



Vaccine implementation varies between countries, but, generally, those with similar levels of income have comparable immunization systems. One exception is Japan. Japan has a level of wealth similar to countries in Western Europe, Australia and the US, but has an immunization program that is considerably less progressive. Most industrialized countries strongly value immunization as a cost-effective means to prevent disease and save on treatment costs, and as a means to preserve economic development. Immunization is also valued by some industrialized countries as an asset against bioterrorism.

Like many other complex and capital-intensive industries, the vaccine industry is highly consolidated. The vaccine market is dominated by a few large vaccine suppliers in industrialized countries. The costs associated with developing new vaccines require that vaccines be sold on the global market in order to be able to recoup R&D investments. Furthermore, almost all countries import at least some vaccines because not all national suppliers produce every antigen available.

Vaccine research and development has largely been restricted to the few vaccine-producing countries. More than two thirds of new vaccines developed in the past 25 years have been developed in the US⁵².

2.1 The global vaccine market

The vaccine market represented about 3% of the pharmaceutical market, at about \$28 billion in 2010⁵³. Five manufacturers (Merck & Co, GlaxoSmithKline, Sanofi Pasteur, Pfizer, and Novartis) account for the majority of the market (79.4% in 2010) (See **Figure 39**)⁵⁴.

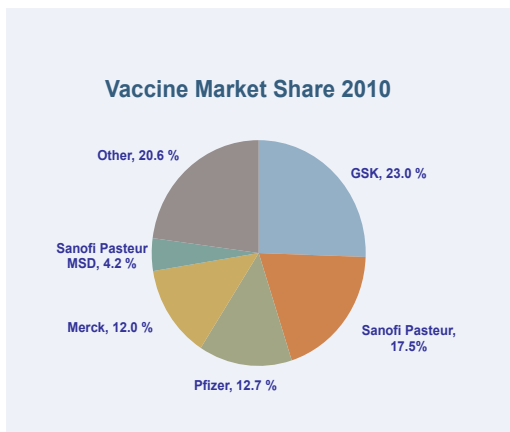


FIGURE 39. THE DOMINANT SUPPLIERS IN THE GLOBAL VACCINE MARKET 2010

The pediatric vaccine market accounted for about 52% of the total vaccine market in 2009. Sales of influenza vaccines, including H1N1 vaccine, were approximately \$5 billion in 2010, accounting for about 18% of the vaccine market.

Growth in the market is expected to continue at around 10% compound annual growth rate (CAR) over the next five years. The pediatric market is expected to grow slightly faster than the adult vaccine market, at 11% versus 8.2% (See **Figure 40**)⁵⁵. By comparison, the pharmaceutical market grew by 4 – 6% in 2010 and is expected to grow at 4 – 7% through 2013⁵⁶.

The growth in the vaccine market is driven by the sales of recently developed vaccines and by new vaccine markets. Several vaccines now generate more than \$1 billion in global

sales (See **Figure 41**)⁵⁷ and the Global Alliance for Vaccines and Immunization (GAVI Alliance) is expected to expend more than \$1 billion per year on vaccines.

New vaccines under development are projected to add to the growth of the current market.

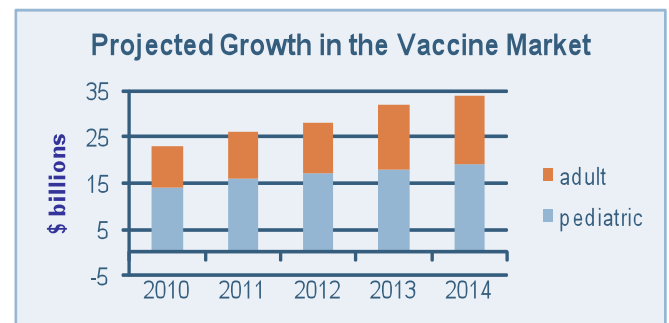


FIGURE 40. PROJECTED GROWTH OF THE VACCINE MARKET BY ADULT AND PEDIATRIC SEGMENTS

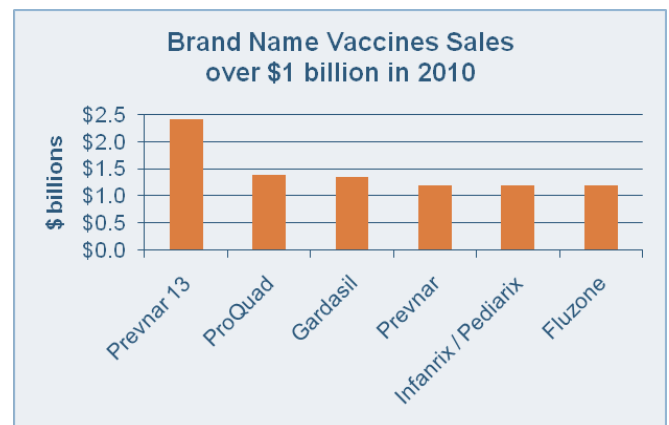


FIGURE 41. BRAND NAME VACCINES THAT GENERATED MORE THAN \$1 BILLION IN SALES IN 2010.

⁵²Douglas RG, Sadoff J, Samant V. The vaccine industry. pp 37. In Vaccines 5th edition, S Plotkin, W Orenstein and P Offit, Eds, Saunders Elsevier, China, 2008.

⁵³Knol. Global Vaccine market 2010. Top vaccine companies and blockbuster vaccines.

<http://knol.google.com/k/krishan-maggon/global-vaccine-market-2010/3fy5eowy8suq3/152#>

⁵⁴Hiller A. Vaccines continue to bolster pharma market. PharmPro. December 2, 2010.

<http://www.pharmpro.com/articles/2010/12/business-Vaccines-Continue-to-Bolster-Pharma-Market/>

⁵⁵Hiller A. Vaccines continue to bolster pharma market. PharmPro. December 2, 2010.

<http://www.pharmpro.com/articles/2010/12/business-Vaccines-Continue-to-Bolster-Pharma-Market/>

⁵⁶Pharmaceutical Drug Manufacturers. Pharmaceutical market trends 2010.

<http://www.pharmaceutical-drug-manufacturers.com/articles/pharmaceutical-market-trends-2010.html>

⁵⁷Knol. Global Vaccine market 2010. Top vaccine companies and blockbuster vaccines.

<http://knol.google.com/k/krishan-maggon/global-vaccine-market-2010/3fy5eowy8suq3/152#>

2.2 Vaccine development

The development process for vaccines is unique. Vaccine development is highly capital intensive and risky. Given the importance of safety with biologics, the vaccine industry is highly regulated. Vaccine development proceeds in an iterative fashion. Less than one-tenth of vaccine candidates achieve licensure. The high failure rate is due to the unpredictability of the biological organisms needed to produce vaccines, and to the uncertainty of how the human immune system will process and react to the vaccine antigen. Some vaccine candidates may produce appropriate levels of immune response, but induce important adverse reactions. Other vaccine candidates may be safe, but ineffective at preventing diseases. With the current tendency to combine several antigens into a single vaccine, the challenges associated with developing safe and effective vaccines are even greater.

