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To,
The Director,
National Pharmaceutical Regulatory Agency (NPRA),
Malaysia

Date: July 25, 2023

Subject: Clarification to justify the purpose of QR code in the outer carton

Name of the Product: LEVETROY - Levetiracetam 100 mg/mL Concentrate for Solution for Infusion, 5 ml Ampoules

Dear Sir/Madam,

We would like to clarify that the purpose of QR code on outer carton of LEVETROY, 5ml is for monitoring inventory of the product, such as batch number, expiry date and manufacturing date. The QR code is NOT for linkage to any website.

We assure the NPRA, Malaysia that QR code on outer carton is as per APPENDIX 19: GENERAL LABELLING REQUIREMENTS of Drug Registration Guidance Document (DRGD) Third Edition, Fourth Revision January 2023.

We request kind authority to accept above clarification and grant us approval for LEVETROY - Levetiracetam 100 mg/mL Concentrate for Solution for Infusion, 5 ml Ampoules.

For, Troikaa Pharmaceuticals Limited

S. Gami
25/07/23



Suresh Gami

Sr. Manager - Regulatory Affairs

Troikaa Pharmaceuticals Limited

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