[National Pharmaceutical Regulatory Agency (NPRA) letterhead]

Our ref: NPRA/007/06/R/001(4) Vol. 2
Date: 25 November 2021

To:
All Product Registration Holders,
All Applicants of the Evaluation on the Need for BE Study Specific Inspection (BEDE),
All Applicants for Bioequivalence (BE) Centre Inspections,

YBhg. Datuk / Dato'/ Prof./ Dr./ Sir/ Madam,

REJECTION OF BE STUDIES CONDUCTED AT THE BE CENTRES SYNCHRON RESEARCH SERVICES AND PANEXCELL CLINICAL LAB FOLLOWING INSPECTION FINDINGS BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION (US FDA)

With due respect, the matter above is referred.

2. For your information, the US FDA had issued a notification to pharmaceutical companies via the US FDA website on 16 September 2021 stating that all clinical and bioanalytical studies conducted at the BE Centres Synchron Research Services and Panexcell Clinical Lab will not be accepted in marketing authorization applications. This notification is done following observations related to data integrity found in US FDA inspections at both BE Centres. The US FDA decided that all BE studies that were conducted at both effected BE Centres would need to be repeated at BE Centres other than Synchron Research Services and Panexcell Clinical Lab. Details of this notification can be obtained from https://www.fda.gov/drugs/drug-safety-and-availability/notification-pharmaceutical-companies-clinical-and-bioanalytical-studies-conducted-panexcell.

3. Following the notification by the US FDA, the National Pharmaceutical Regulatory Agency (NPRA) in the Committee for Premises and Study Inspections Meeting No. 12/2021 on 16 November 2021 decided **TO REJECT** all BE studies conducted at both affected BE Centres mentioned above. This decision will involve the following:

i. Rejection of all application for the Evaluation on the Need for BE Study Inspection (BEDE) received;
ii. Cancellation of all BE study inspection exemptions granted via BEDE applications;
iii. Cancellation of all letter of acceptance issued via the BE Inspection Report Evaluation applications (BEIR);
iv. Rejecting and cancelling all Study Specific Inspection applications including inspections approved in the Ministry of Health Malaysia Trust Fund Meeting.

4. NPRA also decided that acceptance of BE studies from both affected BE Centres to support product registration evaluation by the Centre of Product & Cosmetic Evaluation can only be

considered if the BE studies are conducted at the BE Centres after it had been listed on the NPRA BE Centre Compliance Programme.

5. This decision will be enforced with **IMMEDIATE EFFECT**.

6. Should you require any additional information on this matter, kindly get in touch with our officers via the email beec@npra.gov.my. The cooperation and attention from YBhg. Datuk/ Dato'/ Prof./ Dr./ Sir/ Madam is highly appreciated.

Thank you.

"SHARED PROSPERITY VISION 2030"
"TO SERVE THE COUNTRY"

I who carries out the trust,
{signature}
(ROSILAWATI BINTI AHMAD) RPh. 1413
Deputy Director
p.p. Director
National Pharmaceutical Regulatory Agency,
Ministry of Health Malaysia.

[administrative information]

c.c. Deputy Director, Centre of Product & Cosmetic Evaluation
Deputy Director, Centre of Compliance & Quality Control
Deputy Director, Centre of Regulatory Coordination & Strategic Planning