

Biro Pengawalan Farmaseutikal Kebangsaan National Pharmaceutical Control Bureau KEMENTERIAN KESIHATAN MALAYSIA MINISTRY OF HEALTH MALAYSIA

Rui. Kami

: (20)dlm.BPFK/PPP/01/03 Jld.3

Tarikh: 0 5 SEP 2014

SEMUA PEMEGANG PENDAFTARAN PRODUK

PERSATUAN YANG BERKENAAN (SEPERTI PADA SENARAI EDARAN)

Tuan/Puan.

PERMOHONAN PENDAFTARAN PRODUK BARU MELALUI PROSEDUR SEPARA MANUAL (SEMI MANUAL) QUEST 3

Adalah saya merujuk kepada perkara seperti di atas.

- Sepertimana tuan/puan sedia maklum berikutan kesukaran yang dihadapi oleh semua pelanggan dalam menggunakan sistem Quest 3. Maka, sistem Quest 2 telah diaktifkan semula untuk pendaftaran baru produk tradisional mulai 1 April 2014. Walaubagaimanapun, proses penyaringan masih perlu dikemukakan secara separa manual. (Rujuk surat BPFK bil (28)dlm.BPFK/PPP/06/04 Jld.6 bertarikh 1 April 2014.)
- 3. Disamping itu, mulai 1 Ogos 2014, semua permohonan pendaftaran baru bagi produk kategori seperti berikut perlu dikemukakan melalui Prosedur Separa Manual (Semi Manual):
 - a) Produk Generik (racun berjadual dan bukan racun berjadual)
 - b) Produk Ubat Baru
 - c) Produk Biologik
 - Produk Suplemen Kesihatan
- Bersama ini disertakan carta aliran kerja bagi prosedur penghantaran permohonan pendaftaran baru secara separa manual melalui sistem Quest 3. Pihak tuan/ puan dinasihatkan untuk meneliti aliran kerja ini bagi melancarkan proses permohonan pendaftaran produk.
- Kerjasama sepenuhnya daripada pihak tuan/ puan dalam hal ini amat dihargai.

Sekian, terima kasih.

"BERKHIDMAT UNTUK NEGARA"

Saya yang menurut perintah,

Su A D

SITI AIDA ABDULLAH Timbalan Pengarah

Pusat Pembangunan Organisasi

Pusat Pembangunan Organisasi
Biro Pengawalan Farmaseutikal Kebangsaan Pengarah Regulatori Farmas Kementerian Kesihatan Malaysia

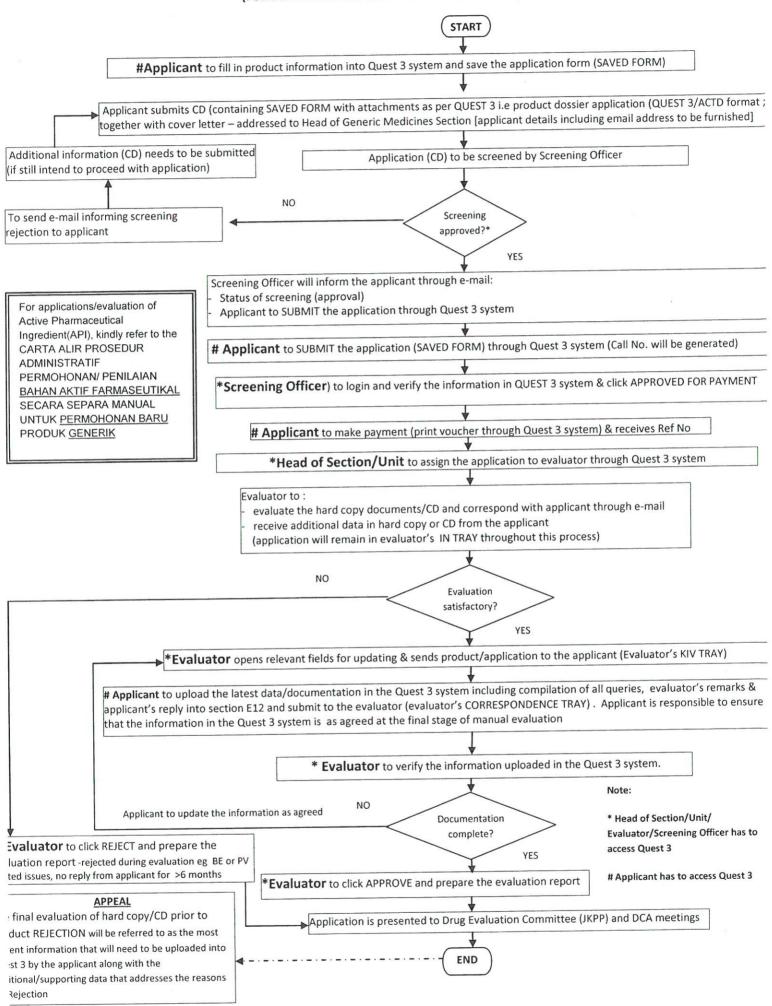
Biro Pengawalan Farmaseutikal Kebangsaan

