



Succeeding in a commoditised market

Lessons from the US
influenza vaccine market

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Lessons from the US influenza vaccine market

The US influenza vaccine market is highly complex, with multiple barriers to entry. As a result, the market is consolidated with only a few dominant players, while limited differentiation and price parity of existing products has led to its commoditisation over time. Yet the market remains attractive, with steady growth expected and key unmet needs to address.

In our experience, we believe there are three requirements for success in this market:

- 1. Innovation:** creativity in addressing the many unmet needs that exist in the market, e.g. vaccine efficacy, route of administration, more robust manufacturing processes etc.
- 2. Targeted market segmentation:** careful segmentation of the market to target specific populations, e.g. high risk populations.
- 3. Effective stakeholder management:** engaging and providing value added services to the multiple stakeholders (e.g. regulators, distributors, buyers), a unique attribute of the vaccine value chain.

In this paper, we look at each of these enablers and how pharma companies may utilise these to successfully build differentiation and position for long-term profitable growth.



Differentiation is critical for realising growth ambitions in the US influenza vaccine market

The US influenza vaccine market is large and growing

The US influenza vaccine market, at US\$ 1.8 billion in 2016, represents approximately 13% of the overall US vaccine market. It is forecast to grow at a CAGR of 4.5%, reaching US\$ 2.4 billion by 2021¹. The US continues to be the world's largest influenza vaccine market, at ~60%, followed by Japan¹.

The steady growth of the US market is expected to be driven by a number of factors, which include demographics (e.g. ageing population, vaccine awareness) and government policy (e.g. Healthy People 2020). Transformative changes in other vaccine markets, due to the entrance of expensive and innovative vaccines such as Gardasil® (Merck) and Bexsero® (GSK) may have also contributed to the renewed interest in the influenza vaccine market.

It is highly complex, with high barriers to entry

The influenza vaccine market is unique and complex due to a number of reasons:

- The influenza vaccines must be reformulated each year, to match the strain(s) of the virus anticipated to circulate in the coming flu season.
- Due to limitations in current technologies and the lengthy production times (approximately seven months), vaccine manufacture is often initiated at the start of the year by betting on the most likely strain(s) for the next season.
- The timely and efficient distribution of vaccine prior to the start of the flu season, and appropriate storage of inventory is critical.

In addition, it is a market with multiple barriers to entry, including significant regulatory burdens, capital intensity (large scale requirements for technology and expertise for vaccine manufacture), unpredictable and volatile demand (due to impact of severity and timing of the annual flu season), and limitations in the current egg-based production processes (lengthy timelines, vulnerabilities to contamination or supply restrictions).

As a result, the market is highly consolidated. In 2015-16, approximately 98% of the market was dominated by established players Sanofi, GSK, AstraZeneca (MedImmune) and CSL/Seqirus². Protein Sciences, with recombinant vaccine Flublok®, was the only significant smaller player (less than 1% of the market).

Market commoditisation has created challenges for incumbents and new market players

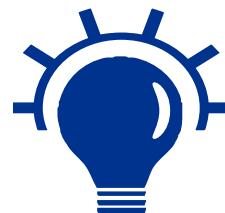
Years of limited innovation and their resulting price parity have led to the commoditisation of this market. To reverse this, and maintain or grow share, companies are investing in building differentiation in the market.

From our experience, success in the influenza market can be linked to three key factors:

- 1. Innovation**
- 2. Market segmentation**
- 3. Stakeholder management**

1. Innovation

Despite its maturation, the US influenza market retains key unmet needs. Creativity in how they are addressed could enable competitors to build differentiation.



Vaccination against influenza is the most cost-effective method of preventing infections, and while the market is well established significant needs remain for safe, more efficacious vaccines that are more rapidly and reliably produced, and offer broader protection against influenza strains.

