QUEST 3+ :
UPDATES ON PRODUCT REGISTRATION PROCESS

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Presentation Outline:

- Introduction of QUEST System
- Background of QUEST System Development
  - Objective
  - Timeline for Development & Completion of Q3+
  - QUEST 3+ System Architecture
  - Integration of systems
  - Browser Compatibility
- QUEST 3+ : Updates on Product Registration Process

INTRODUCTION (QUEST)

- NPCB Online System

- Quality, Efficacy & Safety (QUEST) online submission system

- Online transactions such as application for product registration, variations, re-registration, market sampling and other transactions such as licensing and surveillance activities.

INTRODUCTION (QUEST)

o **Users:**

Front end: Product License Holder, Manufacturer, Importer, Wholesaler and other related users

Back end: NPCB officers (evaluators, administrators)

STATISTICS OF USERS FOR QUEST 2 & QUEST 3

User	Number
Front end (Q2 & Q3) (Product holder, manufacturer, importer, wholesaler, etc)	~ 17,500 (up to June 2015)
Back end (NPCB evaluators)	~ 300

Table 1: Number of registered users for QUEST 2 & QUEST 3

	2012			2013			2014		
	QUEST 2	QUEST 3	Total	QUEST 2	QUEST 3	Total	QUEST 2	QUEST 3	Total
Prescription	109	248	357	21	220	241	16	219	235
Non-prescription	24	59	83	5	49	54	5	47	52
Natural products	38	527	565	0	578	578	25	565	590
Health supplements	5	156	161	0	85	85	0	128	128
Veterinary	45	0	45	63	0	63	207	0	207
Total	**221**	**990**	**1211**	**89**	**932**	**1021**	**253**	**959**	**1212**

Table 2 : Number of products registered through QUEST 2 & QUEST 3 for the year 2012 - 2014

BACKGROUND OF QUEST SYSTEM DEVELOPMENT

2003 → **2008** → **2010** → **2015** → **2016/2017**

2003
- QUEST 2 system modules launched and utilized

2008
- Development of the QUEST 3 system.

2010
- QUEST 3 system modules launched and utilized.

2015
- Utilization of both QUEST 2 and QUEST 3 systems concurrently
- Development of the QUEST 3+ system

2016/2017
- Utilization of sole system of QUEST 3+
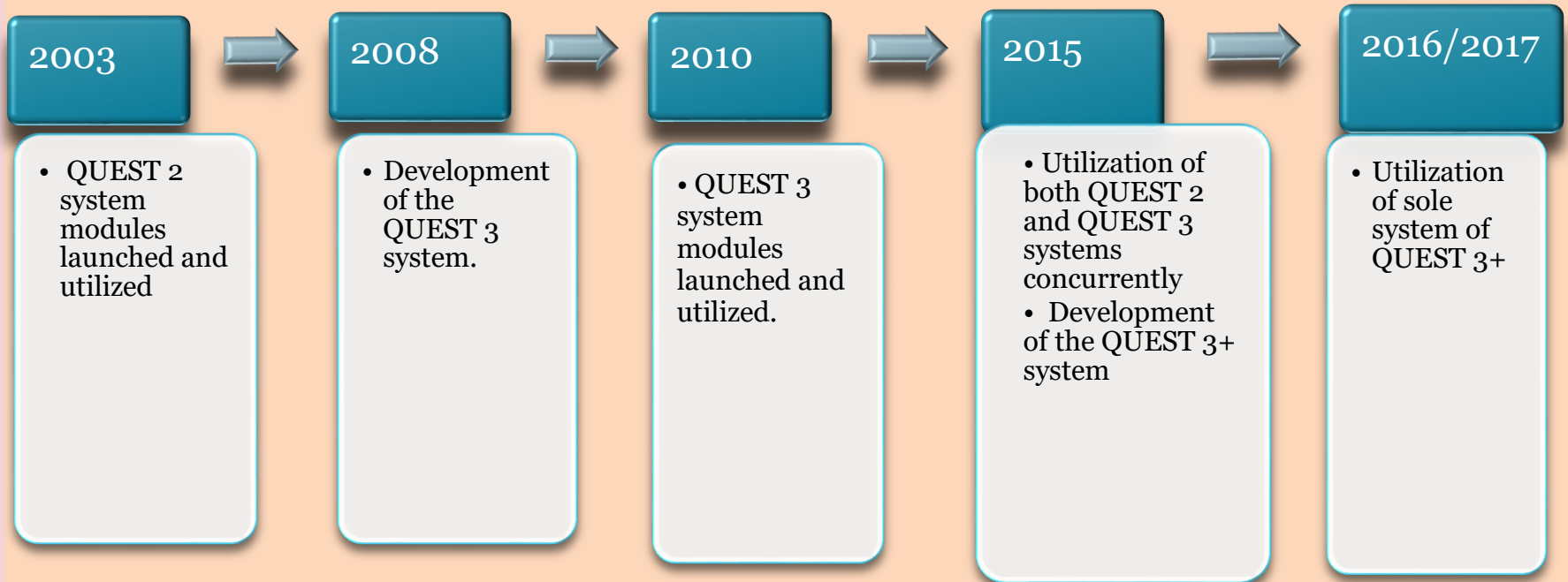
Specification	QUEST 2	QUEST 3	QUEST 3+
Development year	2003/2004	2008/2009	2015/2016

