

بِسْمِ اللّٰهِ الرَّحْمٰنِ الرَّحِیْمِ



## Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

### Regulatory Requirements for Product Registration and Approval of Vaccines in Emergency Situations

Normal Condition For Approving Vaccine Products	Emergency Situation
<p><b>1. <u>Company Profile</u></b></p> <p>The company profile documents should include the detail of the following.</p> <ol style="list-style-type: none"><li>Brief history of company with its detailed address including phone and fax number.</li><li>Brief description of the Organization.</li><li>Organization chart</li><li>List of the product category manufactured</li></ol>	Required in emergency situation

<b>Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority</b>		Authorized by: Director General, MFDA		
Doc. No: MTG/RE-VA/STD-TE 003	Rec. Name: Regulatory Requirements for Product Registration and Approval of Vaccines in Emergency Situations			
Issue No: 01	Issue Date: 01.12.2020	Prepared by: Director Pharmaceuticals, Enforcement Section	Approved by: Deputy Director General, Pharmaceuticals	Copy Letter:
Revision No: 00	Revised Date: -	Verified by: Technical Committee of MTG		Page No: Page 1 of 2

<p><b>2. <u>Product Profile:</u></b></p> <p>The product profile should provide the following information on the finished product;</p> <ol style="list-style-type: none"> <li>Generic or INN name</li> <li>Brand name /Product Name</li> <li>Dosage Form</li> <li>Strength of the finished product</li> <li>Reference of the official standards of the finished product (eg: compendia pharmacopeias or manufacturer's in-house specification).</li> <li>List of all the ingredients in the dosage form and their amount on a per unit basis, as per the label claim and batch quantities.</li> </ol>	<p>Required in emergency situation</p>
<p>GMP certificate (Valid WHO type GMP certificate).</p>	<p>Required in emergency situation</p>
<p>Batch release of lot release certificate of the vaccine</p>	<p>Required in emergency situation</p>
<p>Information of all ADR reports and reported death during the clinical trial</p>	<p>Required in emergency situation</p>

Approved on: 1<sup>st</sup> December 2020



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