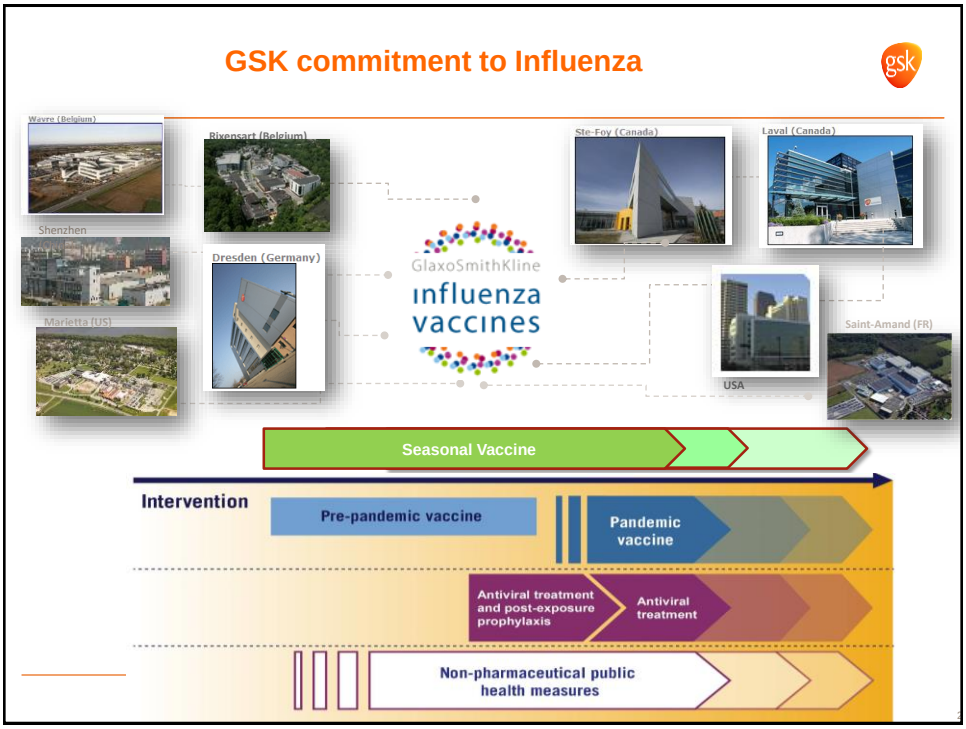
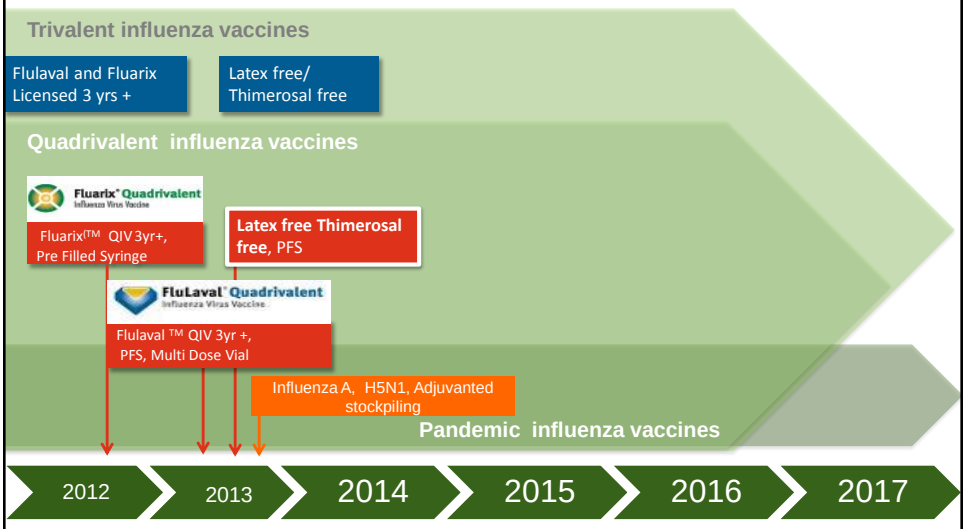

GSK commitment to influenza prevention
Dr Catia Ferreira
Influenza Portfolio
US Medical Affairs Leader
GSK Vaccines