OBJECTIVE OF DEVELOPING A NEW QUEST 3+ SYSTEM

➢ To replace the current legacy systems – Quest 2 & Quest 3 into one system

➢ The system is developed to be equipped with:

❖ Tighter Security features

❖ 5 new online modules with correspondence – slide 29

❖ Effective correspondence features - alerts

❖ More user friendly – online renewal of tokens and PIN blocking management

➢ Phase 1 : To ensure a fully functioning online submission system of QUEST 3+

  (same function and features available as current

  QUEST 2 & QUEST 3)

➢ Phase 2 : To enhance the available functions and features of QUEST 3+ and develop integration with other agencies relevant

➢ *subject for approval by the MOH & Treasury of Malaysia

TIMELINE FOR DEVELOPMENT & COMPLETION OF QUEST 3+

- October 2014 : Tender for the project was opened.
- November 2014 : Vendor selection and tender closed.

- ✓ Q1 2015   : Kick Off meeting with Vendor
- ✓ Q2 2015   : System requirement & Design specification

- ✓ Q3 2015   : User acceptance Test
- ✓ Q4 2015   : Data Migration
- ✓ Q 1 2016   : Final acceptance Test & Handing Over

QUEST 3+ SYSTEM ARCHITECTURE
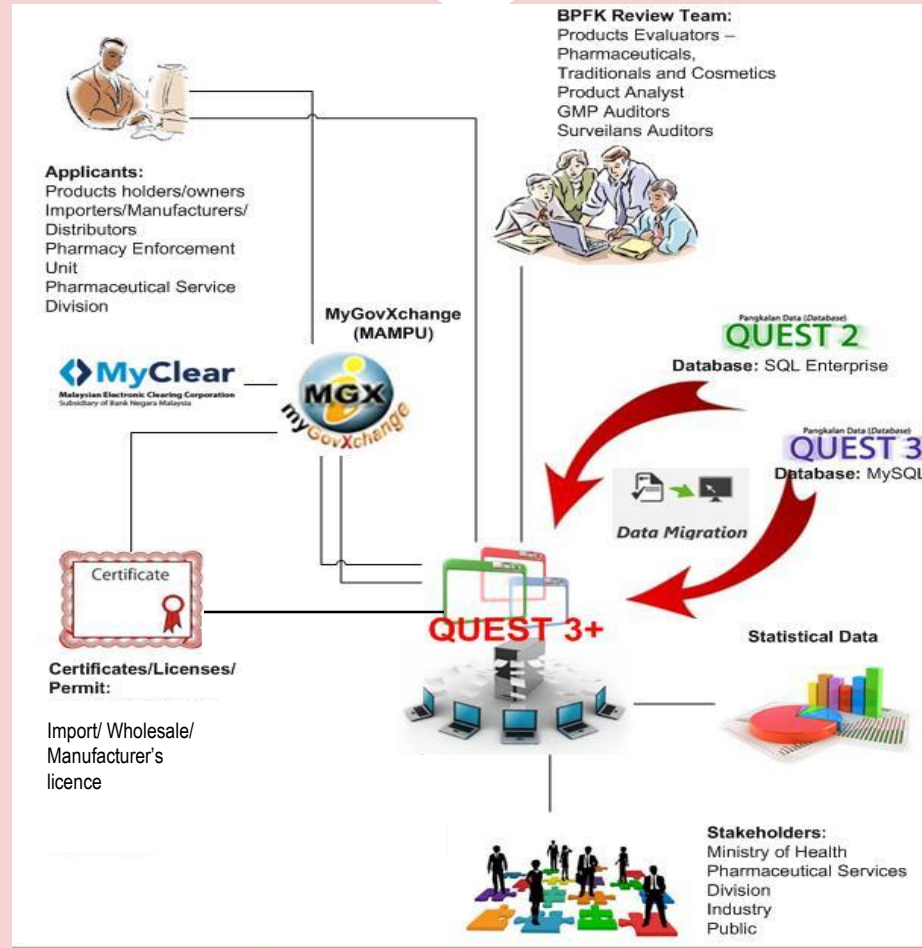
QUEST 3+ SYSTEM INTEGRATION

|	Integrated Sytem	Provider	Features
1.	myGovXchange (MGX) http://mygov.malaysia.gov.my	MAMPU	Online Payment ❖ Secured by MyClear, a subsidiary of Bank Negara Malaysia
2.	Trustgate https://www.msctrustgate.com	MSC Trustgate.com Sdn. Bhd.	Certification Authority for e-business ❖ Online management of forgotten passwords ❖ Online membership renewal