Research to discover new vaccine antigens and novel approaches to immunization usually takes several years, and costs tens of millions of dollars. Once a discovery is made, several developments must be undertaken to reach the licensing stage. Those developments include (See **Figure 42**):

process development, to produce an economically viable vaccine, consistently, in a manner that satisfies regulators; and,

clinical development, to demonstrate the safety and measure the protective effect of the vaccine in humans;

assay development, to develop the appropriate tests to ascertain the purity, potency and stability of the vaccine under development.

Process development is further divided into bulk manufacturing and product finishing. Bulk manufacturing involves the culture of live organisms, followed by separation and purification of the desired antigen. Finishing involves the formulation with either adjuvant and / or stabilizer and the filling of vials or syringes.

Clinical development, as described earlier, involves the iterative process of testing a vaccine candidate in a progressively larger number of human subjects.

Assay development is required because the vaccine candidate will be novel and will, therefore, require specific tests to identify it and characterize the product to the satisfaction of the regulators.

The development of each of these processes is very lengthy, requiring on average 10–15 years. The total development costs can reach close to \$US1 billion (See **Figure 43**)⁵⁸.

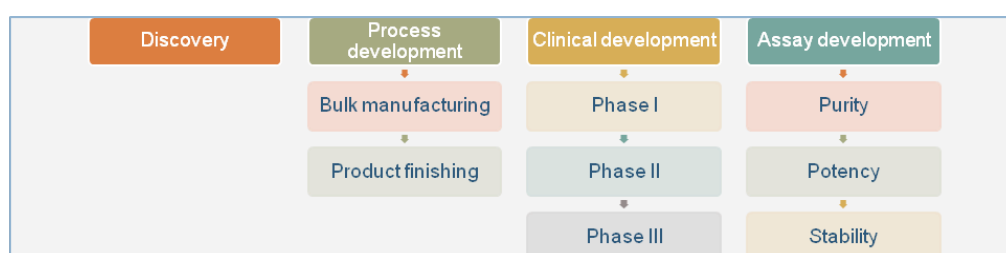


FIGURE 42. DIFFERENT TYPES OF DEVELOPMENT NECESSARY TO REACH THE VACCINE LICENSING STAGE

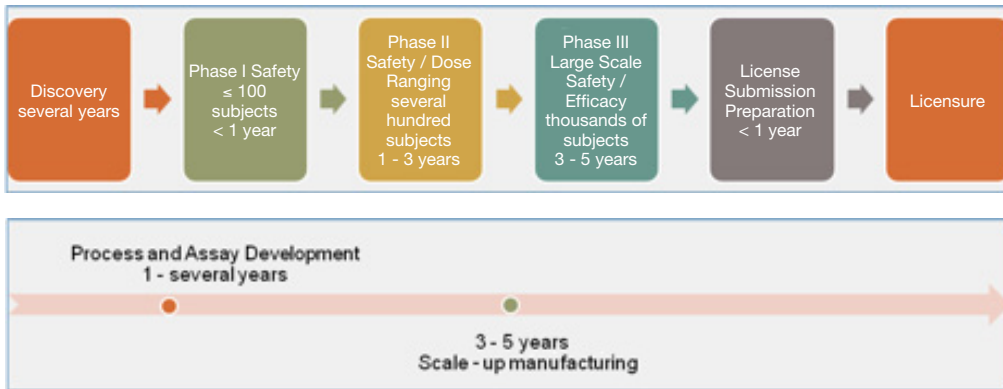


FIGURE 43. VACCINE DEVELOPMENT PROCESS OVER A PERIOD OF UP TO 15 YEARS AT A COST OF UP TO \$1 BILLION

2.2.1 Clinical development

After being thoroughly tested in an animal model, vaccine candidates that are found to be safe and induce immunity can advance to testing in humans. To license a vaccine, three phases of clinical testing must be completed in healthy subjects (See Figure 44)⁵⁹:

Phase I – early safety and immunogenicity trials that involve ≤100 subjects and can be completed in under one year;

Phase II – safety, dose ranging, and immunogenicity trials that involve several hundred subjects and that take 1–3 years to complete ; and,

Phase III – large-scale safety and efficacy trials involving thousands of subjects and requiring 3–5 years to complete.



Image 3. Vaccine manufacturing in an aseptic environment

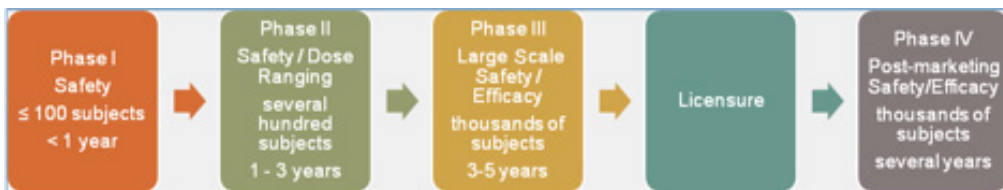


FIGURE 44. THE FOUR PHASES OF CLINICAL DEVELOPMENT OF VACCINES

⁵⁸Bentley W. Research and the University of Maryland. Center for Bioprocess Innovation. <http://www.umresearch.umd.edu/VPRPubfiles/Center%20for%20Bioprocess%20Innovation%201.29.08.pdf>

⁵⁹Douglas RG, Sadoff J, Samant V. The vaccine industry. pp 37. In Vaccines 5th edition, S Plotkin, W Orenstein and P Offit, Eds, Saunders Elsevier, China, 2008.



Clinical testing costs hundreds of millions of dollars to complete. In the first three phases of clinical testing regulators may require data from 90,000 subjects or more to affirm safety and efficacy.

These phases proceed in a stepwise fashion. Only vaccine candidates that are determined to be safe and capable of inducing an immune response advance to the next phase (See **Figure 15 - Section 1.4**). Vaccines under development are compared to a placebo control group to ensure that their observed effectiveness and safety are not random.

A regulator may also require further clinical testing after a vaccine license has been granted. Clinical studies after licensure are Phase IV post-marketing studies. These typically assess safety and or efficacy in very large populations. Because of their size, these studies may detect very rare vaccine-associated events that may have gone undetected in Phase III testing.

Clinical testing costs hundreds of millions of dollars to complete. In the first three phases of clinical testing, regulators may require data from 90,000 subjects or more to affirm safety and efficacy⁶⁰. These subjects may be recruited from multiple trial centers on all continents.

All clinical data collected from clinical testing must be thoroughly analyzed and submitted to regulators for their review.

