it is relevant to actively monitor programme adherence and the factors that influence it, so that early interventions may be triggered. This process not only depends on modern and efficient data-collection mechanisms, but also on a pro-active approach by programme managers.

P22 | ADHERENCE TO NATIONAL IMMUNISATION PROGRAMMES



Most gardeners are convinced of the importance of the Ladybird Programme, although some are sceptical about it: they have never seen an aphid infestation, and grow to believe that they can stop investing in ladybirds. Some others may not use them at all, leaving their gardens vulnerable. Look what happens once aphids get hold of an unprotected garden. The infestation will also challenge the surrounding gardens, forcing those gardeners to work harder and get more ladybirds to tackle the threat. If you think ladybirds are expensive, you will soon discover that fighting an aphid outbreak in your garden may cost you and your neighbours a lot more. This is similar to immunisations. The saying goes: an ounce of prevention is worth more than a pound of cure…

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P23 | ENABLING STOCKPILES FOR HEALTH EMERGENCIES

A vaccine stockpile is generally defined as an accumulated supply of vaccines held in reserve for use at a later time. This might also be a virtual stockpile, such as an agreed-upon quantity of vaccine set aside by manufacturers for emergency allocation on request. Provision of the capacity for rapid mobilisation in response to a proven need is a critical, underlying objective for all stockpiles.[1]

OTHER RELATED TOPICS

- P2 | Vaccination Coverage
- P15 | Vaccine Supply
- P22 | Immunisation Programmes
- P24 | Vaccine Surveillance

