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Ruj. Kami : NPRA/007/06/R/001(20)Jld.2
Tarikh : 31 Januari 2022

SEMUA PEMEGANG PENDAFTARAN PRODUK,
SEMUA PEMOHON PENILAIAN PENENTUAN KEPERLUAN PEMERIKSAAN KAJIAN BIOEKUIVALENS (BEDE),
SEMUA PEMOHON PEMERIKSAAN PUSAT KAJIAN BIOEKUIVALENS (BE)

YBhg. Datuk/ Dato'/ Prof./ Dr./ Tuan/ Puan,

PENOLAKAN KAJIAN BIOEKUIVALENS (BE) YANG DIJALANKAN OLEH PUSAT KAJIAN *MICRO THERAPEUTIC LABS* SUSULAN PENEMUAN PEMERIKSAAN *EUROPEAN MEDICINES AGENCY* (EMA)

Saya dengan hormatnya merujuk kepada perkara di atas.

2. Untuk makluman, pihak EMA telah mengeluarkan notifikasi kepada syarikat-syarikat farmaseutikal melalui laman sesawang rasmi EMA bertarikh 24 Mac 2017 di mana kajian-kajian bioekuivalens yang dijalankan di Pusat Kajian BE *Micro Therapeutic Labs* beralamat di bawah tidak boleh diterima bagi tujuan pendaftaran produk.

Fasiliti 1 : Micro Therapeutic Research Labs Pvt. Ltd Rajam Bhavanam, No. 6, Kamarajar Salai, Selaiyur, East Tambaram, Chennai-600 059, Tamil Nadu.
Fasiliti 2 : Micro Therapeutic Research Labs, No. 29 A, Krishna Madhuravanam, Vellokinar Pirivu, Thudiyalur, Coimbatore-641 029, Tamil Nadu.

Pengumuman ini berikutan penemuan-penemuan yang melibatkan isu ketidakpatuhan Amalan Klinikal Baik (GCP) dan integriti data hasil pemeriksaan EMA di kedua-dua tapak kajian tersebut. Sehubungan dengan itu, pihak EMA telah memutuskan bahawa kajian-kajian BE yang dijalankan sepanjang bulan Jun 2012 sehingga Jun 2016 di kedua-dua fasiliti tersebut tidak boleh diterima sebagai dokumen sokongan bagi pendaftaran produk di negara-negara Kesatuan Eropah. Selain itu, pihak EMA juga memutuskan untuk menggantung status pendaftaran produk yang telah diluluskan menggunakan kajian BE yang dijalankan di kedua-dua fasiliti tersebut sehingga data alternatif dapat dikemukakan untuk membuktikan status bioekuivalens produk yang terlibat. Maklumat lanjut berkenaan pengumuman tersebut boleh dicapai melalui pautan: https://www.ema.europa.eu/en/news/ema-recommends-suspension-medicines-due-unreliable-studies-micro-therapeutic-research-labs.

3. Susulan notifikasi oleh pihak EMA, pihak Bahagian Regulatori Farmasi Negara (NPRA) melalui Mesyuarat Jawatankuasa Penilaian Pemeriksaan Premis dan Kajian Bil 1/2022 pada 10 Januari 2022 telah memutuskan untuk **TIDAK MENERIMA** semua kajian BE

yang dijalankan pada bulan Jun 2012 – Jun 2016 di kedua-dua fasiliti tersebut. Keputusan ini melibatkan perkara-perkara berikut:

i. Penolakan kesemua permohonan Penilaian Penentuan Keperluan Pemeriksaan Kajian Bioekuivalens (BEDE) bagi kajian BE yang dijalankan dalam tempoh Jun 2012 – Jun 2016,
ii. Kesemua kajian BE yang dijalankan di kedua-dua tapak kajian tersebut dalam tempoh Jun 2012 – Jun 2016 perlu diperiksa sebelum diterima untuk penilaian lanjut oleh pihak Pusat Penilaian Produk & Kosmetik (PPPK).
iii. Kajian BE yang dijalankan di kedua-dua fasiliti bermula bulan Julai 2016 dan seterusnya layak dipertimbangkan melalui permohonan BEDE.
iv. Kajian BE yang dijalankan di Fasiliti 1 selepas tarikh 9 Januari 2019 boleh diterima untuk penilaian lanjut pihak PPPK memandangkan fasiliti tersebut telah disenaraikan dalam Program Komplians Pusat Kajian BE NPRA pada 9 Januari 2019 – 8 Januari 2022.