⁶⁰GlaxoSmithKline. European Medicines Agency maintains position on the continued use of Rotarix™ (rotavirus vaccine). Media Center, May 21, 2010. http://www.gsk.com/media/pressreleases/2010/2010_pressrelease_10048.htm

2.3 Vaccine manufacturing

The manufacture of vaccines is achieved from the propagation of living organisms. Some of these may be dangerous human pathogens. Therefore, the manufacture of vaccines is conducted in a highly regulated and controlled environment. All vaccine manufacturers are subject to national and international regulatory control and must comply with specifications for Good Manufacturing Practices (GMP). These requirements vary between countries, but the fundamentals are common:

- ensure that products are safe for use in humans; and,
- ensure that the identity, strength, quality and purity of products consistently meet regulatory specifications.

Manufacturing is conducted in an aseptic environment and closely monitored by quality control measures. Vaccines also require a strict cold chain to maintain their stability. Under most circumstances vaccines are shipped and stored under refrigeration.

The actual production processes vary somewhat for different types of vaccines. Some components of the manufacturing process are specific to either viral or bacterial vaccine production. In all cases, biologicals are inherently variable. Manufacturers must, therefore, carefully characterize and store the master seed viruses or bacteria used to start each production run. This helps to ensure the consistency of the end product.

In general, the production of vaccines entails four basic steps (See **Figure 45**):

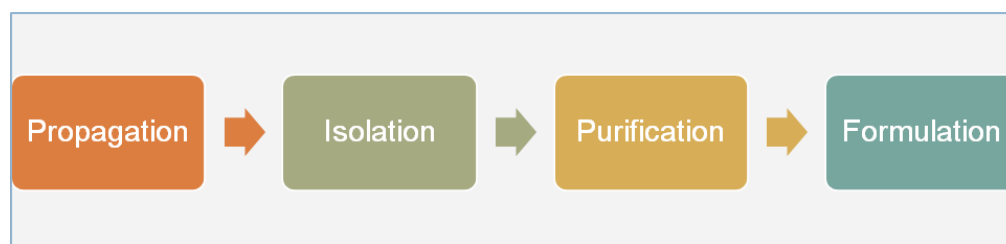


FIGURE 45. THE FOUR STEPS IN THE PRODUCTION OF VACCINES

Propagation entails the multiplication (or amplification) of the living organism used in the vaccine;

Isolation entails the separation of the living organism from the cells or growth media used in the propagation step;

Purification removes all materials that may be adhering to the isolated organisms, or selectively separates the portion of the living organism to be used in the vaccine;

Formulation involves the mixing of the purified product in solutions to obtain a desired concentration. It may also include the addition of preservatives to some vaccines, to ensure the sterility of the product over a longer period of time, or to prevent cross-contamination during dose extraction from vials.

At the end of the manufacturing process, vaccines are typically filled in vials or syringes and packaged for shipping to healthcare providers. (See **Figure 46**).

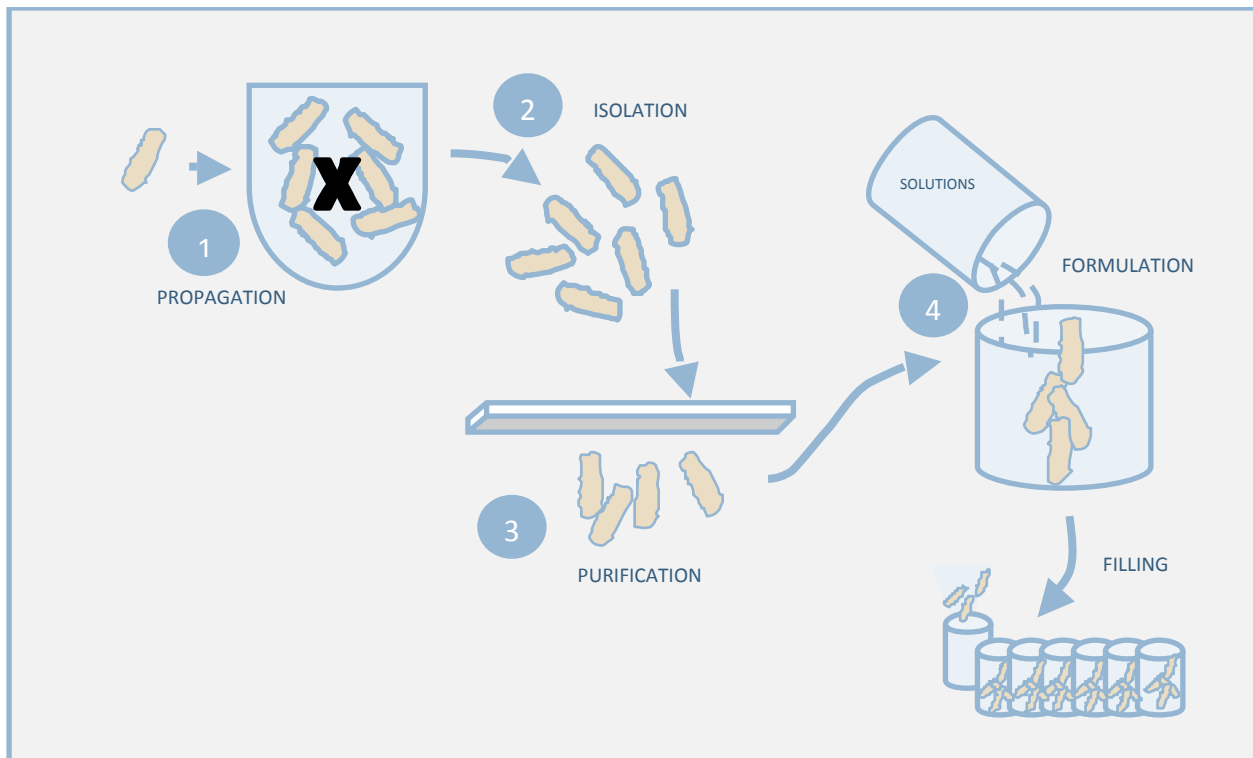


FIGURE 46. PROCESSES INVOLVED AT EACH OF THE FOUR STEPS OF VACCINE MANUFACTURING

VIRAL VACCINES – Because viruses only grow within living cells, viruses for vaccines are propagated in cells (e.g. in chicken eggs) or in continuous cell lines (e.g. Vero cells). Once the virus has been propagated, it must then be isolated from the cells and the cell-culture medium. This may be achieved by several techniques including chemical lyses of the cell, centrifugation and filtration, or homogenization.

The next step, purifying the virus, may likewise involve multiple techniques of centrifugation, ultra-filtration, chromatography, or chemical purification. At this stage, viruses may also be chemically inactivated for killed vaccine preparations.

Then the viral preparation is formulated by mixing it with the constituents that allow each dose to be safely delivered in the right concentration. This is the point where the product may also be combined with other antigens (e.g. measles–mumps–rubella vaccine). The formulated product is filled in vials or syringes. Some vaccines are freeze-dried (lyophilized) at this stage, to prolong their shelf-life.

