

Press Release: For Immediate Distribution

Date: 21st May 2013

Facts Related to Pentavalent Vaccine

New Delhi: With reference to the reports appearing in some sections of Press relating to Easyfive TT vaccine Batch No. P1062/SBP-A, we, at Panacea Biotec, wish to place the following facts to put the matter straight:

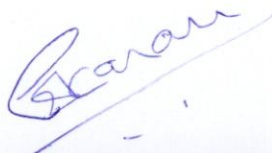
Panacea Biotec is, one of India's leading research based health management company, second largest vaccine producer in India, third largest biotechnology Company in India (ABLE Survey 2011), ranking among top 40 pharmaceutical companies in India, having established brand equity in number of therapeutic segments, e.g. diabetic management, pain management, organ transplantation, renal disease management & oncology, having collaborations & tie-ups with leading national and international pharmaceutical companies/ organisations and having manufacturing facilities for pharmaceutical formulations compliant of US-FDA, UK-MHRA, SA-MCC, & many others and has been a major supplier and exporter of several pharmaceutical products to various countries all over the world including USA, Germany, Australia, Brazil, Russian Federation, Africa and South East Asian countries.

Panacea Biotec has an established presence in vaccines manufacturing business over a period of more than 25 years, with an existing range of 9 vaccines (including Oral Polio Vaccine and Pentavalent Vaccines) in its portfolio and several others including innovative vaccines in pipeline & has been the pioneer as first formulator of trivalent oral polio vaccine (tOPV) to get WHO pre-qualification outside bulk OPV manufacturer in 1988. Panacea Biotec has developed world's first mOPV1, mOPV3 and bOPV, having supplied close to 10 billion doses of OPVs to meet the requirements of Global Polio Eradication Initiative (GPEI) and contributing significantly in India achieve zero polio case since 2011.

Panacea Biotec is not only the pioneer in the world in introducing fully liquid pentavalent (DtwP - Hepatitis B - Hib) vaccine but has also been a major supplier of this vaccine; having supplied over 45 million doses to 31 countries through UN Agencies.

We would like to mention here that pentavalent (Easyfive TT) vaccine Batch No. P1062/SBP-A was manufactured by the Company complying with all the requisite parameters of Quality, Safety & Efficacy as per the Indian Pharmacopoeia and the extant guidelines.

In the light of the extant guidelines as applicable, we wish to state that in relation to the extension of shelf life from 24 months to 36 months, a Level III Category change (Annual Notification - Minor Quality Changes), a mere notification of such change to the drug regulatory



authority was sufficient. As per the extant guidelines, the changes included under Reporting Category Level III (which include extension of shelf-life) may be implemented by the manufacturer without any prior review by the Licensing Authority. Therefore, a suitable representation in this behalf had already been submitted by the Company to the concerned authority.

In the light of the Circular dated 1st October, 2012 issued by Govt. of India, the trade name is no longer an issue.

In view of the provisions as applicable, there is no distinction between a product manufactured for the domestic market and/or for export markets. Therefore, any controversy in this regard is without any basis.

In this regard, we also wish to state that till a batch is released by the manufacturer, the manufacturer can undertake all such steps as may be deemed required including relabeling which is also a part of manufacturing activity.

In fact, no batch was released or re-released by Panacea Biotec without being it cleared by the CDL, Kasauli. In that view of the matter, it is thus clear that all the extant rules and guidelines have been followed by Panacea Biotec.

We further wish to clarify that in consonance with the highest standards being followed by the Company, the Company has already issued recall notice with respect to the said batch. However, the Quality, Safety & Efficacy of the said batch always remain uncompromised.

We, once again, reiterate and confirm that we, at Panacea Biotec, remain committed to manufacture, sell and distribute the products of the highest quality by complying with all extant rules and guidelines so as to ensure the Quality, Safety and Efficacy of its products.

For more information, please contact :



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