Unmet needs, required innovations and recent marketed examples:

Unmet need	Required innovation (recent marketed product examples)
Immunogenicity The currently available vaccines are of limited efficacy, particularly against identified 'high risk' groups (e.g. children under 3 years and persons over 65 years)	<ul style="list-style-type: none">— Improved efficacy through methods to enhance the immune response, e.g. use of adjuvants or higher or novel antigenic content— Examples: Fluad® (Seqirus) or Fluzone High-dose® (Sanofi)
Delivery technologies Availability of multiple delivery mechanisms (beyond injections) can improve compliance and ensure broader vaccine coverage	<ul style="list-style-type: none">— Alternative routes of administration of vaccine, such as sprays or needle-free technologies— Examples: FluMist® (Novartis) or Afluria® (PharmaJet)
Shorter time to manufacture The current egg-based manufacturing process requires ~seven months for end to end production, and poses a significant risk during pandemic situations due to inability to meet demand	<ul style="list-style-type: none">— Improved technologies that enable faster manufacture, with surge capacity during threat of pandemics, such as cell-based or recombinant platforms— Examples: Flucelvax® (Seqirus), FluBlok® (Protein Sciences)
Reliability of supply The current egg-based manufacturing process is vulnerable to delays due to potential limitations in chicken egg supplies and carries high risks of contamination	<ul style="list-style-type: none">— Robust manufacturing technologies that are not reliant on egg supplies, such as cell or recombinant platforms or newer technologies such as DNA or synthetic vaccines— Examples: Flucelvax® (Seqirus), FluBlok® (Protein Sciences)
Cross-reactivity against antigenic drift Due to ongoing evolution of influenza viruses there is potential for antigenic mismatch between the flu vaccine and circulating viruses, thereby reducing the effectiveness of the vaccine	<ul style="list-style-type: none">— Vaccines with broader strain protection, e.g. beyond-quadrivirals or universal vaccines— Predictive analytics or agile, on-demand manufacturing processes to improve the match between the flu viruses in circulation and the vaccine

2. Market segmentation

Success in commoditised markets can often be linked to effective targeting of market segments. Targeting of two high-risk populations, children and the elderly, enabled MedImmune and Sanofi to build differentiation in the market.



While a market can be segmented in multiple ways (demographics, behavioural, geographic), the following two case studies demonstrate how companies have built differentiation through targeting underserved populations.

1

FluMist®, MedImmune

Product overview:

FluMist® is MedImmune's Live Attenuated Influenza Vaccine (LAIV), formulated to be delivered as a nasal spray.

Key demographic:

Approved by the FDA for use in persons 2 through 49 years of age³. The US Centre for Disease Control and Prevention (CDC) identifies children under five years of age as a group especially at risk of complications from influenza⁴.

In 2014, based on trial data which indicated a greater efficacy of LAIV in younger children, the US Advisory Committee on Immunization Practices (ACIP) issued a rare 'Preferential Recommendation' for the use of FluMist® in children aged 2 to 8 years⁵.

While the preferential recommendation was dropped the following year, due to limited evidence of consistently better protection, FluMist® continued to dominate the paediatric market.

Outcome:

MedImmune expected an increased demand for LAIV following the ACIP recommendation, and planned to make 18 million doses of FluMist® for the US market for the 2014-15 season, up from the 15 million produced for the 2013-14 season⁶.

"About 85% of kids who come in get FluMist®, if they don't its contraindicated or they specifically ask not to have it" – Paediatrician⁷

2

Fluzone High-Dose®, Sanofi

Product overview:

Fluzone High-Dose® is an Inactivated Influenza Vaccine (IIV), formulated to contain a higher hemagglutinin (HA) antigen concentration (four times the antigen content of Fluzone standard-dose).

Key demographic:

Approved for the use of persons 65 years of age and older³.

As ageing weakens the immune system, older people have a reduced ability to mount a strong immune response after vaccination, putting them at a higher risk of severe illness from influenza. Therefore a higher dose of antigen in the vaccine is expected to give older people a better protection against seasonal flu.

Trial data indicated the High-Dose® vaccine was 24.4% more effective in preventing the flu in adults 65 years of age and over, compared to a standard-dose vaccine⁸.

Outcome:

In the 2016-17 season, Sanofi expected approximately 60% of vaccinated seniors in the US to receive Fluzone High-Dose® (up from 50% in the 2015-16 season)⁹.

"The data suggests that Fluzone High-Dose® performs substantially better than the standard vaccine. But I think that there's still upside and room for improvement beyond that". – General Physician⁷

"People do think it should get a preferential recommendation for senior citizens" – General Physician⁷

3. Stakeholder management

The multiple stakeholders (e.g. regulators, distributors, buyers) are a unique and key attribute of the vaccine value chain, and effective engagement is key to ensuring timely sale of products.