P23 | ENABLING STOCKPILES FOR HEALTH EMERGENCIES

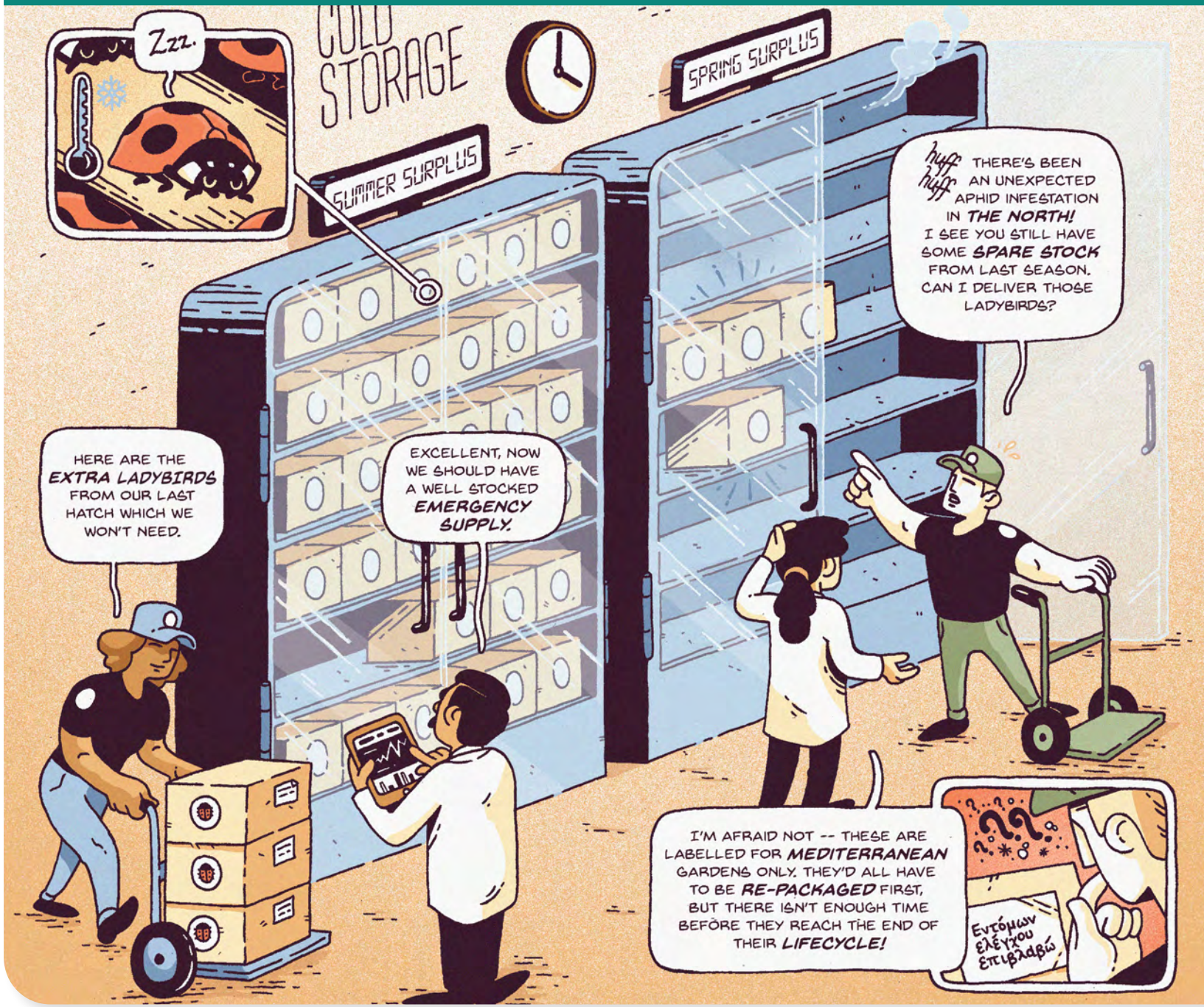
KEY CONTEXT AND TRENDS

- Vaccine shortages are a major global and regional problem. Supply interruptions are multifactorial often unavoidable and difficult to predict.[2]
- Global vaccine stockpiles have proven to be a solution in case of emergency threat. They provide countries with the capacity for rapid response to emergencies, such as outbreaks of meningitis.[1]
- After experiencing major interruptions of its paediatric vaccine production since 2000, the United States now has a model for stockpiling paediatric vaccines that represents an effective collaboration between the Centers for Disease Control and Prevention and vaccine manufacturers.[3]
- Europe operates in a fragmented market. The different languages spoken across Europe mean that leaflets and packaging are printed in different languages for the different member states making the move of vaccines across countries challenging.
- Articles 12 and 13 of Commission Decision 1082/2013 establish that when the European Commission recognises the existence of a pandemic, Article 21 of Regulation (EC) 1234/2008 can be triggered to allow for special authorisation procedures.[4]
- The 2018 European Union Council Recommendation on cooperation against vaccine-preventable diseases (VPDs) had opened up the possibility of European-level vaccine stockpiling mechanisms to make vaccination available in case of outbreaks.[5]

KEY MESSAGES

- Stockpiling could be explored as an investment in preparedness against disease outbreaks in Europe. However, it is not an ultimate solution to supply shortage problems in general.
- The fragmentation of health systems in Europe poses serious barriers for stockpiling vaccines. Simplifying labelling and packaging across European countries may help reduce these barriers.
- Creating an effective plan to manage an effective and sustainable vaccine stockpiling model in the EU could benefit from the US model and experience. Important challenges and principles to solutions include:
  - Ability to move products across countries.
  - Strong and coordinated governance for managing stocks.
  - Fair process for establishing pricing and cost of stockpile.
  - Size of stockpile needs to be driven by vaccination recommendations.
- As a tool to promote supply stability, stockpiling of vaccines at the European level will require significant efforts by governments to harmonise regulatory requirements, as well as an allocation of financial resources.[1]
- Cost and supply security are two factors that policymakers must consider when determining the use of stockpiles and other strategies to address emerging and re-emerging diseases.[1]

P23 | ENABLING STOCKPILES FOR HEALTH EMERGENCIES



We have seen how vulnerable the ladybird supply chain is. The long maturation process and intense quality controls make supply vulnerable to disruption. In addition, our product is a living, biological entity, which cannot be stocked on shelves indefinitely. Still, our ladybird producer has found a smart way to create a buffer stock to address unexpected emergency garden pests. In this smart cold storage, ladybirds are stored for just a couple of months before they are shipped for use. See? We are now mid-summer, and the summer surplus offers a comfortable stock. There are still a few batches of ladybirds from spring stock available. So our dynamic driver just arrived from the Nordic orchards, where gardeners are fighting a desperate battle against an aphid outbreak. The spring surplus ladybirds are just what he needs. But there is another obstacle: those batches are packaged and licensed for the Mediterranean, and they will not be approved for use in the North, even though the ladybirds are exactly the same.