BACTERIAL VACCINES – Bacteria do not require living cells to propagate and are instead grown in bioreactors containing specific culture media. After propagation, isolation may be conducted by centrifugation or specific polysaccharide extraction techniques. Purification is specific to the antigen, but may include chemical precipitation or fractionation, or ultra-filtration and chromatography steps. At this stage, carrier proteins may be conjugated to some polysaccharide vaccines and the conjugate vaccine is then purified by various filtration or chromatography techniques. The purified products are then formulated and at this stage may be combined with several other antigens. Some polysaccharide vaccines contain several types of polysaccharide (e.g. pneumococcal polysaccharide vaccine contains 23 different types of polysaccharide), and some bacterial vaccines are combined with other bacterial and / or viral antigens (e.g. diphtheria-tetanus-pertussis-*Haemophilus influenzae* type b-Hepatitis B or DTP-Hib-HepB).

2.3.1 Cost trends in vaccine development and manufacturing

Vaccine manufacturing has evolved dramatically over the last half century (See **Image 4**, **Image 5**, **Image 6**)⁶¹. New techniques for the manufacture and testing of vaccines have transformed the manufacturing environment. New vaccines, like multivalent conjugate vaccines, are considerably more complex to manufacture than traditional inactivated whole-cell ones. The increased sophistication of the manufacturing process means that the cost of manufacturing has significantly increased in the last few decades.

In addition, the regulatory environment has evolved to a point where as many as 500 quality control tests may be conducted in the manufacture of a single vaccine⁶².



Image 4. Vaccine manufacturing in the 1950s

Vaccine manufacture is highly capital intensive. A manufacturing facility alone will cost up to €500 million (about ¥52.6 billion at September 2011)⁶³. As manufacturing costs are largely fixed, large manufacturers may produce vaccines in massive amounts (e.g. hundreds of millions of doses every year) to achieve economies of scale in production.



Image 5. Vaccine manufacturing in the 1970s

But scaling vaccine production requires a significant investment in time. Even for relatively simple processes, such as vaccine packaging, up to two years may be required to install and validate new packaging machinery. Building a new manufacturing facility takes on average five years to complete and validate with regulatory authorities (See **Figure 47**).



Image 6. Vaccine manufacturing in the 2000s

⁶¹Rutty CJ, Barreto L, Van Exan R, Gilchrist S. Conquering the Crippler, Canada and the Eradication of Polio. *Can J Pub Health* 2005; 96 (2) : 12-24.

⁶²GlaxoSmithKline. *Global Vaccines Public Policy Issues. Addressing developing world production – technology transfer.* December 2009.

<http://www.gsk.com/policies/Technology-Transfer-Vaccines.pdf>

⁶³Pharmaceutical Networking. *GlaxoSmithKline – New vaccine manufacturing plant – St-Amand-les-Eaux, France.* 2010.

<http://www.pharmaceutical-networking.com/glaxosmithkline-new-vaccine-manufacturing-plant-st-amand-les-eaux-france/>

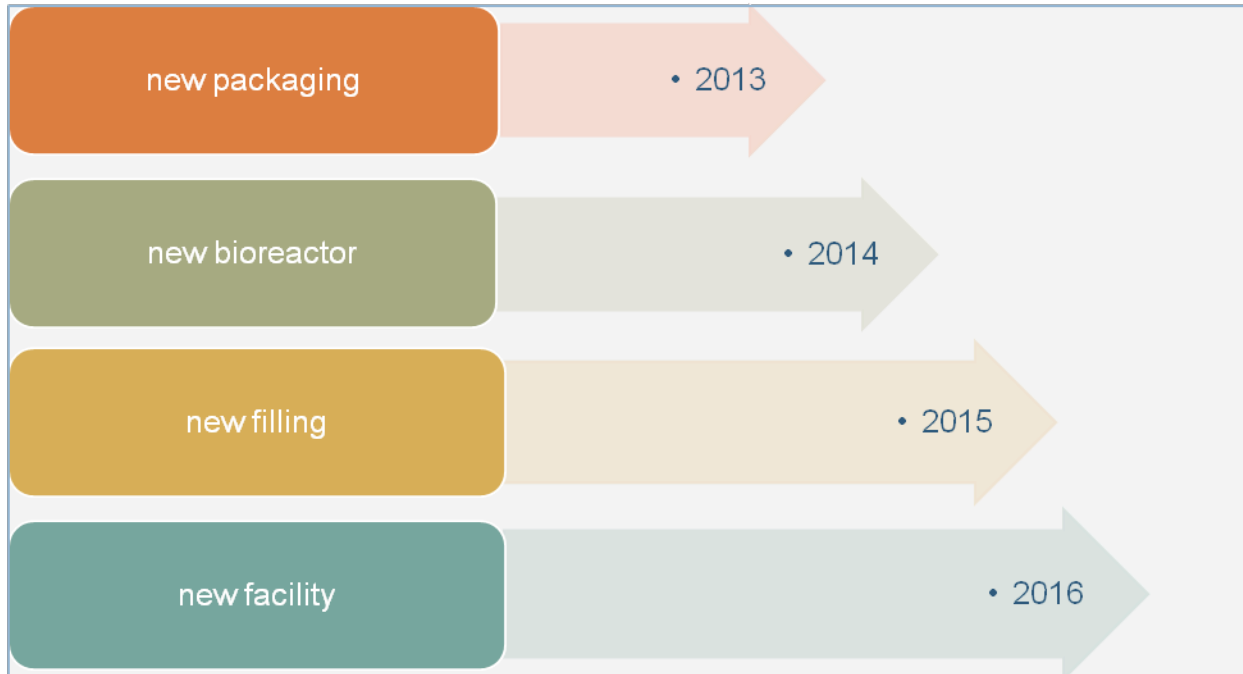


FIGURE 47. TYPICAL TIMELINES TO INSTALL AND VALIDATE NEW INDUSTRIAL CAPACITY FOR DECISIONS MADE IN 2011

2.4 Vaccine registration and approval

Because of their biological nature and that they are largely administered to healthy individuals, the entire vaccine development and manufacturing process is regulated. Before vaccines are licensed, the three successive phases of clinical development must be approved by a national regulatory authority and may only proceed from one phase to the next upon approval of the national regulator. When a Phase III trial has been completed, the manufacturer must apply for a license to sell the vaccine. The license application review is so thorough and complete that it takes between one and two years to complete (See **Figure 48**). The regulator has the authority to refuse or withdraw a product license if the manufacturer is not compliant with current regulations.

After vaccines are licensed, manufacturing is strictly controlled by regulators who test and have authority over the release of each production batch of vaccine. Regulators test for:

- safety;
- identity;

- purity;
- potency; and,
- sterility.

