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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
1. Company Profile The company profile documents should include the detail of the following. a. Brief history of company with its detailed address including phone and fax number. b. Brief description of the Organization. c. Organization chart d. List of the product category manufactured	Required in emergency situation

2. <u>Product Profile:</u> The product profile should provide the following information on the finished product; a. Generic or INN name b. Brand name /Product Name c. Dosage Form d. Strength of the finished product e. Reference of the official standards of the finished product (eg: compendia pharmacopeias or manufacturer's in-house specification). f. 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.	Required in emergency situation
GMP certificate (Valid WHO type GMP certificate).	Required in emergency situation
Batch release of lot release certificate of the vaccine	Required in emergency situation
Information of all ADR reports and reported death during the clinical trial	Required in emergency situation

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