FRUSTRATING!

Similar challenges occur when we try to set up dynamic stockpiles for vaccines. Usually, we stockpile vaccines without labels, though the variance in labelling requirements still makes the entire process complex.

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P24 | VACCINATION MONITORING AND SURVEILLANCE

Surveillance data is critical for adapting policies, implementing National Immunisation Programmes (NIPs), and monitoring progress towards policy goals. To ensure a supportive and effective vaccine ecosystem, surveillance capabilities need to be capable of effectively assessing the burden of vaccine-preventable disease (VPD), evolving epidemiology, vaccine safety, effectiveness of vaccination policy, and vaccination coverage rates (VCR).[1]

OTHER RELATED TOPICS

- P2 | Vaccination Coverage
- P3 | Outbreaks
- P5 | Healthcare Systems
- P9 | Vaccination Ecosystem
- P11 | Coalitions
- P16 | Vaccine Safety
- P18 | Vaccine Confidence
- P21 | Vaccination Access and Equity
- P22 | Immunisation Programmes
- P23 | Stockpiles
- P25 | Information Systems

P24 | VACCINATION MONITORING AND SURVEILLANCE

KEY CONTEXT AND TRENDS

- European Union countries are obliged by law to report surveillance data to the European Centre for Disease Prevention and Control (ECDC). This includes vaccine-preventable diseases (VPD).
- The European Vaccination Coverage Collection System (EVACO) was established in 2013 to improve the quality of vaccine coverage data by defining and implementing standards.[2]
- Surveillance of VPD and Vaccine Adverse Events Reporting Systems (VAERS) are still fragmented in Europe due to differences between national vaccination schedules, absence of an EU reporting infrastructure, and lack of information systems integration.[1]
- Surveillance priorities in the coming years will be influenced by[3]:
  - Growing use of electronic health records.
  - Increasing genomic data from microbiological diagnostics.
  - Enhanced health surveillance systems for migrating populations, immigrants, refugees, and travellers.
  - Socio-demographic indicators and behavioural determinants such as vaccine scepticism.
- The EU Council called on the European Commission "to explore, together with member states, options for establishing an EU platform for the monitoring of the safety and effectiveness of vaccines".[4]

KEY MESSAGES

- Addressing fragmentation and barriers between VPD surveillance systems may be achieved by enhancing communication and aligning work between national and supranational stakeholders.[1]
- There is lack of harmonisation across the region in the way Vaccine Coverage Rates (VCR) are calculated and collected. Gaps in coverage data may hinder the EU and member states to rapidly respond to outbreaks. Countries should adopt the surveillance standards for VPD as defined by EVACO.[2]
- The European Commission, ECDC, and European Asylum Support Office (EASO) should work together to improve the monitoring of the health status of immigrant populations and asylum seekers, with a particular focus on vaccination coverage.
- Monitoring hesitancy should become part of VPD monitoring and surveillance systems.[3,4]
- All stakeholders must contribute to an EU platform for vaccine safety and effectiveness monitoring in response to the call of the EU Council.[4]

P24 | VACCINATION MONITORING AND SURVEILLANCE

The Regional Gardeners Association has identified the fragmentation of Garden Outbreak Alert Trigger Systems (GOATS) as one of the key concerns of the region. After long negotiations, it convinced all local and national associations to pool resources and develop a state-of-the-art Digital Information Monitoring System. The problem is that not all individual gardeners have been informed about these rapid developments. And some feel very uncomfortable that their performance is monitored by a remote agency. What about privacy? And will that data be used only for the benefit of the gardeners? Such concerns are very valid, and the Regional Gardeners Association should make every effort to set up transparent processes, audits by gardeners, and strict data protection. This is important, actually, for every surveillance system.

