APPLICANT'S CONSENT TO SHARE PRODUCT ASSESSMENT AND GMP INSPECTION REPORTS WITH NATIONAL MEDICINES REGULATORY AUTHORITIES (NMRA's)

I, ……..……..…….. the undersigned on behalf of …… who is the Marketing Authorisation Holder/Applicant, do hereby consent that the Tanzania Medicines and Medical Devices Authority (TMDA) shares the Assessment and GMP Inspection reports with Medicines National Regulatory Authorities (NRAs) for the medicinal product(s) listed below.

I further consent that, if relevant, the sharing should also be extended to results of laboratory testing and subsequent variations as well as information and documentation on any actions taken by TMDA post-marketing authorization of the medicinal product.

Medicinal Product(s) Details:

S/No.	Product Brand Name/ Common Name (INN)	Product Strength	Product Dosage Form and Pack Size	Name and address of FPP Manufacturer	TMDA Registration Number
1.					
2.					

Manufacturing facility Details:

S/No.	Name and Physical address of the manufacturer	Summary of activities of manufacture (e.g. manufacturing, packing). Indicate dosage forms and type of products (e.g. tablets; cephalosporin containing products), production line
1.		
2.		

Name of Authorized Signing Official *("the Applicant/Marketing Authorization Holder"):*……

Company Name:……..

Physical address & Postal address:……

……

Email: ……..

Telephone:……..

Signature …….. Date:……

Please sign the completed template, scan and send it as an attachment by email to medicines@tmda.go.tz and copy it to begumisa.casmil@tmda.go.tz with subject: "Consent to TMDA to share documents for the product(s) <name of the product(s)>". A signed paper copy should also be sent to TMDA, at the address shown below.

TMDA Headquarters, Plot No. 56/1, Block E, Kisasa B Centre, Swaswa Road, P. O. Box 1253, Dodoma – Tanzania, Telephone: +255 (26) 2961989/2061990/+255 (22) 2450512/2450751/2452108, Email: info@tmda.og.tz, Website: **www.tmda.go.tz** Toll free: 0800110084