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Wockhardt Preps To Deliver 100M Doses Of AZ Vaccine

Talks On With Other Vaccine Developers

by **Vibha Ravi**

As the MHRA prepares to grant approval to the Oxford/AstraZeneca vaccine, Wockhardt is set to supply 100 million doses for the UK government's own use and its WHO commitments. The company is also in talks with global vaccine developers to manufacture their COVID-19 vaccines for emerging economies

As the [University of Oxford/AstraZeneca PLC](#)'s COVID-19 vaccine moves closer to approval in the UK, [Wockhardt Limited](#) is preparing to manufacture 100 million doses of AZD1222 for the government's own use and its World Health Organization (WHO) commitments.

Post the UK government's formal request to the Medicines and Healthcare Products Regulatory Agency to assess the vaccine, Prime Minister Boris Johnson's recent inspection of Wockhardt's Wrexham facility has set the ball rolling for its procurement soon.

Under a previously announced agreement, Wockhardt has committed fill-finish production lines at the facility owned by its subsidiary, CP Pharmaceuticals, to the government. (Also see "[Coronavirus Update: BioNTech And Fosun Launch Vaccine Trial In China](#)" - Scrip, 6 Aug, 2020.) At a virtual press conference on 1 December, Wockhardt founder chairman Habil Khorakiwala mentioned that this unit in North Wales is the only fill-finish facility in the UK.

While the company has been receiving standing charges for the unit so far, it now expects real money to start flowing in with manufacture of the Oxford/AZ vaccine set to begin. Further purchase

Oxford/AZ's COVID-19 Vaccine Cuts Virus Spread By 60%

orders are expected from the UK government as the latter ties up supply agreements with more COVID-19 vaccine developers.

“We are looking at what is possible in the near future... and we already have a firm order for more than \$50m and we expect some more to come in. So, we expect to make \$50-100m here,” said Khorakiwala.

The company intends to supply up to 350 million doses annually on a multidose vial basis to the UK government through the Wrexham unit which is capable of manufacturing vaccines of “all technologies available today” and has been vetted by the UK government’s technical team as well as other experts.

While [Pfizer Inc./BioNTech SE](#) and [Moderna, Inc.](#) will most likely supply their finished vaccine to UK, if they supply only the drug substance, the UK government is committed to get it manufactured by Wockhardt in the fill finish form. (Also see "[AZ Will Sideline ‘Lucky Mistake’ To Secure COVID-19 Vaccine Approval](#)" - Scrip, 27 Nov, 2020.)

Talks On With Other Vaccine Developers

Meanwhile, Wockhardt is also wooing other global vaccine developers, including those that don’t have their own manufacturing plants. Apart from the UK unit, Wockhardt has facilities at Aurangabad in India to produce bacterial and mammalian cell culture vaccines.

“Globally around 15 billion doses are required, and the current manufacturing capacity worldwide is only five to six billion doses. The requirement in emerging markets is expected to be as much as 10-12 billion doses. So, there is a large gap which is going to be a challenge and we want to fill that gap” Khorakiwala noted.

With an annual capacity to produce one billion vials of drug substance and fill-finish form of vaccines at its UK and India-based facilities, Wockhardt is willing to manufacture COVID-19 vaccines for companies wanting to tap emerging markets. Its marketing expertise is also on offer for those looking to sell their vaccines in India.

“We can’t make inactivated vaccines, but we make mammalian vaccines and have a very large capacity for bacterial vaccines which can be ramped up very quickly. For a technology transfer, we have a research team of 120 people. We are simultaneously talking to large number of vaccine

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Oxford University/AstraZeneca’s COVID-19 vaccine cuts the spread of the virus by 60%, apart from having 70% efficacy in reducing infections in vaccinated individuals. While that is good news for their Indian partner, Serum Institute, the 90% efficacy shown in a subset due to a dosing error causes a dilemma.

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developers worldwide and discussions are at different stages. Once something concrete comes up, we will make an announcement,” Khorakiwala said.

The company’s facilities are approved by regulators in India, Russia, Brazil, Mexico and others. However, in 2013 the US Food and Drug Administration (FDA) had issued an import alert for its Aurangabad-based Waluj and Chikalhana facilities. In June 2019, the company announced that an inspection by the agency had not found any major irregularities at the Chikalhana unit and zero observations were received after inspection of its bioequivalence centre at Aurangabad.

This is one of the reasons Wockhardt plans to cater to emerging markets rather than regulated markets like the US. (Also see "[One More On QIDP List – Does It Help Wockhardt?](#)" - Scrip, 1 May, 2020.)

While Wockhardt has “made the Indian government aware” of its manufacturing potential, it hasn’t had discussions with companies like [Serum Institute of India Pvt. Ltd.](#), [Bharat Biotech](#), [Zydus Cadila](#) and [Biological E. Ltd.](#) so far to make their COVID-19 vaccines “perhaps because they have enough capacity,” he replied in response to a question on potential Indian alliances.

Khorakiwala declined to comment on questions regarding a manufacturing tie-up with the Russian Direct Investment Fund (RDIF) for its Sputnik V vaccine. [Dr. Reddy’s Laboratories Ltd.](#) and [Hetero Drugs Ltd.](#) have so far partnered RDIF for its COVID-19 vaccine, which has just entered Phase II/III adaptive trials in India. (Also see "[Cyberattacked Dr. Reddy’s Keeps Eye On Sputnik Plans](#)" - Scrip, 30 Oct, 2020.)

Addressing Other Challenges

Apart from addressing questions on the company’s plans, industry veteran Khorakiwala also fielded questions on availability and distribution challenges for COVID-19 vaccines.

“We don’t believe there will be a shortage of vials. These are not single dose but multi-dose vials. For example, the AstraZeneca vaccine has eight doses per vial and almost all vaccine manufacturers have multiple dosages. So, from that point of view the fill finish capacity requirement is much less than drug substance requirement,” he observed.

He also said transport and storage of some vaccines like that of Pfizer/BioNtech are not expected to be an insurmountable problem as India has the capability to store and transport products like ice-creams and meat, which have deep freeze requirements. (Also see "[Precious Cargo: DHL Gears To Deliver COVID-19 Vaccines](#)" - Scrip, 1 Dec, 2020.)

Availability is more of a concern, as only small quantities of these vaccines will be available on a month to month basis, he noted.

“To reach out to people who need it will be an execution challenge. The (Indian) government is fully aware and has a large machinery available, so if a proper approach is taken and resources are used properly it will work,” Khorakiwala said.

Responding to a question on whether the government should consider involving private hospitals for the immunization drive, he said the government should look at a multi-pronged approach and could in fact, also utilize number of “small five to 10-bed facilities”. Apart from the pharmaceutical business, the Wockhardt group also owns and runs private hospitals.