

Alcimed

The changing world vaccine market: from innovative technologies to therapeutic vaccines

Paris, 17 March 2016 - The increasing demand in emerging countries, the changing business landscape, the development of new vaccines and the appearance of new technologies for their administration are transforming the world of vaccines. Alcimed, consultants in innovation and development of new markets, reviews the change in the world vaccine market.

The vaccine market is currently divided into two categories of producers. On one side, 4 multinationals control almost 65% of the market in terms of value but only 20% of the market by volume. On the other side, producers in emerging countries are gaining in importance through the development of new low-cost vaccines.

A strongly-growing market with new vaccines appearing

The vaccine market¹ is currently experiencing very strong growth; from a value of 26 billion dollars in 2011², it rose to 32.3 billion dollars in 2014³. This growth should be maintained or even intensify in the coming years, **approaching 80⁴ billion dollars in 2025**.

Several factors explain this growth:

Growth in demand for **routine vaccines in emerging countries** with larger and more widespread vaccination programmes, resulting in an upsurge in the quantity of vaccines order by the local authorities and Non-Governmental Organisations.

In parallel, the **production of combined vaccines**, which immunise against several diseases in a single injection is increasing and leading to new vaccines being put on the market, complex to produce and therefore considerably more costly than the current vaccines.

In the coming years, these trends will be supplemented by the **production of new vaccines immunising against previously-incurable infectious diseases**. While Sanofi Pasteur recently obtained authorisation to market its vaccine against Dengue fever in Mexico, vaccines against pandemic diseases such as Ebola are expected in the relatively near future.

¹ Refers to prophylactic vaccines, preventive vaccines, as opposed to therapeutic vaccines with a curative effect.

² Development of the global pharmaceutical and vaccine markets 2005-2015 (in billion US dollars) – Statista

³ Vaccines Market worth \$57.8 billion by 2019 – markets and markets

⁴ Alcimed estimate

⁵ FierceVaccines

A moving business landscape: do the multinationals still have a future in the market of emerging countries?

Although in terms of value the market is still dominated by 4 producers, Merck, Sanofi, GSK and Pfizer, which together represent more than 65%⁵ of the market, **a few producers from emerging countries are making names for themselves in terms of volumes of vaccines produced**. Among them, the Indian producers *Serum Institute of India* and *Biological E*, respectively first and fourth-largest supplier to Gavi member countries, the Brazilian *Butantan Institute* and *Bio-Manguinhos*, as well as the Chinese CNBG. Producing low-cost vaccines, with costs continuing to fall, these companies are gaining market share, driven by self-sustaining research in their countries and by a desire to develop on the international stage. Today they are increasingly sought by NGOs and governments of emerging countries and newly-industrialised nations, affecting market prices worryingly for the European and American leaders.

In fact, besides lower labour costs in the emerging countries, the technological and regulatory differences that exist between these two groups of producers are forging significant price differences. For a technological viewpoint, companies in emerging countries produce their vaccines using less innovative and costly methods. In addition, stricter regulatory constraints imposed by Europe and the US also lead to additional costs.

"Up against this trend, the producers in western countries are reviewing their strategic positioning. So, companies such as Janssen Vaccine and Pfizer are now seeking to refocus on the production of new vaccines. We can therefore ask ourselves the question about the future of these large pharmaceutical groups in the markets of emerging countries. Will the multinationals refocus their activities on developing high value vaccines and abandon emerging markets, to the benefit of local companies?", wonders Aurélie Malécot-Chabanel, Alcimed.

Alcimed

Also being developed, a **universal flu vaccine**, that would make it possible to immunise against all strains of the flu virus, could appear in several years. Two separate teams at Janssen Vaccines and the American National Institute of Allergy and Infectious Diseases are working on the development of such a vaccine.

Ever more innovative technologies serving patient safety and well-being

Parallel to the development of new vaccines, a certain number of innovative administration technologies are now being developed or perfected. These innovations are driven by the search for **safer, more effective and less painful means of administration**.

Among the innovative technologies now being marketed, **single injection systems with self-locking syringe**, which have been designed to limit the problems of re-using needles in developing countries. The efficacy and potential savings in antigens offered by the intradermal route have also led to marketing syringes with micro-needles. By using a much shorter needle than a conventional syringe, this technology simplifies intradermal injection. Furthermore, patches comprising a set of micro-needles also used for intradermal injection are currently under development.

Simultaneously, the fear of needles and pain associated with injections has stimulated the development of various alternative technologies. The **jet injector** is the first to become available. Marketed by PharmaJet, it eliminates all safety concerns associated with needles by propelling the vaccine under the skin using a gas- or air-pressurised system. However, it is currently quite painful and relatively inaccurate in the quantities administered. Following the wave of the jet injector, other technologies are now under development. These include **transdermal patches** currently in clinical trials, or **creams and pills**, which are currently in early-stage research.

Research is also focusing on better understanding and improved **heat-stability of vaccines but changing their formulation**, so making it possible to explore new transport routes by allowing products to leave the cold-supply chain during the distribution process.

Towards therapeutic vaccines

Although historically vaccines have been intended to prevent disease, a new form of vaccine has recently emerged: therapeutic vaccines. **Their purpose is to treat patients already affected by the disease.**

Therapeutic vaccines currently represent a very small market, limited to vaccines against skin, prostate and bladder cancers, and a few vaccines against pollen allergies. However, a large part of the vaccine pipeline involves therapeutic vaccines⁵. With expected growth greater than for prophylactic vaccines, therapeutics vaccines could significantly affect tomorrow's market.

It is actually estimated that the market for therapeutic vaccines will reach 4.82 billion dollars in 2020, with annual growth of 33.6%⁶, and will take on a really significant scale in the next 10-15 years. The main vaccines under development are aimed at treating cancer: breast, ovarian and pancreatic cancers, to mention just a few.

In parallel, several trials are in progress to develop vaccines against diseases such as Aids and Alzheimer's, or to combat certain allergies, such as mites.

"However, pure vaccine expertise is not enough to develop these therapeutic vaccines. Ultimately, this should provide the opportunity for new companies to take their place in the sector, so affecting the current business landscape", explains Anne-Charlotte Pupin, Alcimed Project Director.

ABOUT ALCIMED

Alcimed (www.alcimed.com) is a consultancy company in innovation and development of new markets,

⁵ Medtrack

⁶ Global Therapeutic Vaccines Market Growth, Trends & Forecast 2015 – 2020 – Modor intelligence

Alcimed

specialised in life sciences (healthcare, biotech, food processing), chemistry, materials and energy, as well as aeronautics, aerospace, defence and Public Policy. Alcimed counts on a team of 180 employees, sub-divided by sector and able to handle extremely varied missions from marketing & sales subjects (market surveys, targeting new needs, positioning a new product, etc.) to strategic issues (development strategy, research & assessment of acquisition targets, organisation of an activity, design/assessment/deployment of public policies, etc.). The company's head office is in Paris and it also has offices in Lyon and Toulouse, as well as in Germany, Belgium, Switzerland, England and the United States.

MEDIA RELATIONS: ComCorp Agency

Marie-Caroline Saro – +33 1 58 18 32 58 / +33 6 88 84 81 74 - mcsaro@comcorp.fr