Regulators also monitor the consistency of product from one production batch to the next (See **Figure 49**). Inactivation and attenuation are also checked to ensure that the product does not expose to risk. Regulators will subject the product to multiple tests, with redundant checks, to ensure that the testing itself is yielding correct results.

General **safety testing** is performed by injection of the final container product in the abdomen (intraperitoneal) of mice or guinea pigs.

Identity testing is specific to the nature of the vaccine, but can include neutralization of a live-attenuated viral vaccine with an antiserum.

Purity testing must demonstrate that the vaccine is free of

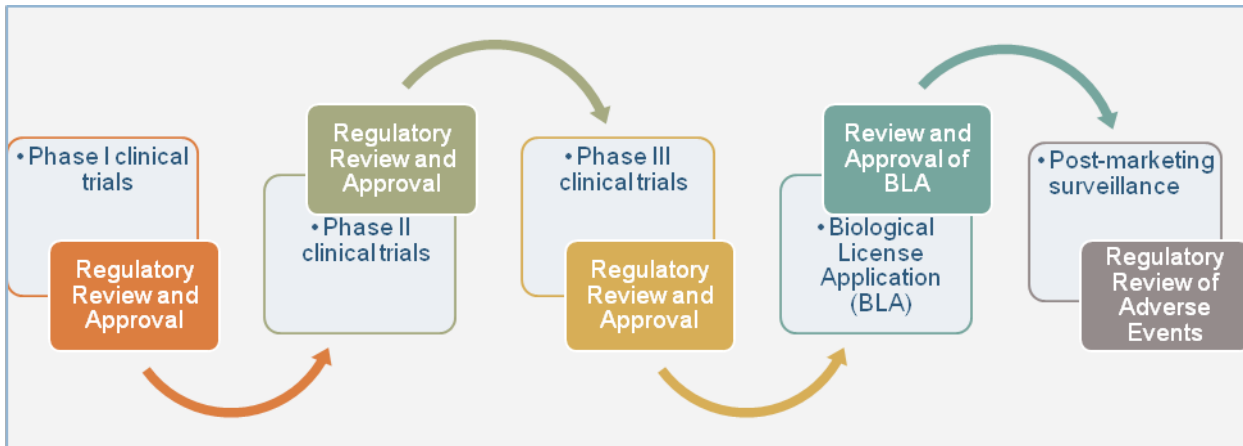


FIGURE 48. REGULATORY PROCESS FOR VACCINES UNDER DEVELOPMENT

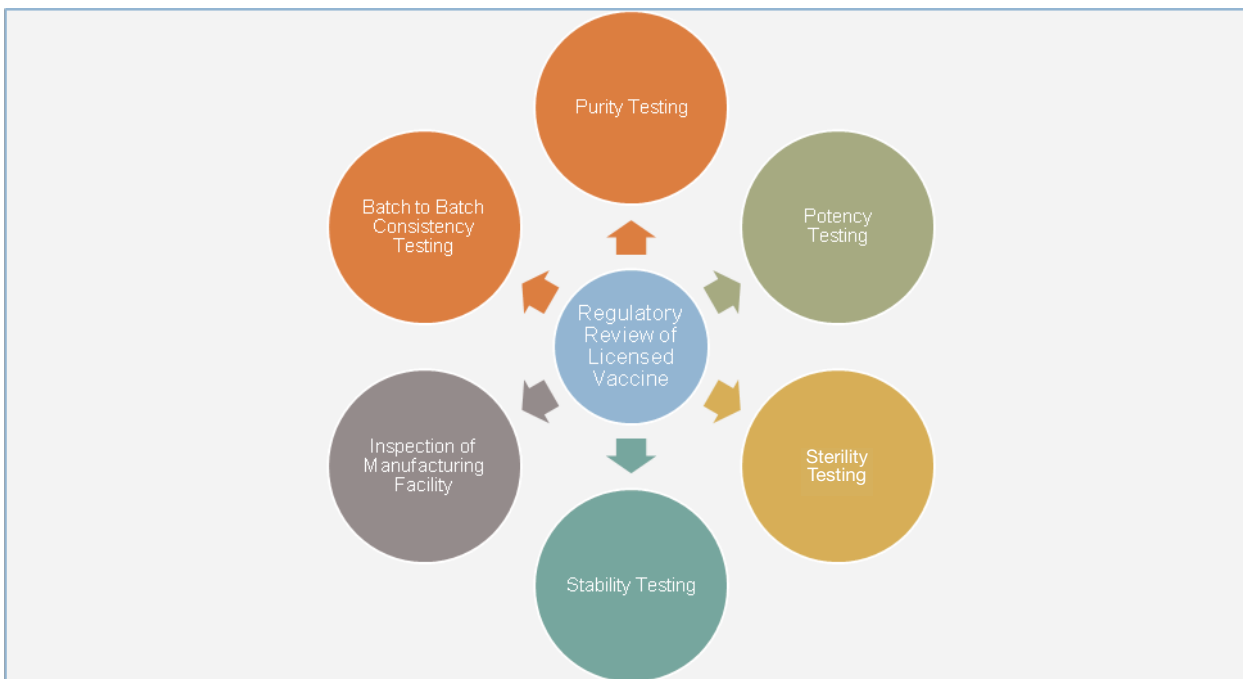


FIGURE 49. REGULATORY TESTING OF LICENSED VACCINES

extraneous materials, including moisture and pyrogenic substances. The products used in the manufacture of the vaccine must also meet standards of purity.

Potency testing involves demonstrating that the vaccine confers protective immunity. The tests are specific to the vaccines being tested, but often involve virulent challenge in an animal model, or virus titration, or other quantification of an antigen. It is also necessary to demonstrate that the potency of the individual components of a combination vaccine are preserved when combined (because some antigens can reduce the immune response to others).

Sterility is tested on both bulk and finished vaccines.

Regulators require viral seeds and cell substrates used in vaccine production to be tested to ensure that they do not introduce contaminants. Cell substrates are well characterized to ensure that they are as safe as possible.

Regulators also regularly inspect manufacturing facilities to ensure compliance with current Good Manufacturing Processes (GMPs). GMPs are a set of guidelines that ensure consistency in quality of production.

Regulators control the labels on final containers and accompanying product inserts. Labeling and package inserts must be supported by scientific data and the regulator reviews the language to ensure that it is not misleading, or false. Any changes will usually require the regulator's approval first. Regulators may also regulate the advertising of products and monitor advertising for misleading claims. Claims for products must be balanced with information about their safety.

In order to produce safe and efficacious vaccines and to comply with regulations, vaccine manufacturers carry out extensive quality assurance and quality testing during the manufacture of vaccines. Up to 500 quality control tests may be conducted in the manufacture of a single vaccine⁶⁴. Quality testing may account for as much as 70% of the time to manufacture⁶⁵.