4. Keputusan di atas adalah berkuat kuasa **SERTA MERTA**.

5. Untuk maklumat lanjut berhubung perkara ini, sila berhubung dengan pegawai NPRA melalui e-mel beec@npra.gov.my. Kerjasama dan perhatian daripada pihak YBhg. Datuk/ Dato'/ Prof./ Dr./ Tuan/ Puan dalam perkara ini adalah amat dihargai.

Sekian, terima kasih.

"WAWASAN KEMAKMURAN BERSAMA 2030"

"BERKHIDMAT UNTUK NEGARA"

Saya yang menjalankan amanah,

(DR ROSHAYATI BINTI MOHAMAD SANI) RPh. 1449
Pengarah
Bahagian Regulatori Farmasi Negara
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Timbalan Pengarah
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Bahagian Regulatori Farmasi Negara

Timbalan Pengarah
Pusat Komplians & Kawalan Kualiti
Bahagian Regulatori Farmasi Negara

Timbalan Pengarah
Pusat Koordinasi & Perancangan Strategik Regulatori
Bahagian Regulatori Farmasi Negara

[National Pharmaceutical Regulatory Agency (NPRA) letterhead]

Our ref: NPRA/007/06/R/001(20) Vol. 2
Date: 31 January 2022

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 BIOEQUIVALENCE (BE) STUDIES CONDUCTED AT THE BE CENTRE MICRO THERAPEUTIC LABS FOLLOWING INSPECTION FINDINGS BY THE EUROPEAN MEDICINES AGENCY (EMA)

With due respect, the matter above is referred.

2. For your information, the EMA had issued a notification to pharmaceutical companies via the EMA website on 24 March 2017 stating that all BE studies conducted at the following two facilities of the BE Centre Micro Therapeutic Labs will not be accepted in marketing authorization applications.

Facility 1 : Micro Therapeutic Research Labs Pvt. Ltd Rajam Bhavanam, No. 6, Kamarajar Salai, Selaiyur, East Tambaram, Chennai-600 059, Tamil Nadu.
Facility 2 : Micro Therapeutic Research Labs, No. 29 A, Krishna Madhuravanam, Vellokinar Pirivu, Thudiyalur, Coimbatore-641 029, Tamil Nadu.

This notification is done following observations related to GCP non-compliance and data integrity found in EMA inspections at both facilities. The EMA decided that the data from BE studies conducted at both affected facilities between June 2012 and June 2016 cannot be accepted as supporting data for marketing authorization in the EU. This decision also led to the EMA suspending marketing authorisation of products registered with BE studies conducted at both facilities until alternate data establishing bioequivalence is provided. Details of this notification can be obtained from https://www.ema.europa.eu/en/news/ema-recommends-suspension-medicines-due-unreliable-studies-micro-therapeutic-research-labs.

3. Following the notification by the EMA, the National Pharmaceutical Regulatory Agency (NPRA) in the Committee for Premises and Study Inspections Meeting No. 1/2022 on 10 January 2022 decided **TO REJECT** all BE studies conducted at both affected facilities mentioned above. This decision will involve the following:

i. Rejection of all application for the Evaluation on the Need for BE Study Inspection (BEDE) for BE studies conducted between June 2012 and June 2016;

ii. All BE studies conducted at both facilities between June 2012 and June 2016 will require inspections before acceptance for further evaluation by the Centre of Product & Cosmetic Evaluation (CPCE);

iii. BE studies conducted at both facilities from July 2016 onwards will be eligible for BEDE application.

iv. BE studies conducted at Facility 1 can be accepted for further evaluation by CPCE if the studies were conducted after 9 January 2019 as the facility has been listed in NPRA BE Centre Compliance Programme from 9 January 2019 – 8 January 2022.

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

5. 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}
(DR ROSHAYATI BINTI MOHAMAD SANI) RPh. 1449
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