Biovac to manufacture combo vaccines for Sanofi Pasteur

The Biovac Institute will be partnering with multi-national pharmaceutical company, Sanofi Pasteur, in a technology transfer to locally manufacture one of the leading combination vaccines, it was announced yesterday, 2 April 2012.

The agreement will see Sanofi Pasteur entrust Biovac with late stage manufacturing operations for the processing of the multi-national's bulk product into a finished vaccine product for sale and distribution by Biovac.

Speaking on the technology transfer announcement, Biovac CEO and Deputy CEO of Litha Healthcare Group Limited, Dr Morena Makhoana said, "Up until now we have concentrated our efforts on building the physical infrastructure required to create a world class vaccine manufacturing facility. We have now reached the point where we need to bolster our vaccine portfolio by adding more products to our planned production line and this will be achieved through technology transfer agreements like this one with Sanofi Pasteur."

The partnership will result in Biovac manufacturing an innovative and complex combination vaccine in its Cape Town facility and supplying the vaccine to the South African public sector hospitals and clinics through the Government's Expanded Programme on Immunisation (EPI).

Commenting on the nature and process of this collaboration, Dr Makhoana adds, "A technology transfer is a complex and lengthy process and takes approximately three years from initiation to commercially manufacturing the vaccine.

"The first step will be to undertake training which will be done on site at our facility in Cape Town, as well as Sanofi Pasteur's facilities in France. Once the processes have been transferred, Biovac will initiate on-site trials in order to simulate the processes learnt. This will be done under the guidance of Sanofi Pasteur. Upon completion of the tests, regulatory filing of the registration dossier will be done in preparation for approval, for the commercial manufacturing of the vaccine for distribution. Although it is a lengthy process, if done well, it will stand Biovac in good stead for years to come."

Additionally, Biovac will benefit from the transfer of specialist skills which is a key factor of the agreement. This will incorporate Sanofi Pasteur passing on:

- Technical assessment and guidance to set up and run a vaccine filling and packaging facility, including advice in the choice of appropriate equipment;
- advice on the implementation of the technical support to enable Biovac to process the bulk product in compliance with the necessary quality standards, which would then allow Biovac to supply the finished vaccine to the public market;
- developing local quality control expertise through on-site and off-site (France) training required for both equipment and vaccine finished product; and
- lastly the provision of technical guidance and training on the use of technical information for the purpose of

processing the formulated bulk vaccine into finished vaccine product.

The production of this vaccine will be added to the products to be manufactured at the facility, which is planned to be operational in 2013.