How vaccines are regulated in the US

The US Biologics Control Act, enacted in 1902, noted that testing the purity of a final product was insufficient to ensure quality. It required that manufacturing facilities be inspected. In 1944, the Public Health Services Act empowered the US government to license both biologicals and biological manufacturing facilities. It became illegal for biologicals to be sold without a license.

Vaccines are regulated by the Food and Drug Administration's Center for Biologics Evaluation and Research (CBER). Vaccine developers must apply to CBER for permission to both develop and sell vaccines (See **Figure 50**).

Prior to licensure, vaccines are regulated by the Investigational New Drug (IND) Regulations. The vaccine developer (sponsor) must apply for permission to conduct a clinical study. The application must include information about:

- the composition of the investigational new product;
- the source of the investigational new product;
- the method of manufacture of the investigational new product; and,
- the methods used to determine the safety, purity, and potency of the investigational new product.

The sponsor must also provide a summary of all laboratory and animal pre-clinical testing. A description of the proposed clinical trial and the qualifications of the investigators are also required (See **Figure 51**). The endpoints for vaccine licensure include vaccine safety and efficacy, but safety must be demonstrated at each phase of the study.

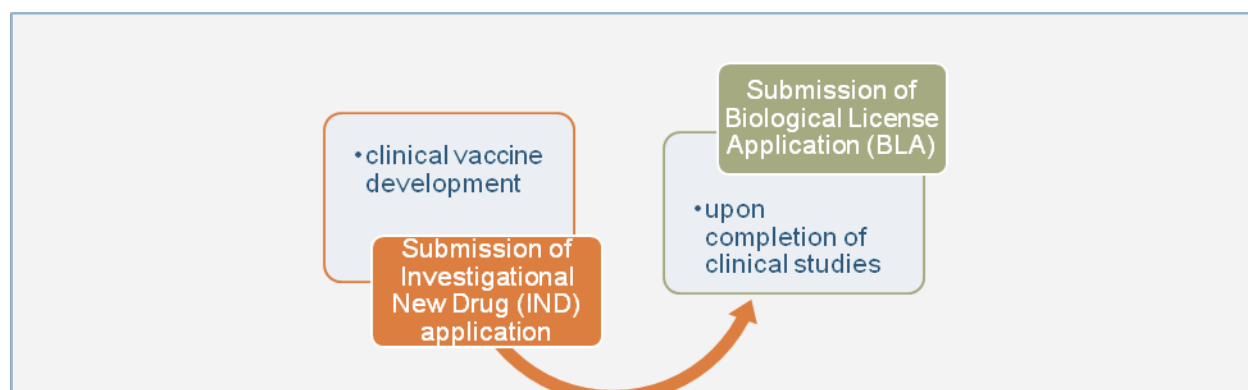


FIGURE 50. PERMISSIONS THAT MUST BE SOUGHT FROM THE FDA'S CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER) FOR THE DEVELOPMENT AND SALES OF VACCINES

⁶⁴GlaxoSmithKline. Global Vaccines Public Policy Issues. Addressing developing world production – technology transfer. December 2009. <http://www.gsk.com/policies/Technology-Transfer-Vaccines.pdf>

⁶⁵Cutcliffe N. 2010. Pathway to access: Manufacturing, supply, and procurement systems. In: Building on the legacy of vaccines in Canada: value, opportunities, and challenges. BIOTECH Canada. http://www.biotech.ca/uploads/vic/vaccines_7_2010.pdf



FIGURE 51. REQUIREMENTS FOR AN INVESTIGATIONAL NEW DRUG APPLICATION

When studies are near completion and show promise of safety and efficacy, the sponsor may submit a Biologics License Application (BLA) to the CBER Office of Vaccines Research and Review (OVRR). The application must submit evidence of compliance with standards for all of the requirements shown in **Table 14**. In addition, the application must include a description of:

- the manufacturing process;
- data on stability;
- product samples and lot test results;
- samples labels, enclosures and containers;
- address of locations of manufacture; and,
- an environmental assessment.

Evidence of Compliance	Required submissions
Organization and personnel	Manufacturing process
Buildings and facilities	Stability data
Equipment	Lot testing results
Control of components, containers and closures	Product samples
Production and process controls	Sample labels
Packaging and labeling controls	Enclosures and containers
Holding and distribution	Environmental assessment of manufacture
Laboratory controls	
Records to be maintained	

TABLE 14. REQUIREMENTS FOR A BIOLOGICS LICENSE APPLICATION (BLA) SUBMISSION

The BLA also includes a site inspection. This involves an in-depth review of:

- facilities;
- records;
- production processes;
- equipment;
- quality control methods; and,
- personnel.

Once a vaccine has been licensed, post-marketing regulation requires manufacturers to submit test samples and test results from each production lot. CBER must “release” or reject the lot based on the results submitted and/or its own testing. Manufacturers are inspected at least every two years (every year for influenza vaccine producers, since there is a new influenza formulation every year) for:

- process related issue (documentation of processes);
- quality related issues (reporting of out-of-specs, product release, training of personnel); and,
- facility and production related issues (heating, ventilation, air conditioning).

See **Figure 52**.

How vaccines are regulated in countries other than the US

Industrialized countries have similar regulatory agencies to the US FDA’s CBER. But each country’s requirements of vaccine manufacturers are slightly different. In addition, supra-national regulators, such as the European Union’s

Committee for Medicinal Products for Human Use (CHMP) at the European Medicines Agency (EMA), may also regulate vaccines.

In Europe, manufacturers can license vaccines either through a centralized procedure of the EMA, which allows for a single market authorization within EU member states, or they can alternatively license through their national regulatory authority. If they license through their national regulatory agency, licenses will be limited to the country where the license was issued.

Regulatory harmonization

Europe, the US and Japan, have sought to increase regulatory harmonization between countries through the International Conference on Harmonization (ICH) of drugs. Increasingly, national regulatory agencies are exchanging information. The EMA and US FDA, for instance, have confidentiality agreements that allow for the exchange of information on legal and regulatory issues, inspection reports, and post-marketing surveillance. The US FDA also has similar confidentiality agreements with the NRAs of Australia, Canada, France, Germany, Israel, Japan, Mexico, New Zealand, Ireland, Singapore, South Africa, Switzerland and the UK.



FIGURE 52. AREAS INSPECTED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER) AT VACCINE MANUFACTURING SITES

2.5 Vaccine funding

Routine immunization of children is considered one of the most cost-effective interventions in health. Governments have a vested interest in immunization because, in addition to protecting the individual, immunizations also protect the community from disease. Therefore, all governments recommend vaccines for public use as a cost-effective means to reduce the occurrence of diseases and their associated treatment or management costs.

