

**The Standard Criteria for Investment Activities to obtain the approval of the Ministry of Industry under MIC Notification(15/2017) section(d) sub-section(7)**

Sr. No	Business Activities	Criteria
1.	Manufacturing of Vaccine	<p>(a) It is required to control the virus, used in the vaccine production by establishing National Biosafety level. And High level of quality control on virus quality is necessary. Safety control for virus should be in accordance with International Regulations to ensure not to disseminate to outside and not to use as Biological Weapon.</p> <p>(b) Investment shall be an internationally recognized (US FDA, EU GMP, Australia's TGA, WHO Prequalified) vaccine company, and the vaccine shall be an internationally registered. Clinical Trial Data with respect to Safety, Efficacy and Quality of the vaccine must be submitted.</p> <p>(c) The vaccine production should be allowed only for the whole process production such as production through virus culture process and, if it produce Recombinant Engineering Technology, through Master Cell production process.</p> <p>(d) Must have appropriate Biosafety Labs for viruses, used in the vaccine production.</p>