Kementerian Kesihatan Malaysia

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http://www.bpfk.gov.my

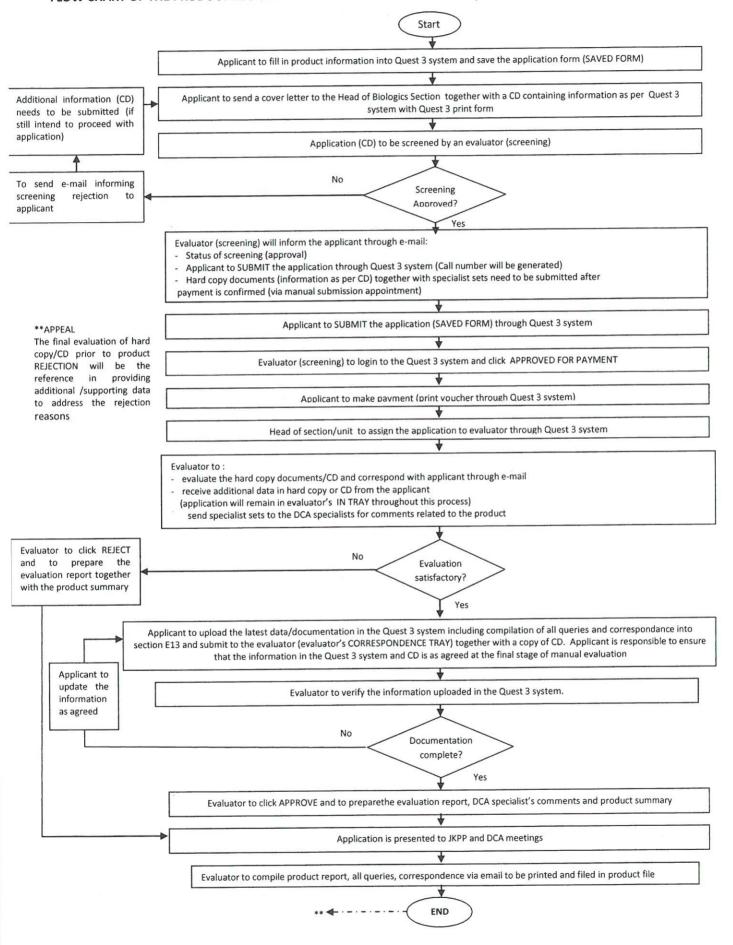
FLOW CHART ON THE SEMI-MANUAL SUBMISSION PROCEDURE FOR GENERIC MEDICINES APPLICATIONS FOR REGISTRATION (FOR SCHEDULED AND NON-SCHEDULED POISONS)



FLOW CHART OF THE PRODUCT REGISTRATION APPLICATION PROCEDURE (SEMI MANUAL) FOR NEW DRUG SECTION Start

Applicant to fill in product information into Quest 3 system and save the application form (SAVED FORM) Applicant to send a cover letter to the Head of New Drug Section together with a CD containing information as per Quest 3 system with Quest 3 print form Additional information (CD) needs to be submitted (if still intend to proceed with Application (CD) to be screened by an evaluator (screening) application) Screening No To send e-mail informing approved? screening rejection applicant Evaluator (screening) will inform the applicant through e-mail: - Status of screening (approval) Applicant to SUBMIT the application through Quest 3 system (Call number will be generated) Hard copy documents (information as per CD) together with specialist sets need to be submitted after payment is confirmed Applicant to SUBMIT the application (SAVED FORM) through Quest 3 system **APPEAL The final evaluation of hard Evaluator (screening) to login to the Quest 3 system and click APPROVED FOR PAYMENT copy/CD prior to product REJECTION will be the Applicant to make payment (print voucher through Quest 3 system) reference in providing additional /supporting data address the rejection Head of section/unit to assign the application to evaluator through Quest 3 system Evaluator to: - evaluate the hard copy documents/CD and correspond with applicant through e-mail receive additional data in hard copy or CD from the applicant (application will remain in evaluator's IN TRAY throughout this process) send specialist sets to the DCA specialists for comments related to the product Evaluator to click REJECT Evaluation and to prepare the evaluation report together satisfactory? with the product summary Yes Evaluator to key in the queries into Quest 3 system and send to applicant (evaluator's KIV TRAY) Applicant to upload the latest data/documentation in the Quest 3 system including compilation of all queries, evaluator's remarks & applicant's reply into section E13 and submit to the evaluator (evaluator's Applicant to CORRESPONDENCE TRAY) together with a copy of CD. Applicant is responsible to ensure that the information in update the the Quest 3 system and CD is as agreed at the final stage of manual evaluation information as agreed Evaluator to verify the information uploaded in the Quest 3 system. Documentation complete? Yes Evaluator to click APPROVE and prepare the evaluation report, DCA specialist's comments together with product summary Application is presented to JKPP and DCA meetings

FLOW CHART OF THE PRODUCT REGISTRATION APPLICATION PROCEDURE (SEMI MANUAL) FOR BIOLOGICS SECTION



FLOW CHART ON THE SEMI-MANUAL SUBMISSION PROCEDURE FOR HEALTH SUPPLEMENT PRODUCT APPLICATIONS FOR REGISTRATION