GSK commitment to Influenza
Wavre (Belgium)
Rixensart (Belgium)
Ste-Foy (Canada)
Laval (Canada)
Shenzhen
Dresden (Germany)
GlaxoSmithKline
influenza vaccines
Marietta (US)
USA
Saint-Amand (FR)
Seasonal Vaccine
Intervention
Pre-pandemic vaccine
Pandemic vaccine
Antiviral treatment and post-exposure prophylaxis
Antiviral treatment
Non-pharmaceutical public health measures

US Influenza vaccines update *
Current status (2014)



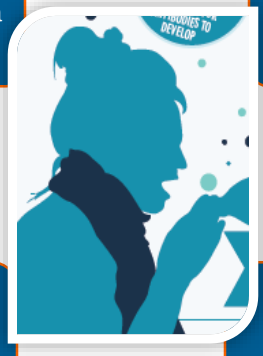
*Focused on US product approvals only. Other GSK Influenza brands and products not represented in this slide

Cornerstone of influenza prevention

GSK Quadrivalent seasonal influenza vaccines: Fluarix and FluLaval Quadrivalent

Fluarix Quadrivalent | FluLaval Quadrivalent

- Understanding influenza burden of disease
- Pediatric influenza prevention*
- Influenza seasonal prevention support preparedness for Pandemic
- Adult /Elderly influenza prevention



* Indication: 3yrs and above

http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM220624.pdf
http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM366070.pdf

GSK Investment in Influenza Vaccines:
Increased Production Capabilities

GSK is investing heavily in manufacturing and distribution capabilities over the next three years:

- Two Bulk Manufacturing Locations; Ste Foy, Canada and Dresden, Germany.
- Two new filling lines in Ste Foy
- New syringe labeler (packaging line) in Marietta PA to handle increased flu demand
- Increase cold storage and delivery speed at our distribution center
- Upgrade our e-commerce site and distribution processes

'**14/'15 Influenza Season:**

GSK anticipates supplying **35 million doses, two thirds** of which will be **Quadrivalent**

'**15/'16 Influenza Season**:

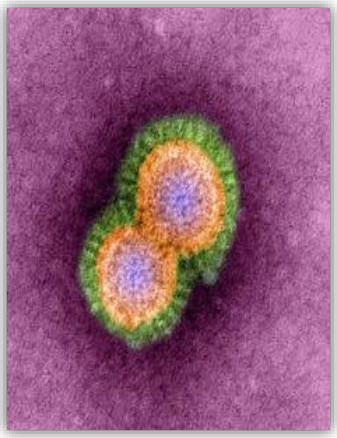
GSK anticipates having the capacity to supply **45 million doses of Quadrivalent**.

GSK's final production volumes are based on customer and patient demand.

Influenza A , H5N1, monovalent adjuvanted pandemic vaccine was approved by FDA, November 2013

First Adjuvanted Influenza vaccine in the USA

- Influenza A , H5N1, monovalent adjuvanted pandemic vaccine indicated for prevention of disease caused by the influenza A virus H5N1 subtype contained in the vaccine.
- It is approved for use in persons 18 years of age and older at increased risk of exposure to the influenza A virus H5N1 subtype contained in the vaccine
- Developed in collaboration with BARDA

