



Saving Lives with Affordable, Accessible Vaccines

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Millions of babies, children and adults around the world receive vaccinations that protect us against devastating diseases such as diphtheria, measles, polio and whooping cough, which are caused by pathogenic bacteria and viruses.

Unlike most medicines that cure or treat an existing disease or infection, vaccines prime our own immune systems to be ready and waiting for the invading microorganism, so that it can destroy the infecting pathogen before we become ill. Some of the world's most deadly and disabling diseases have now been all but eradicated in many countries through routine childhood vaccination. The number of cases of polio, for example, has decreased globally by 99% since 1988¹.

One in five infants receive no basic vaccinations

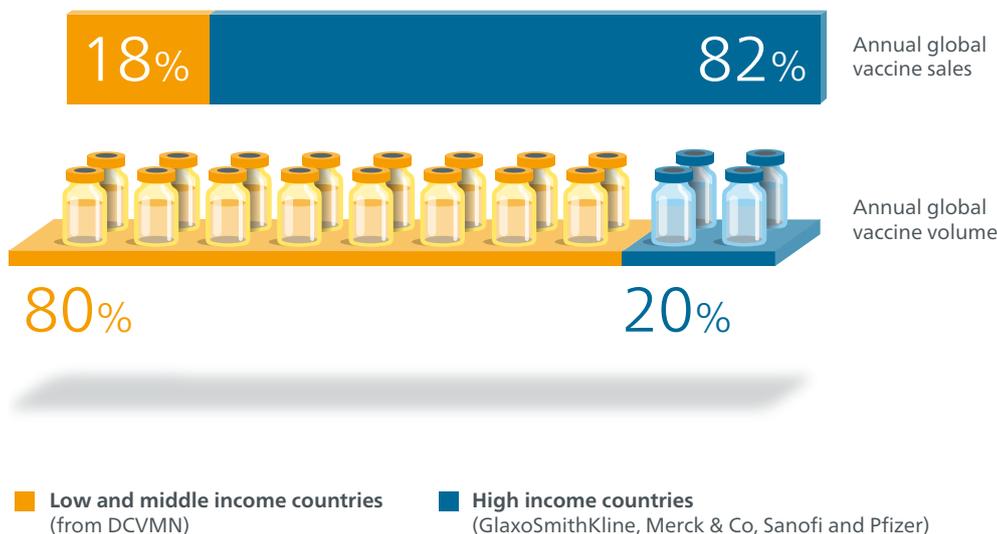
Today there are effective vaccines against 26 diseases, and a global pipeline of more than 120 new products in development includes 60 vaccines that are important to the developing world². The current scope of vaccination worldwide prevents about 2-3 million deaths annually³, but if we could increase the reach of vaccination programs even further then another 1.5 million lives could poten-

tially be saved every year³. UNICEF says that nearly one in five infants misses out on the basic vaccines they need to stay healthy and protected⁴. Getting life-saving vaccines to people in remote villages, ensuring an adequate transport cold chain, and establishing clinics and access to medical staff and equipment are all major challenges in poor or inaccessible regions.

Vaccine manufacturing divide

WHO projects that the global vaccine market could be worth \$100 billion by 2025⁵, but there is a huge volume and value divide between the high income countries of the developed world, and the low-to-middle income countries of the developing world. High-income countries account for about 82% of global vaccine sales value – primarily by the big four multinational vaccine manufacturers, GlaxoSmithKline, Merck & Co, Sanofi and Pfizer – but only for about 20% of annual global volume of vaccines used.

Vaccine Market Size



This top tier of manufacturers commands premium prices for vaccines developed using the latest technologies, which may offer benefits such as fewer side effects. These vaccines are marketed in high-income countries that can afford them. A second tier of high volume, lower cost manufacturers includes more than 50 producers in Latin America, the Middle East and Africa, and Asia Pacific, who are members of the Developing Countries Vaccine Manufacturers Network (DCVMN) alliance. The DCVMN producers aim to provide a sustainable supply of quality, affordable vaccines to the developing world.

Preventive medicine for the developing world

Agencies such as UNICEF and PAHO (Pan American Health Organization) purchase bulk vaccines from DVMN manufacturers on behalf of low- and middle-income countries, which in total account for only about 18% of annual global vaccine sales value, but about 80% of the number of doses sold globally every year. UNICEF supplies vaccines for 45% of the world's children aged under 5 years, and in 2016 secured 2.56 billion doses of vaccines for distribution in 95 countries⁵. The availability of low cost, safe and effective vaccines is critical for ensuring that populations in the poorest nations have access to life-saving preventive medicines.

So what is a vaccine?