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P25 | IMMUNISATION INFORMATION SYSTEMS

Immunisation Information Systems (IIS) are defined as a confidential, population-based, computerised database that records all vaccination doses administered by participating providers to persons residing within a given geopolitical area.[1]

OTHER RELATED TOPICS

- P3 | Outbreaks
- P4 | Life-Course
- P16 | Vaccine Safety
- P21 | Vaccination Access and Equity
- P22 | Immunisation Programmes
- P24 | Vaccine Surveillance

P25 | IMMUNISATION INFORMATION SYSTEMS

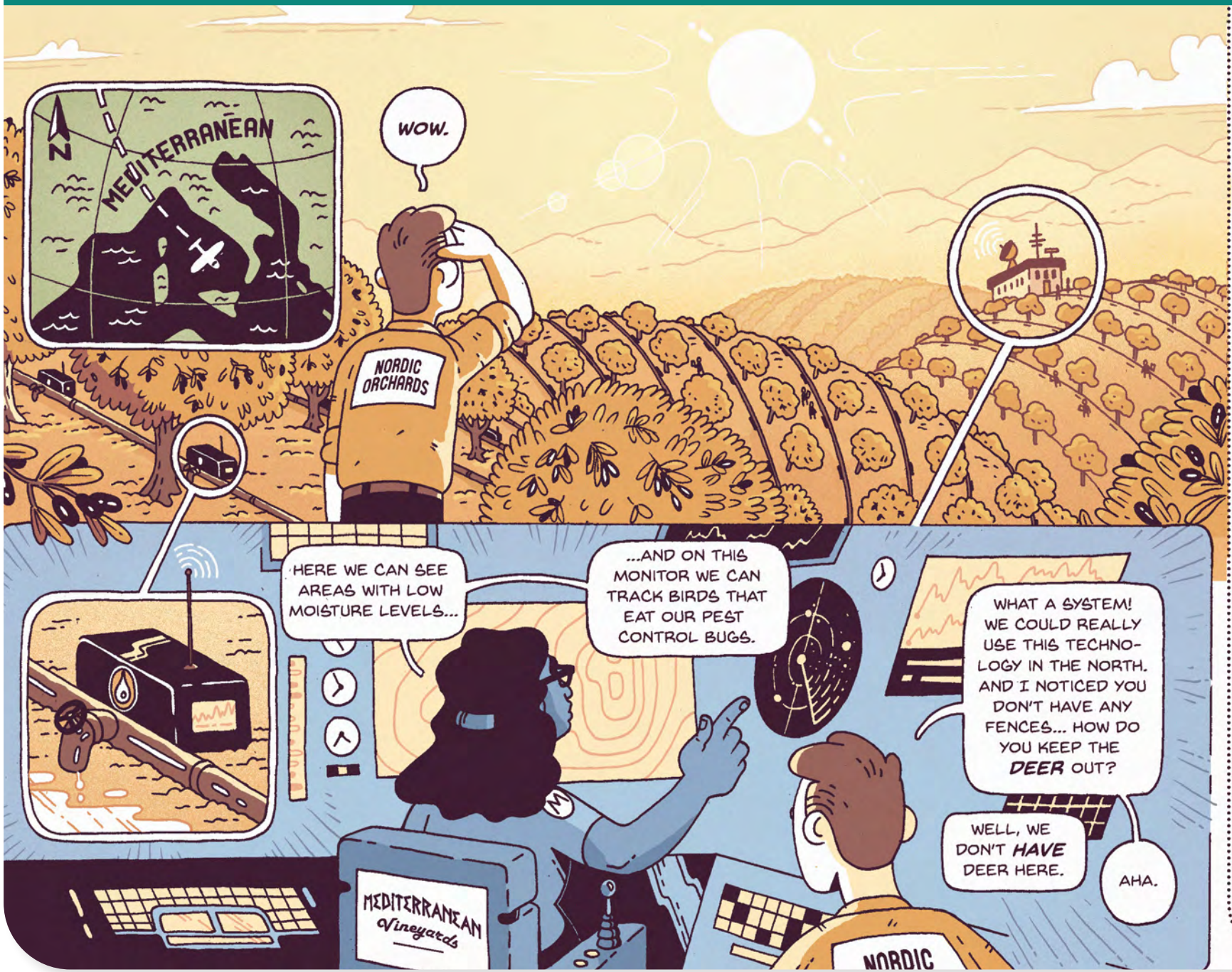
KEY CONTEXT AND TRENDS

- The European Union (EU) lacks standards for collecting immunisation data. Member state systems vary in capabilities and information captured.[1]
- Several factors block a reliable comparison of vaccination coverage between EU countries[2]:
  - Only some countries use a population register as the basis for their vaccination programmes.
  - Some countries use the registries of general practitioners to monitor vaccination uptake and send invitations to individuals.
- The European Council and the World Health Organisation (WHO) recognise the Immunisation Information System (IIS) as an integral part of well-functioning health systems.[3,4]
- The European Centre for Disease Prevention and Control (ECDC) published guidelines highlighting expertise and tools to establish a minimal set of IIS functionalities across the EU.[5]
- As of 2017, 21 out of 27 countries surveyed had an IIS or were piloting one.[1]
  - Of the 27 countries surveyed, 10 could record vaccination at any age; 14 could record immunisations administered in the past.
- Most immunisation registries are based on childhood immunisation programmes, yet lack a comprehensive, life course vaccination registry encompassing the entire population.

KEY MESSAGES

- Most EU citizens only rely on paper records for their paediatric medical history and may not have access to those records. Many people do not know whether they have been vaccinated against some diseases, when was the last time they got vaccinated, or whether they are up to date on their records.
- IIS represents a significant way forward for life course vaccination programme monitoring.[6] It is critical to invest financially in IIS to adequately protect the population.
