



Credit: Egyptian Drug Authority

1 August 2022 – The World Health Organization (WHO) has announced that Egypt’s National Regulatory Authority (NRA) for vaccines reached Maturity Level 3 (ML-3) – the second highest in the WHO classification of national regulatory systems. This makes Egypt’s NRA the first to reach ML-3 for vaccine regulation in the Eastern Mediterranean Region and the ninth at global level.

Reaching ML-3 offers Egyptian vaccine manufacturers the eligibility to apply for WHO pre-qualification and WHO Emergency Use Listing of their manufactured products, which will eventually allow Egypt to export COVID-19 vaccines to other countries.

WHO classification is carried out based on its Global Benchmarking Tool to ensure vaccine quality, safety and effectiveness. Achieving Maturity Level 1 means some elements of the regulatory system exist. Maturity Level 2 indicates an evolving national regulatory system that partially performs essential regulatory functions. Maturity Level 3 confirms that a stable, well functioning and integrated regulatory system is in place. The highest level, Maturity Level 4, is achieved by a regulatory system operating at an advanced level of performance and continuous improvement.

An official benchmarking mission of the Egyptian Drug Authority – conducted by 15 international assessors during 13–17 March 2022 and using an evaluation tool cross cutting 9 functions with a set of indicators and sub-indicators – revealed that the Egyptian Drug Authority had attained ML-3.

Recently, Egypt and 5 African countries have emerged as the first African recipients of mRNA technology under the global mRNA technology transfer hub initiative. An mRNA vaccine is a type of vaccine that uses a copy of a molecule called messenger RNA (mRNA) to produce an immune response. This platform is used to manufacture vaccines against COVID-19 and can be applied to produce other types of vaccines; it is also used in several applications of immunotherapy for infectious diseases and cancers.

Egypt is among the Region's main producers of medical and pharmaceutical products, including vaccines. WHO has been providing constant support to the country's national regulatory authorities since 1998, with accelerated support since 2006. Over the last 2 years, WHO has offered technical support to the Egyptian Drug Authority through several missions, in addition to continuous virtual follow-up, as part of the Organization's efforts to strengthen regulatory capacity of medical products in all of WHO's Member States.

Saturday 27th of April 2024 09:29:04 AM