Effectively managing the highly complex stakeholder landscape for vaccine manufacture, delivery and sales, and providing a value add for each segment is critical for companies to secure market share and sales growth.

Regulators

Stakeholder role:

The Advisory Committee for Immunisation Practices (ACIP), an expert advisory committee of the CDC, releases annual recommendations of which vaccines should be used during the upcoming flu season. It is a critical step which determines reimbursement by payers and uptake by prescribers.

Key factors in successful engagement:

- Engaging early to ensure alignment.
- Ensuring a strong recommendation, potentially through targeting identified requirements, e.g. high risk groups.

“Yes, people really do listen to ACIP recs. With FluMist in children, that really drove it in the marketplace”.
— General Practitioner⁷

“If a vaccine carries an ACIP recommendation, the insurers, with very few exceptions, have to pay”.
— General Practitioner⁷

“If ACIP says we do not recommend for use, it’s death [to the vaccine]”.
— General Practitioner⁷

Distributors

Stakeholder role:

Due to the seasonality of demand, influenza vaccines are rarely purchased directly from the manufacturer. Wholesale distributors play a key role in the transport of vaccines to the end customer, in particular in demonstrating stability of cold chain supply, and thereby form a key stakeholder group to be managed.

Key factors in successful engagement:

- Demonstrating a reliable source of supply.
- Favourable contractual terms, e.g. margins, rebates for unsold vaccines.

“A lot of these contracts are 3/4/5 year deals and a lot of it is heavily driven by cost and margin. To a certain degree in the US, flu vaccines are commoditised in that there’s not a lot of brand recognition by customers, by physicians”.
— Director, Distribution, Retail Pharmacy Chain⁷

Buyers

Stakeholder role:

Buyers of vaccines include wholesale distributors, public and private providers (e.g. hospitals, retail pharmacies, private clinics) and the Government (e.g. U.S. Department of Defence). Given the price parity, demonstration of added value is a key driver of uptake among this stakeholder group.

Key factors in successful engagement:

- Demonstration of added value, e.g. through product bundling.
- Flexibility in contracting, e.g. rebates/refunds on unsold stock.
- Reliability of supply.

“There’s got to be some kind of track record. We have to have some kind of history where they have experience, the resources and the wherewithal for supply”.
— Director of Pharmacy, Private Hospital⁷

“There is not really a lot of brand recognition, being a relatively commoditised market. So [sales] are really driven by cost, the ability to get a reliable supply, without quality issues, and value adding agreements like bundling”.
— Director, Hospital Procurement⁷

Three factors for success in a commoditised market

Commoditisation of markets is often inevitable, and it preceded by a number of warning signs:

- **Product similarity:** convergence of product technologies or features resulting in a high degree of substitutability
- **Price sensitivity:** parity of products results in increased demand by customers for lower prices
- **Market consolidation:** struggling to grow margins, companies often consolidate, aiming to gain advantages in economies of scale

While thriving in a commodity market may be challenging, the lessons from the influenza vaccines market on innovation, market segmentation and stakeholder management serve as useful indicators and are common features of success across sectors. Consistent investment in these three key areas can help companies build differentiation in the market, carve out market share and deliver on growth ambitions.



Footnotes

1. KPMG analysis of Global vaccine market features and trends, World Health Organisation.
2. KPMG analysis of company reports and websites, 2016.
3. FDA.gov, accessed 2016.
4. People at High Risk of Developing Flu-Related Complications, CDC.gov, accessed 2017.
5. Advisory Committee on Immunization Practices (ACIP) recommends a preference for using the nasal spray flu vaccine, 25 June, 2014, CDC.gov.
6. ACIP cites preference for nasal-spray flu vaccine for young, Centre for Infectious Disease Research and Policy, 25 June 2014.
7. KPMG primary research, 2016
8. Fluzone High-Dose Seasonal Influenza Vaccine, CDC.gov.
9. Sanofi Pasteur Ships First of its 2016-2017 Seasonal Influenza Vaccine Doses in United States, 26 July 2016, sanofipasteur.com.

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KPMG Global Strategy Group works with private, public and not-for-profit organisations to develop and implement strategy from 'Innovation to Results' helping clients achieve their goals and objectives. KPMG Global Strategy professionals develop insights and ideas to help address organisational challenges such as growth, operating strategy, cost, deals and transformation.



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