Which vaccines a government recommends depend on several factors. For example:

- the epidemiology of a vaccine-preventable disease (i.e., how frequently it occurs, how many people it affects when it does occur);
- the severity of a disease (i.e., whether it can be fatal); and,
- the public's concern for the disease (e.g. meningitis).

How governments select which vaccines to use is also variable from country to country. Usually, governments rely on their National Technical Advisory Groups (NITAGs) to review the balance of benefits and risks associated with available (or soon to be available) vaccines. Their recommendations may be periodically reviewed and modified, if epidemiology changes (e.g., the eradication of smallpox) or safety issues arise.

Many countries are also mandated by their national laws to fund recommended vaccines, to ensure that the target population has sufficient access to recommended vaccines.

2.5.1 US Advisory Committee on Immunization Practices (ACIP)

The goals of the Advisory Committee on Immunization Practices (ACIP) are to provide advice that will reduce the incidence of disease and increase safe use of vaccines. The committee members are appointed by the Secretary of Health and Human Services (HHS) to provide guidance to HHS and the CDC on the control of vaccine-preventable diseases. The committee develops written recommendations on age of vaccination, number of doses, and contraindications. HHS and the CDC must endorse ACIP's recommendations for them to be enacted.

ACIP's recommendations are the basis for the annual CDC "childhood and adolescent" and "adult" immunization schedules. Vaccines recommended for routine administration in children are covered by the Vaccines for Children program (VFC). The VFC covers children up to 18 years of age who are eligible for Medicaid, uninsured, Native American, or underinsured. These vaccines are provided to private sector providers for vaccination of eligible children (about 45% of

birth cohort) (See **Figure 53**). Historically, HHS and the CDC have endorsed all ACIP recommendations.

In addition, the section 317 Federal Grant Program, appropriated annually by Congress, can be used to ensure coverage of both children and adults who would otherwise not have access to ACIP recommended vaccines, through the public or private sectors.

In the US, most private insurers cover ACIP recommended vaccines and about 55% of children have insurance coverage for immunization. Under the Affordable Healthcare Act, health insurers must now provide ACIP recommended vaccines at no out-of-pocket expense to the policyholder, and insurers cannot charge premiums for vaccines.

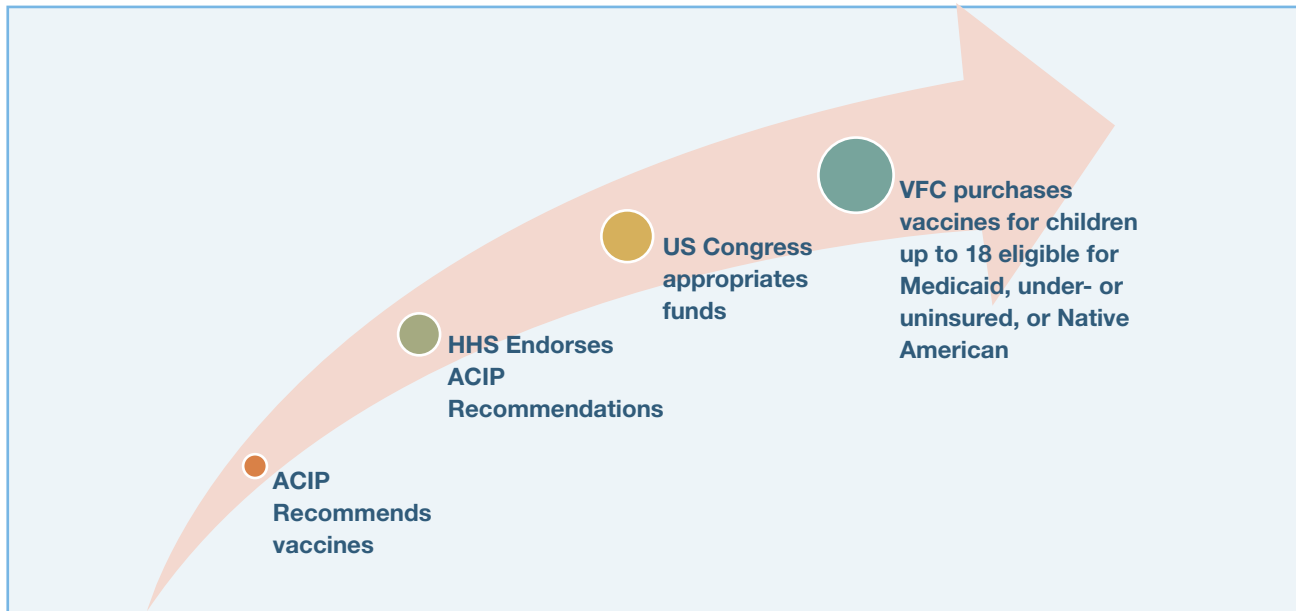


FIGURE 53. FUNDING FOR THE VACCINES FOR CHILDREN (VFC) PROGRAM IN THE US



The goals of the Advisory Committee on Immunization Practices (ACIP) are to provide advice that will reduce the incidence of disease and increase safe use of vaccines.

2.5.2 Australia

The decision to adopt a vaccine into the national immunization schedule includes advice from the Australian Technical Advisory Group on Immunisation (ATAGI) and an economic assessment of the candidate vaccine by the Pharmaceutical Benefits Advisory Committee (PBAC). A decision to adopt a vaccine incurs an obligation to fund the new vaccine. The decision is made by the Minister for Health and Ageing, or the government’s cabinet, if funding of more than AUS\$10 million is required (See **Figure 54**).

The National Immunisation Committee, in turn, is responsible for the implementation of the Immunise Australia Program. The Immunise Australia Program provides vaccines at no charge through the National Immunisation Program (NIP) Schedule, which currently includes 16 vaccines⁶⁶.

Funding is provided by the Australian government through a number of channels, including governments of States and Territories for the NIP, Medicare (the universal health insurance in Australia), the subsidy of immunization provided through private care, and to the Victorian Cytology Service for the administration of HPV (See **Figure 55**).