- IIS needs to be established or strengthened so it can function as both a management tool and for surveillance purposes.[7]
- EU-wide implementation of the IIS supports[5]:
  - Immunisation programme performance monitoring (eg vaccination coverage rates, vaccine safety, and trends).
  - Public health decision-making (eg improve vaccine equity, identify the poorly reached).
  - Equitable distribution in vaccination services.
- Countries should follow ECDC guidelines to establish a minimal set of IIS functionalities across the EU.[1] This aligns with the EU Joint Action on Vaccination Work Package #5.[1,8]

P25 | IMMUNISATION INFORMATION SYSTEMS



Our friends of the Nordic Orchards Association have heard a lot of good things about the innovative IT applications of the Mediterranean Vineyards Association to monitor the nutrition status of their population of vines.

During their study trip, Nordic gardeners are amazed at the level of detailed information that helps keep the vineyards healthy. The Mediterranean system collects the irrigation status of each individual vine. This became possible when all the Mediterranean gardener associations agreed to use regional standards allowing data exchange. This required not just technical solutions, but also regulations for data protection, and above all, mutual trust and regional leadership.

This is not so different from the challenges we face in implementing an EU-wide Immunisation Information System.

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P26 | INNOVATION IN VACCINES

Vaccine innovation faces economic obstacles as more sophisticated technologies are needed to develop vaccines and target populations for new vaccines may be narrow instead of universal.[1]

In the next three perspectives, MSD provides a view on the importance of innovation, illustrates its footprint of vaccine development over the past century, and sketches key elements for a future of inclusive and sustainable vaccination.

OTHER RELATED TOPICS

- P3 | Outbreaks
- P4 | Life Course
- P8 | Procurement
- P9 | Vaccination Ecosystem
- P13 | R&D
- P12 | Health Systems Pressures
- P17 | EU Regulatory Issues

