Vacsera is a state-owned company which began as a small laboratory established in 1897 by Health Dept. producing small-pox vaccine followed by Rabies vaccine in 1907. It is still the only company producing vaccines in Egypt.

EGYVAC, The Egyptian Company for Production of Vaccines, Sera & Drugs is one of the affiliated companies of The Holding Company for Biological Products & Vaccines (Vacsera) that is specialized in the production and distribution of vaccines. EGYVAC is the only producer of vaccines & sera & Drugs in Egypt. It is the oldest manufacturer of vaccines in Africa and the Middle East.

Influenza vaccine production project:
EGYVAC is aiming to produce a WHO prequalified influenza vaccine to cover the local needs for the flu vaccine, and to export our vaccine to the global markets.

Our goal: To establish, test and completely documented egg-based influenza production facility with initial capacity of 500,000 doses of trivalent seasonal influenza per year, with expansion possibilities up to 1.5 million doses seasonal influenza and 12 million doses mono-valent pandemic vaccine per annum with minimal investment. And also to produce 1 billion doses of avian influenza vaccine.

However, suitability and sustainability of this project will be a major issue and as major concern, so the multi-use facility will represent chance to render the influenza project sustainable.

The new flu facility have been built and installed in the 6th of October City, Egypt, and meet the latest GMP requirements. Relevant systems in this facility shall be qualified according to international standard.

Building of the new influenza

The new influenza facility covers 3150 m² by 3 levels:
1st Floor: For eggs incubator area plus prefilled syringe (in the future)
2nd Floor: For bulk production (adapted to whole and split virus)
3rd Floor: For utilities (HVAC, etc)

Achievements to Date:
1. The construction and external finishing of the facility have been finished.
2. Review and approve of many project documents: BOD, VMP, URSs, Sops, Tender conditions and Process Technology Transfer.
4. Laboratory scale production of experimental lot of mono-valent vaccine with harvest volume equal to 1500 ml and final volume mono-valent bulk equal to 100 ml (strain used H1N1 mother seed (NIBSC), conduction of the relevant Q.C tests, execution of analytical method validation protocols and validation of critical process steps such as inactivation process validation.
5. Staff training on steps of production of both cell based and egg based Influenza vaccine.
External: RIVM, BARDA, BTEC
Internal: GMP, Cleaning Validation Cell Culture Techniques

Planned work until 2016

The stability studies, pre-clinical studies, clinical studies and preparation of license dossier will take another year, so the product will be in the market by the end of 2016.

N.B.: The political events will make some delay to complete the project as in the plane also the economic conditions play a big role to complete the rest of the investment, since the rest of the investment will be covered by VACSERA/EGYVAC through bank loan.

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