

Q&A

Questions	Answers
1. Will clinical trial be affected by the moratorium of QUEST system?	<ul style="list-style-type: none"> • No. The work flow will be as it is since it is still in manual submission
2. Is there Product Updating?	<ul style="list-style-type: none"> • No Product Updating. • Please approach BPFK if there is incomplete data (e.g. text field and attachment discrepancy.) • Data will be updated on case-to-case basis. • Subject to BPFK approval.
3 Screening submission	<ul style="list-style-type: none"> • Screening online submission by 13th Mei 2016 at 5.000pm. Results of screening (Approved/rejected) will be informed to applicant by 23th May 2016. Payment must reach BPFK by 1st June 2016.
4 Can we do Product Renewal Application	<ul style="list-style-type: none"> • No renewal during moratorium period. • Renewal with payment must be done by 1st June 2016. Otherwise, applicant shall renew in Q3+ on 1st August 2016onwards.
5 Cosmetic	<ul style="list-style-type: none"> • Cosmetic notification will not be affected as much as pharmaceutical products. • Cosmetic will have 1 month moratorium (1st June 2016 – 1st July 2016). Submission of renewal on 1st July 2016 • Payment to be made to BPFK by 1st June 2016.

<p>6 Request Longer Transitory Period for renewal soon-to-expired-products</p> <p>7 USB Token</p>	<ul style="list-style-type: none"> • Applicants/product holders bear the responsibility to keep track the status of their own products. • Renewal of pharmaceutical products including traditional products can be done as early as 6 months before the expiry date. • If the product is going to expire within the moratorium period of 1st June 2016 to 31st August 2016, applicant has to do the renewal with payment by 1st June 2016. • If product expiry after 31st August 2016 –either or i) renew now as renewal is open up to 6 months before expiry date.ii) renew in QUEST3+ • For applicants who don't have pending tasks like renewal, correspondence and new submission, they should have no concern about the moratorium. • Existing USB Token provided by DigicertSdnBhd can be used in QUEST3+ until it is expired. Thereafter, new token must be applied from MSC Trustgate. • If you have pending tasks in Quest2 or Quest3, please renew your token with DigicertSdn Bhd. As Quest2 and Quest3 will still in production until 1 July 2017. • Link for MSC TrustgateSdnBhd tokens will be available once Q3+ is launched
<p>8 For imported product. Request to extend dateline for renewal.</p>	<ul style="list-style-type: none"> • Renewal extended until 1st June 2016.
<p>9 Generic product</p>	<ul style="list-style-type: none"> • For generic products which are given exemption of GMP inspection till 1st July 2016, they still have to comply to screening/variation by 13th Mei 2016. • May contact Mr. Tan or Head of respective sections if special consideration is needed.
<p>10 Contingency plan (urgent variation)</p>	<ul style="list-style-type: none"> • Submission of variation by 13th Mei 2016 at 5.00pm. Result (approved/ reject). By 1st June 2016, applicant to proceed with payment. There will be no correspondence for screening and variation. BPFK is committed to finish all the pending variation submissions by 1st July 16. However, conditional approval may be granted in order to fasten the process. Manual submission during the moratorium period is not allowed. • Variation fee will be charged from 1st July 2016 and onward.
<p>11 Existing variation</p>	<ul style="list-style-type: none"> • Existing variations evaluation will be on going till 1st July 2017.

12 Slide/QnA	<ul style="list-style-type: none"> • Compilation of Q&A and slides will be uploaded in BPFK website. • Applicants may refer to respective section (ICT for technical questions, PPP for registration and variation matters) if there are further questions. Representatives from PPP : Pn. Somiyation, Dr. Azizah, Pn. Seetha. • Associations will be requested to select few companies to join in Provisional Acceptance Test (PAT).
13 Data migration	<ul style="list-style-type: none"> • There will be 2 phases of migration. • Migration of registered and rejected products including attachments from Q2 and Q3 to Q3+ by 1st August 2016. • Applications that are approved during 1st June 2016 to 1st July 2017 will be migrated to Q3+ on scheduled basis. • Applicants to take note that attachments in Q3+ could not be viewed until 1st June 2016 though Q3+ is launched on 1st July 2016. • All Attachments Q2 and Q3 will be migrated into Q3+.
14 Safety update changes	<ul style="list-style-type: none"> • Safety variation/updates/warning will proceed as usual. • Applicants to pay variation fees although the request to amend data (e.g. label) is issued by DCA as the amendment is for consumers.
15 Submitted and paid applications by 1 st June 2016	<ul style="list-style-type: none"> • To continue evaluation in Q2 and Q3 until 1st July 2017
16 Payment	<ul style="list-style-type: none"> • Q3+ only accept online payment. (Refer to Slide page no 12) • No bank draft (no manual). No AMEX credit card option in Q3+. All payments must go through Q3+.
17 Can my oversea principal make a payment for submission?	<ul style="list-style-type: none"> • Can, with a valid token.
18 Receipt generation	<ul style="list-style-type: none"> • Receipt will be issued on the name of registered company in system. Receipt is auto generated by the system once payment is made.
19 Licensing/CPP	<ul style="list-style-type: none"> • Moratorium will not affect License Application. All application may be submitted after Quest 3+ go live.

20 Correspondence	<ul style="list-style-type: none"> All submission will receive full integrated comment after evaluation (Active Pharmaceutical Ingredient Unit/Center of Quality Control/Center of Product Registration).
21 Timeline in Quest3+	<ul style="list-style-type: none"> Will be calculated based on working days. Public Holidays and weekends are not included in timeline.
22 Token expired before 1 st July 2017	<ul style="list-style-type: none"> Tokens expiring before 1st July 2017 are encourage to renew token if the still product under evaluation in Quest 2 or Quest 3.

For General issue regarding Q3+ applicant may contact Helpdesk (ext 5560, 5561, 5562)

For Technical issue regarding Q3+ (registration, evaluation, screening) applicant may contact Pusat Pendaftaran Produk

Online Payment options available in QUEST3+:

1. Business to Customer (B2C) – Personal Account

- i) [Affin Bank Berhad](#)
- ii) [Alliance Bank Malaysia Berhad](#)
- iii) [AmBank \(M\) Berhad](#)
- iv) [Bank Islam Malaysia Berhad](#)
- v) Bank Rakyat
- vi) [CIMB Bank Berhad](#)
- vii) [Hong Leong Bank Berhad](#)
- viii) [Malayan Banking Berhad](#)
- ix) [Public Bank Berhad](#)
- x) [RHB Bank Berhad](#)
- xi) [United Overseas Bank \(Malaysia\) Bhd.](#)

2. Business to Business (B2B) – Corporate Account

- i) Maybank

3. Credit Card

- i) VISA
- ii) MasterCard

	MasterCard Internet Gateway Service (MiGS) gateway	MyGovXchange (MGX) gateway
Payment Method	Credit card: MasterCard & VISA	FPX (Online banking): B2B & B2C
Service Charge before GST (Costat NPCB)	1.8%	B2B: RM1.00/transaksi B2C: RM0.50/transaksi