P26 | INNOVATION IN VACCINES

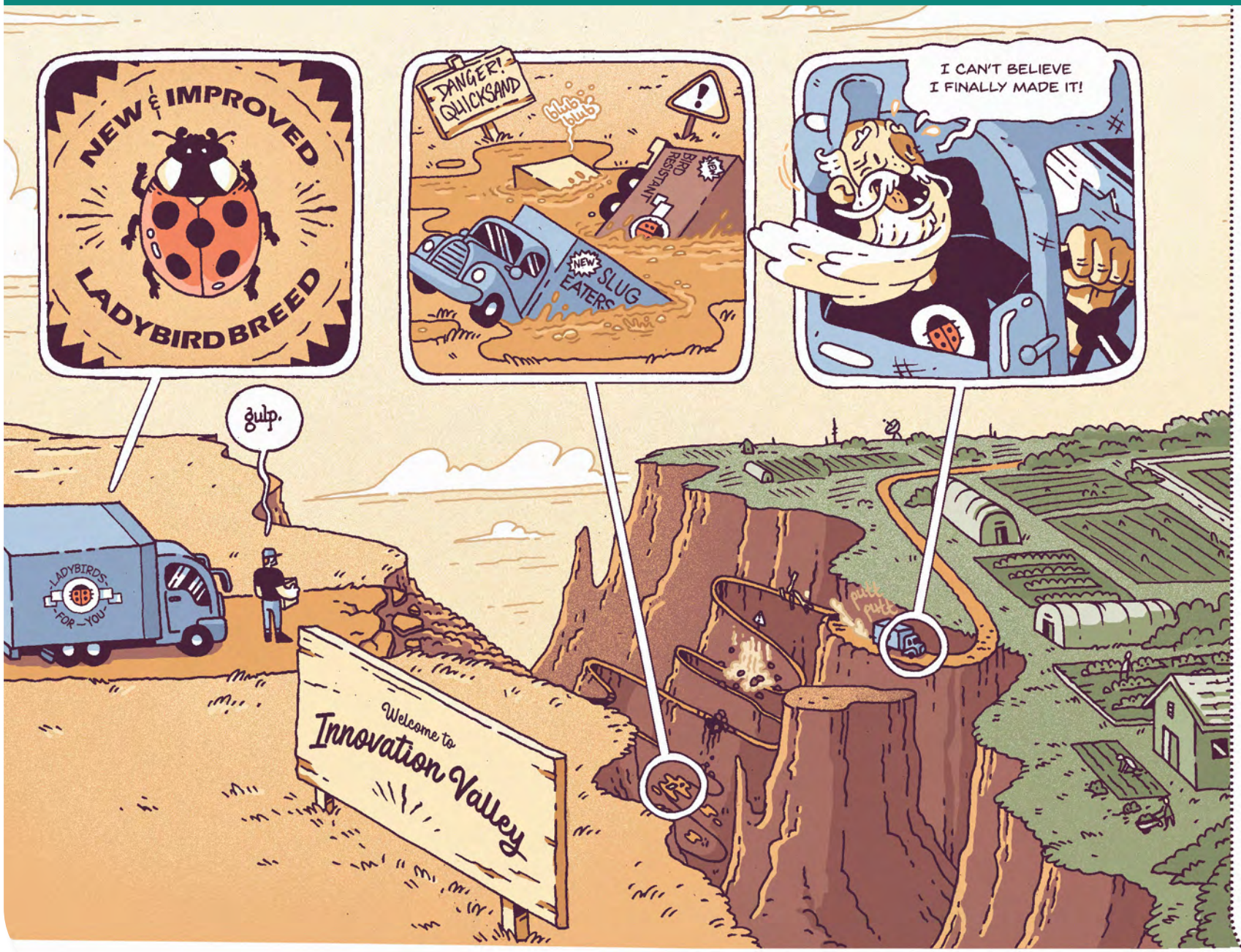
KEY CONTEXT AND TRENDS

- Disease burden and severity were early drivers of vaccine development, followed by scientific advances in microbiology.[1]
  - Diseases producing strong, durable immunity were the easiest targets for early successful vaccine development.[1]
  - Technological advances were needed to address more difficult pathogens.[1]
- Current product innovation involves costly, highly-engineered techniques restricted to advanced laboratories, such as in the academia and pharmaceutical sectors.[1]
- Increasing regulatory requirements further drive vaccine development costs.[1]
- The final part of the vaccine innovation pipeline includes clinical trials, scale-up of manufacturing, and investment in process development. This part is referred to as the 'valley of death', as the above trends have increased costs so much that many candidate vaccines do not get through.[1]

KEY MESSAGES

- Currently, there are vaccines to protect against 30 vaccine-preventable diseases (VPDs) with hope that more could be developed against diseases such as HIV and malaria.[3]
- Three challenges are slowing vaccine innovation[2]:
  - Higher technical complexity and commercial uncertainty.
  - Increased opportunity cost.
  - Increased investment requirements for mid- and late-stage research and development (R&D) and manufacturing.
- Costs for vaccine R&D, especially for outbreak pathogens (eg Ebola and Zika virus) may need to be subsidised in the future to make development more feasible.[2]
- For vaccine innovation to be valued once it comes to market, a policy environment is needed that recognises innovation across the product lifecycle and ecosystem.
- We need a working definition of vaccine innovation that not only addresses breakthrough discoveries—hard won gains, but also places value on incremental innovation—gains that allow us to do more and do things better than before.

P26 | INNOVATION IN VACCINES



Innovating organic, eco-friendly pest control has become more challenging over the decades. In the early days, gardeners were happy to receive any newly discovered insect that would help them keep infestations under control.

