

Government of the People's Republic of Bangladesh
Directorate General of Drug Administration
Ministry of Health and Family Welfare
Aushad Bhaban, Mohakhali, Dhaka-1212
www.dgda.gov.bd

Memo No.: DGDA /Admin/40-1/08 (Part)/ 527

Date: 25/05/2023

Subject: Use of DGDA-Regulatory Information Management System (DGDA-RIMS) for Submitting Vaccine/Biosimilar Product Registration Applications.

We are pleased to announce that the launching of the DGDA-RIMS for the registration application of vaccine/biosimilar products in Bangladesh took place on May 11, 2023. This system is in line with the recommendation of WHO assessor as per the WHO Global Benchmarking Tool for DGDA's maturity level 3.

The DGDA-RIMS has been developed by DGDA with the technical assistance of USAID MTaPS program and is now live in the DGDA website (rims.dgda.gov.bd). A comprehensive training program and User Acceptance Test (UAT) was conducted to DGDA and the marketing authorization holders (MAH) for vaccines.

From 25 May 2023, and onwards, all manufacturers of vaccines/biosimilars are required to apply using DGDA-RIMS with a gmail address. For any assistance related to software operation, DGDA is available to provide support. To aid in software use, a user manual is available online (www.dgda.gov.bd) for all users.

We are confident that DGDA-RIMS will enhance the efficiency and accuracy of the registration process for vaccine/biosimilars. We appreciate your cooperation and look forward to your successful use of the DGDA-RIMS system.

ok

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5 MAY 2023

Distribution:

1. Managing Director, Incepta Pharmaceuticals Ltd.
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Director General
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