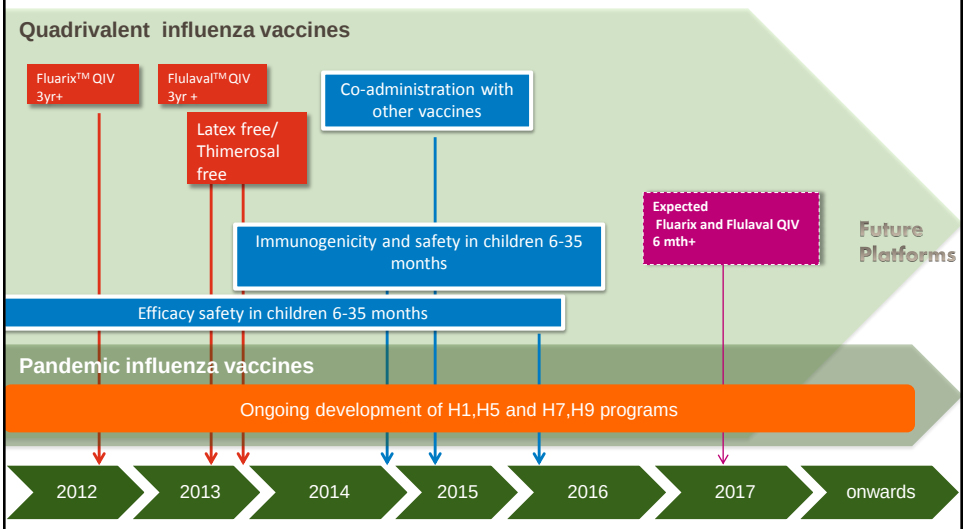


H5N1 avian flu virus particles
http://www.nato.int/docu/review/2007/issue4/english/analysis6.html

http://www.gsk.com/media/press-releases/2013/h5n1-vaccine-approved-by-the-u-s--fda-as-pandemic-influenza-prep.html

US influenza prevention update

Future Clinical development of GSK influenza vaccines



https://clinicaltrials.gov/
www.gsk.com

Summary

GSK remains a committed partner to influenza prevention

- Quadrivalent Influenza vaccines provide broader seasonal influenza prevention : two A strains and two B strains (Yamagata and Victoria).
- Seasonal program focused on broadening of age indication for Fluarix and FluLaval Quadrivalent influenza
- Commitment to increase capacity for manufacture of influenza vaccines and continued R&D development of influenza vaccines
- Seasonal program supports ongoing development and preparedness of Pandemic influenza program

FLUARIX AND FLUARIX QUADRIVALENT are vaccines indicated for active immunization for the prevention of disease caused by influenza virus subtypes A and type B contained in the vaccine. FLUARIX AND FLUARIX QUADRIVALENT are approved for use in persons 3 years of age and older.

- **Important Safety Information**
- Do not administer FLUARIX to anyone with known severe allergic reactions to egg proteins (a vaccine component) or a life-threatening reaction to previous administration of any influenza vaccine
- If Guillain-Barré syndrome has occurred within 6 weeks of receipt of prior influenza vaccine, the decision to give FLUARIX should be based on careful consideration of the potential benefits and risks
- The tip caps of the prefilled syringes may contain natural rubber latex which may cause allergic reactions in latex-sensitive individuals
- If FLUARIX is administered to immunosuppressed persons, including individuals receiving immunosuppressive therapy, the immune response may be lower than in immunocompetent persons
- Syncope (fainting) can occur in association with administration of injectable vaccines. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope
- In clinical trials with FLUARIX, the most common adverse reactions in adults included injection site pain and redness, muscle aches, fatigue, and headache. In children 5 years to <18 years of age, the most common adverse reactions were similar to those in adults but also included injection site swelling. In children 3 years to <5 years of age, the most common adverse reactions included pain, redness, and swelling at the injection site, irritability, drowsiness, and loss of appetite. (See Adverse Reactions section of the Prescribing Information for FLUARIX for other potential adverse reactions and events.)
- Vaccination with FLUARIX may not result in protection in all vaccine recipients

http://www.gsk.com/

FLULAVAL and FLULAVAL QUADRIVALENT are vaccines indicated for active immunization against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine. FLULAVAL and FLULAVAL QUADRIVALENT are approved for use in persons 3 years of age and older.

- **Important Safety Information**
- Do not administer FLULAVAL to anyone with known severe allergic reactions (eg, anaphylaxis) to any component of the vaccine including egg protein or to a previous dose of any influenza vaccination
- If Guillain-Barré syndrome has occurred within 6 weeks of receipt of a prior influenza vaccine, the decision to give FLULAVAL should be based on careful consideration of the potential benefits and risks
- If FLULAVAL is administered to immunosuppressed persons, including individuals receiving immunosuppressive therapy, the immune response may be lower than in immunocompetent persons
- Syncope (fainting) can occur in association with administration of injectable vaccines. Procedures should be in place to avoid falling injury and to restore cerebral perfusion following syncope
- In comparator-controlled clinical trials with FLULAVAL, adverse reactions included pain, redness, and swelling at the injection site; headache; fatigue; and myalgia/arthralgia. (See Adverse Reactions section of the Prescribing Information for FLULAVAL for other potential adverse reactions and events)
- Vaccination with FLULAVAL may not result in protection in all vaccine recipients

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Thank You