When traditional garden pests disappeared, the production of flowers and fruits flourished. Yet that success was accompanied by new pests emerging, providing new challenges for the growing garden and vineyard ecosystem.

New, improved, pest controls were needed. They should still be eco-friendly, but safety requirements became very strict.

So, the road of innovation became longer and more challenging. Some people joked that the old 'Innovation Valley', had become a 'Valley of Death' since the risk of rejecting a newly developed ladybird breed had increased too much. This is comparable to the challenges in vaccine innovation.

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MSD'S FOOTPRINT IN EUROPE:

Vaccines are one of the greatest public health success stories in history.[1] MSD is a proud contributor to that story with over 125 years of experience in the discovery and development of innovative healthcare products.[2]

100 YEAR HISTORY of INNOVATION

DISCOVERING

DEVELOPING

DELIVERING

1890

HENRY K. MULFORD

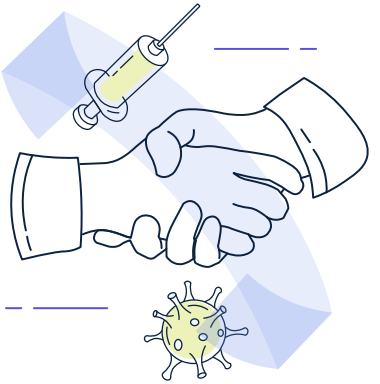
Pioneer of diphtheria antitoxin smallpox vaccine[3]

1960

DR. MAURICE HILLEMAN

*Developed **40+ vaccines** (e.g. MMR & HPV)*[4]

NOW

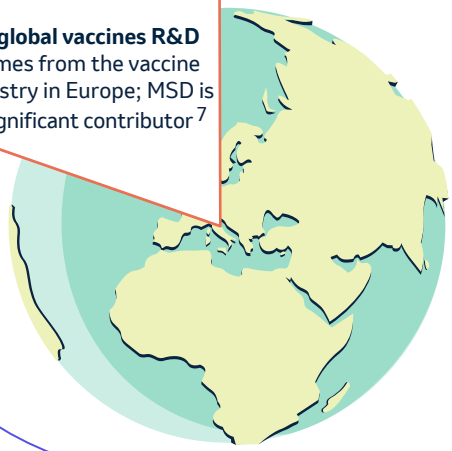


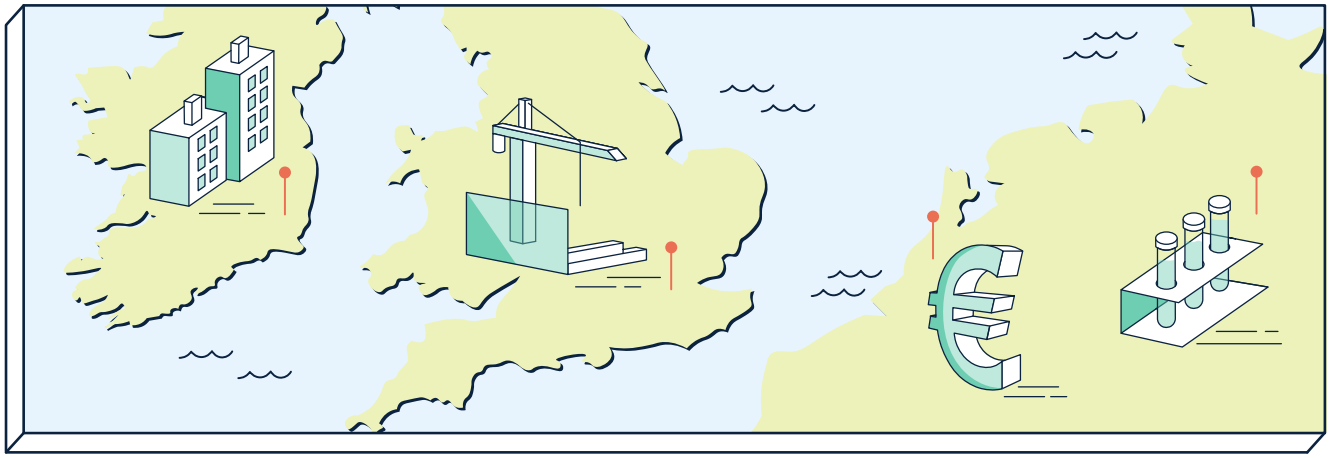
MSD has a long-lasting contribution to public private partnerships to bring innovative vaccines in response to unmet medical needs, such as Ebola [5]