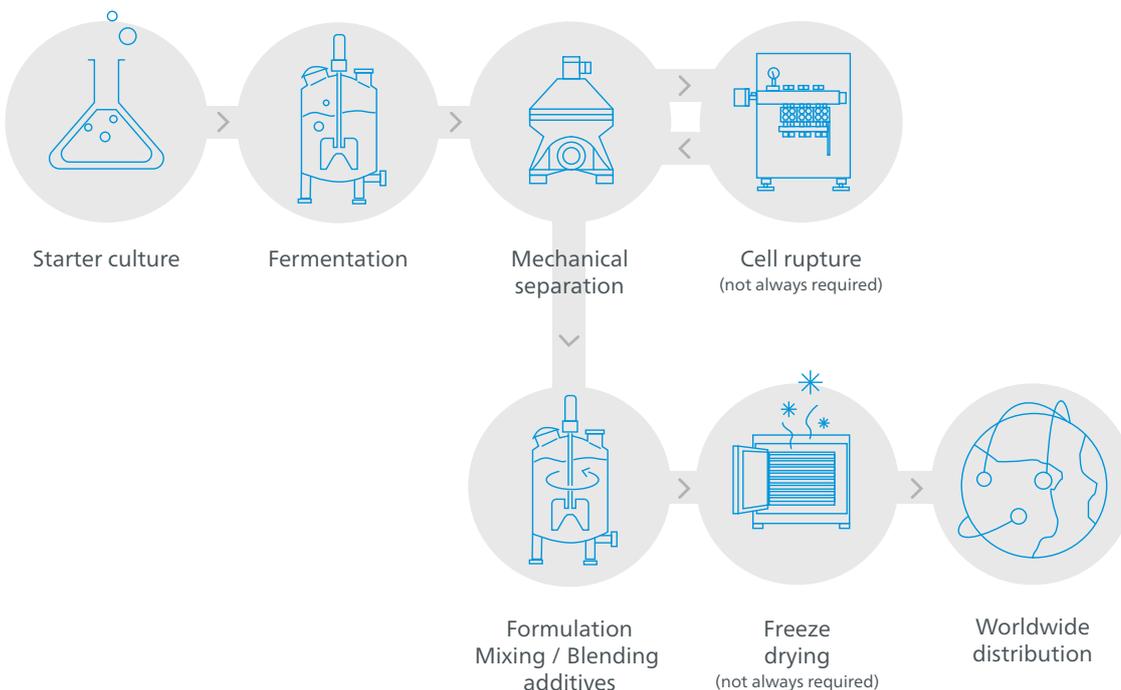
Vaccines are biological preparations that are themselves harmless. The vaccine mimics a part of the harmful bacterium or virus, and this triggers the body's immune system both to destroy what it

perceives as a foreign invader, and also to generate a long-lasting memory in readiness for a future attack. If the vaccinated individual encounters the live microorganism in the future their immune system unleashes a fast antibody response to kill the new infection before it can take hold.

A vaccine may comprise a weakened, but live form of the bacterium or virus, or an inactivated form of the microorganism, or even part of a bacterial toxin. The biological components of the vaccine are manufactured at industrial scale in bacterial, yeast or mammalian cells, which are grown in fermenters, bioreactors, or even hens eggs – still the most common approach for producing seasonal influenza vaccines.

Manufacturing a single batch of vaccine can take several months. The manufacturing process for any type of vaccine will involve multiple steps, including fermentation, separation and homogenization, together with mixing, formulation and potentially freeze drying. Each stage is subject to strict quality control procedures to ensure the consistency, safety and efficacy of every dose of vaccine that leaves the plant. Vaccine producers make huge capital investments in equipment, automation and process control technologies that must all pass inspection by regulatory agencies such as WHO. Additional clearance by national regulatory bodies such as FDA in the United States is needed before vaccines can be sold within individual countries.

Vaccine Production



Technologies for global vaccine manufacture

GEA is a global leader in the design and configuration of microbial and cell fermentation systems for the global vaccine industry. We supply stand-alone, modular technologies and also configure and install end-to-end vaccine plants. Our expertise spans cell culture systems, cell separators, homogenizers and filtration units, as well as formulation and freeze drying solutions. We can in addition supply and configure biological inactivation systems for waste and effluent treatment.

GEA works in close partnership with every vaccine customers. We support some of the biggest multinational vaccine companies with the design and installation of new plants, expansions and upgrades. We also partner with DCVMN manufacturers around the globe to support the safe, reliable production of low cost vaccines.

Partnering with manufacturers in emerging markets

GEA understands that producers in emerging markets may not have access to high quality, safe plants from their local industry. We partner with these manufacturers to supply key process, technology and engineering expertise in the field of vaccine production, and supply critical equipment for separation, freeze drying, fermentation or cell rupture. Our equipment ensures that manufacturers in developing nations can construct WHO-approved vaccine manufacturing facilities in their own countries, providing millions of doses of vaccines for local populations. Home-grown vaccine production reduces costs, transport and cold chain requirements, and carbon footprint.

GEA knowhow also helps DCVMN producers design and configure new greenfield vaccine facilities that are more efficient, profitable and sustainable, to secure environmentally sound, safe and affordable vaccine manufacture for future generations.

Hurdles to global access

Some vaccines are effective after just one dose, whereas other vaccines are only effective after two or three doses, which sometimes must be given weeks apart. This isn't a problem in developed nations with established healthcare infrastructures, and where there is no barrier to repeated healthcare access. However, the need for repeat dosing can be a real problem in isolated areas where people may have to walk miles with their children and babies to see doctors and other healthcare providers who might only visit sporadically.

Similarly, while some freeze-dried vaccines may be stable at ambient temperatures, other formulations require a complete transport cold chain, which is a huge problem remote regions. UNICEF – the world's biggest purchaser of vaccines – procured \$80 million worth of cold chain equipment in 2017⁶, and works with partners and governments to ensure effective cold chain.

Smart technologies for new formulations

GEA is also combining its knowhow in formulation technologies, freeze- and spray-drying work with the expertise of vaccine developers and manufacturers to help develop new processes for vaccine manufacture and formulation. Our spray-drying and freeze-drying technologies are helping innovative technology companies to develop temperature-stable vaccine preparations that have a long shelf-life without the need for refrigeration, and which can be transported more easily to challenging and remote areas.

1. <http://www.who.int/news-room/fact-sheets/detail/poliomyelitis>
2. http://www.who.int/influenza_vaccines_plan/resources/session_10_kaddar.pdf
3. <http://www.who.int/campaigns/immunization-week/2017/infographic/en/>
4. <http://www.unicef.org/immunization>
5. http://www.unicef.org/supply/index_vaccines.html
6. http://www.unicef.org/supply/index_68352.html