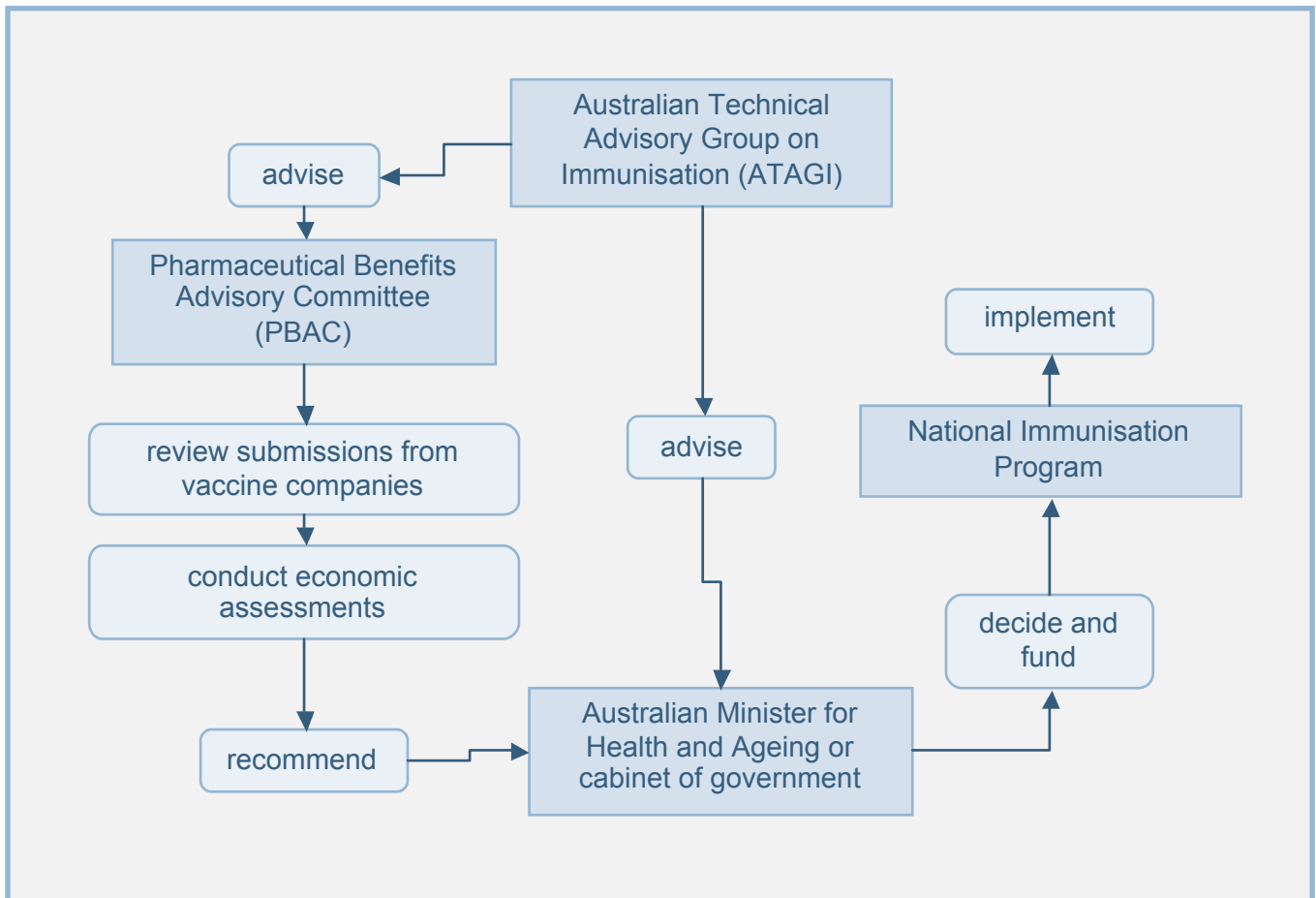


FIGURE 54. DECISION-MAKING PROCESS FOR VACCINE FUNDING IN AUSTRALIA

⁶⁶Australian Government. Department of Health and Ageing. Immunise Australia Program. About the Program. <http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/about-the-program>

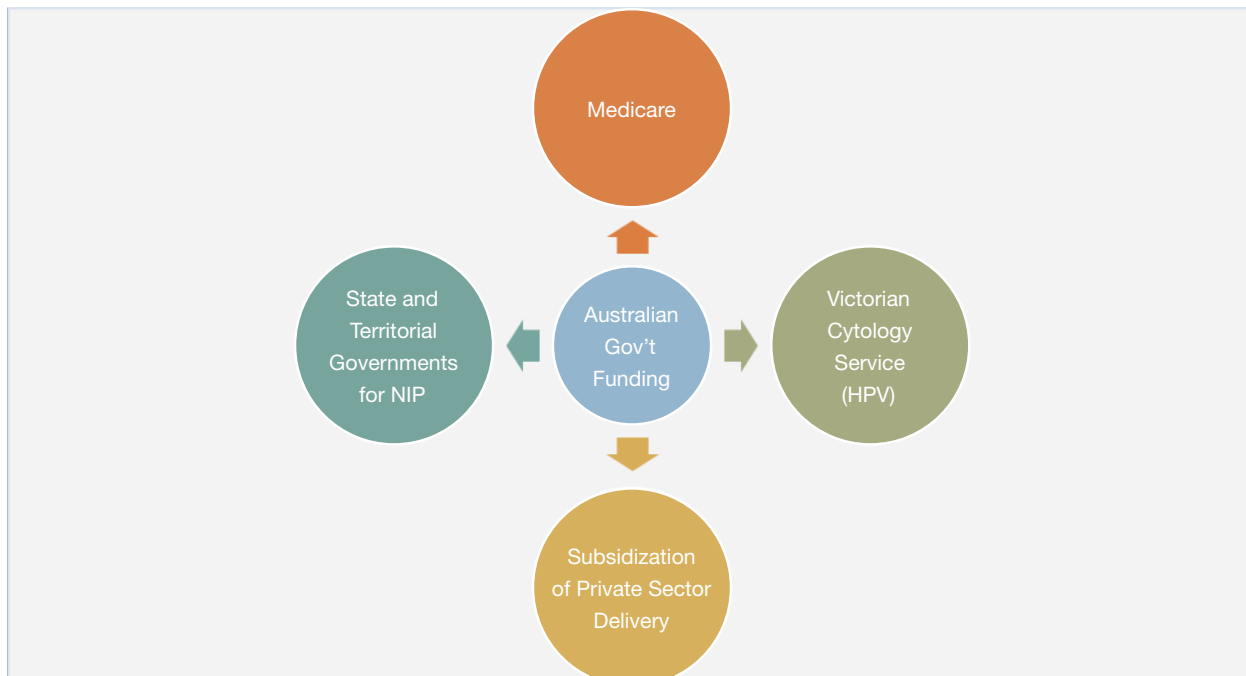


FIGURE 55. CHANNELS OF GOVERNMENT FUNDING FOR IMMUNIZATION IN AUSTRALIA

2.5.3 Other

Most industrialized countries have similar advisory groups (see **Table 13**, section 1.8) and formal funding processes for immunization. In Europe, the source of funding varies between countries. In Germany, the costs of immunization are covered mostly by statutory insurance provided by employers. In other European countries, such as the UK, the national government provides for all recommended vaccines to the public at no cost.

Most countries in the Asia-Pacific region rely on national expert immunization committees to recommend vaccines and most countries then provide recommended vaccines at no cost through public sector health outlets.

Many developing countries do not have functioning NITAGs and may rely heavily on the WHO for immunization policy and on donor funding for immunization. A full review of NITAGs is available in Vaccine at: http://www.sivacinitiative.org/download/Vaccine_Supplement_NITAGs_19042010.pdf.