MSD IS AT THE FOREFRONT OF DISCOVERING NOVEL SOLUTIONS IN THE PREVENTION OF INFECTIOUS DISEASES GLOBALLY [6]

80%

of global vaccines R&D comes from the vaccine industry in Europe; MSD is a significant contributor [7]





CARLOW, IRELAND [8]
€220 million investment to build MSD's 1st vaccine manufacturing site in Europe of 200,000 sq ft

LONDON, ENGLAND [9]
€1.32 billion investment to set-up a new discovery research center site of 220,000 sq ft

HAARLEM, NETHERLANDS[10]
Part of the MSD program to improve facilities which invests €16 billion throughout the world

BURGWEDEL, GERMANY [11]
Expansion to produce ebola vaccine

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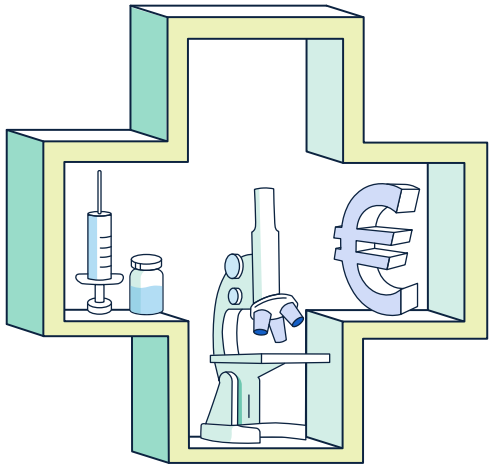
UNLOCKING THE FULL POTENTIAL OF VACCINATION

Currently, **MSD is supplying vaccines at the highest-ever annual production rate**, having distributed 180 million doses, almost double the number since 2010.[1]

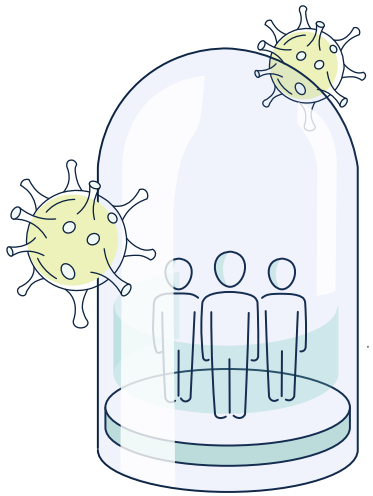
HEALTHY & SUSTAINABLE VACCINE ECOSYSTEMS[2]



Support a healthy vaccine market that is continuously investing in innovative vaccines

Ensure sustainable innovation that makes vaccines accessible and affordable to all through the utilization of harmonized and efficient regulatory systems

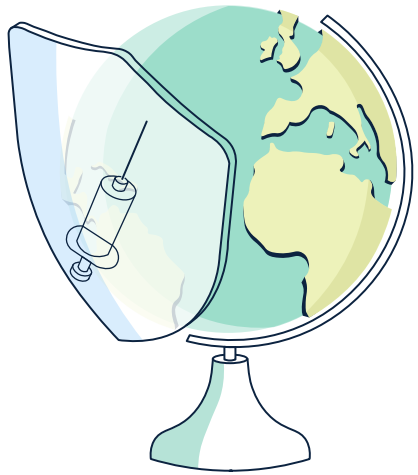
RESILIENT IMMUNISATION SYSTEMS[3]



Ensure optimal and collective population protection through high vaccination coverage rates

Utilize digital tools and new technologies to support vaccine development, services, awareness, and monitoring [4]

VACCINES AS KEY PARTNERS AGAINST GLOBAL THREATS[5]



Leverage the use of vaccines in the fight against cancers, antimicrobial resistance, and emerging infectious diseases [6,7,8]

Relieve the strain on healthcare systems attributable to non-communicable diseases which represent a substantial burden [9]

Protect social capital and contribute to the Sustainable Development Goals (SDGs) [10, 11]

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