Table 3 : List of systems to be integrated with Quest 3+
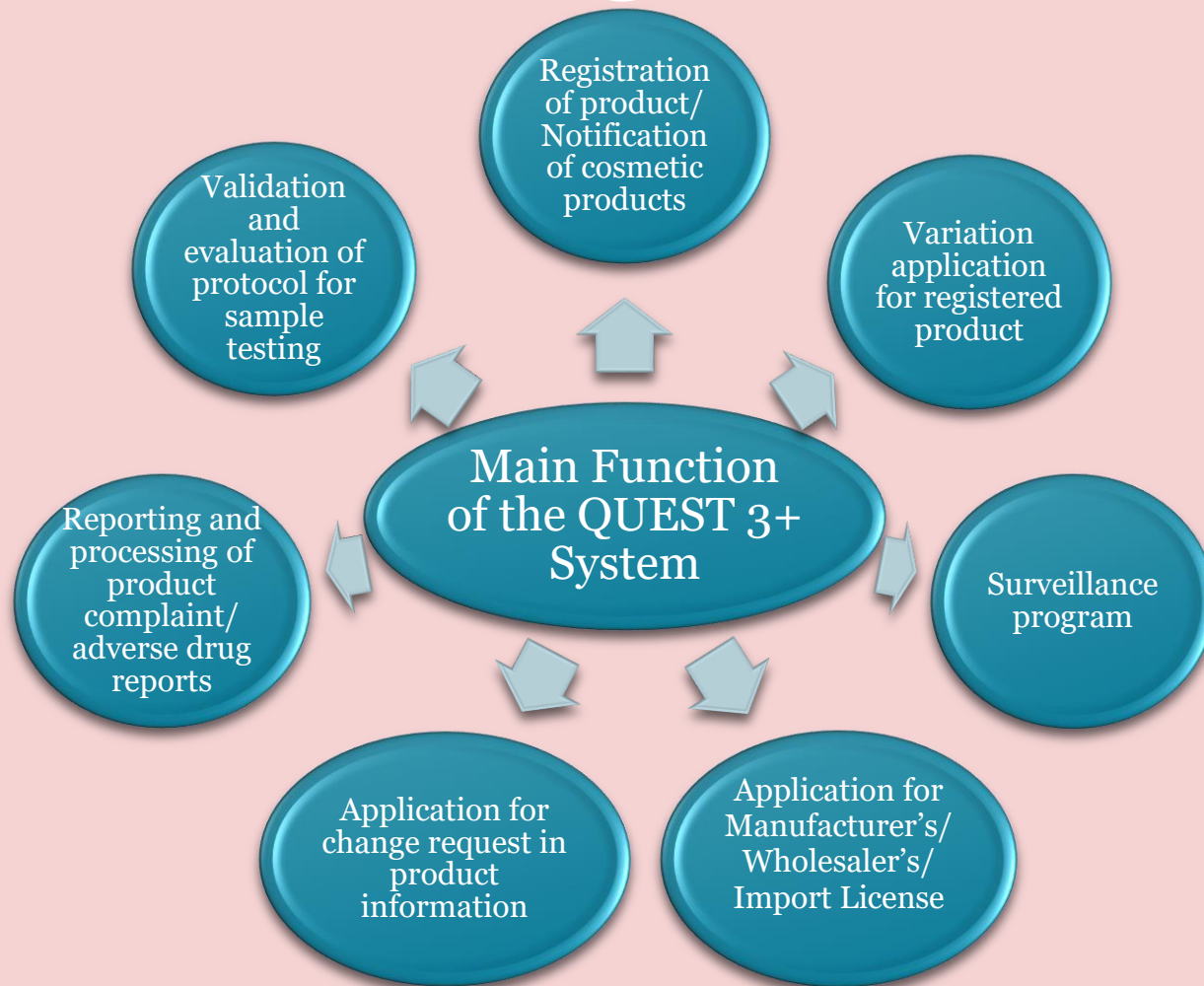
USERS OF THE QUEST 3+ SYSTEM
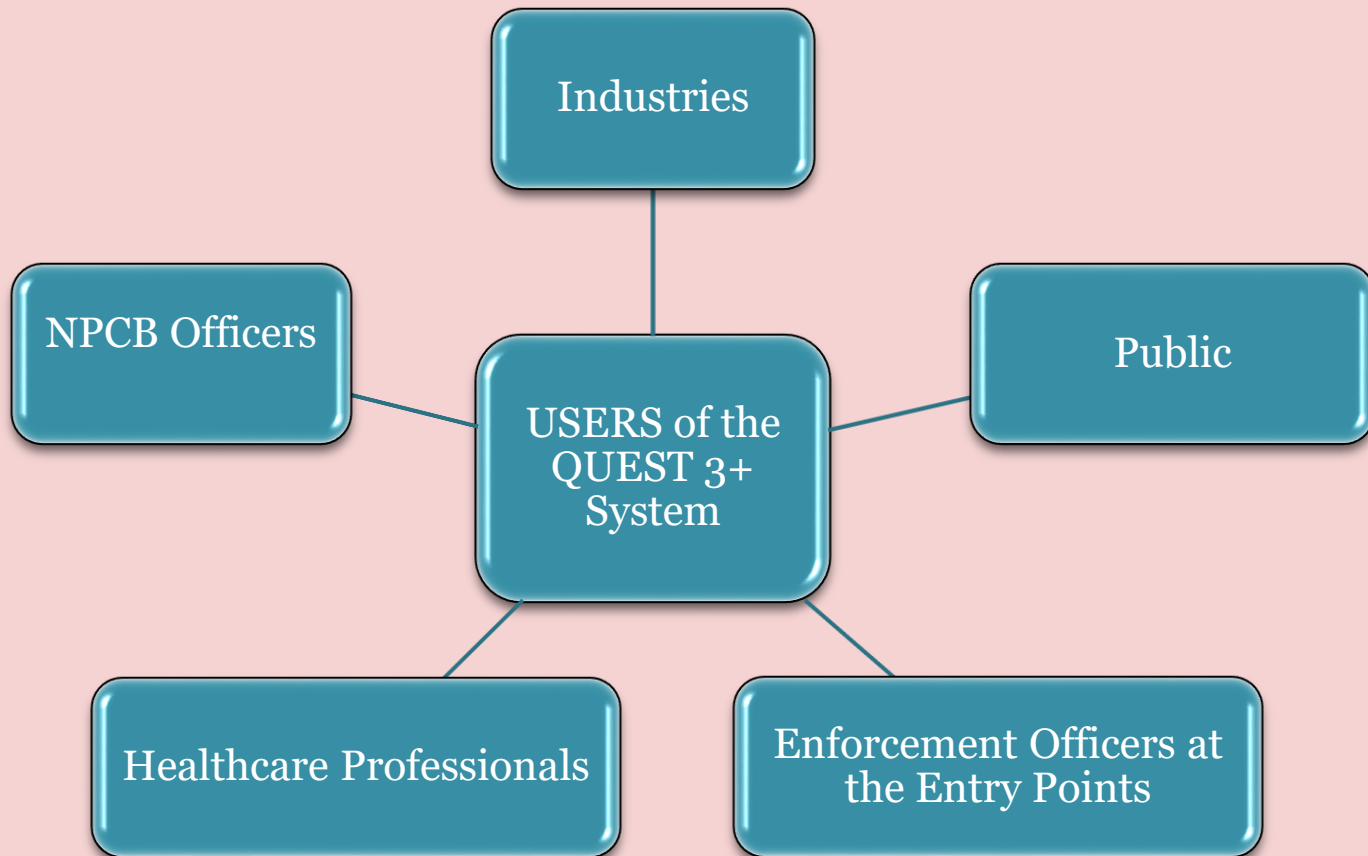
RATIONALE FOR DEVELOPMENT OF QUEST 3+

SHORT TERM

- More complete work cycle
- Shorter time for document submission
- Shorter overall registration process
- Increased productivity

LONG TERM

- Data confidentiality
- Information integrity
- Promote for a greener environment
- Fast and consistent evaluation and decision making process

LIST OF MODULES AND SUBMODULES

Pendaftaran Syarikat

1. *Permohonan/Penilaian Pendaftaran Syarikat Baru*
2. *Permohonan Penilaian Pertukaran Authorized Person*
3. *Permohonan/Penilaian Supplementary Holder*
4. *Permohonan Pembaharuan Keahlian*
5. *Permohonan Pembatalan Keahlian Syarikat Berdaftar*

Pendaftaran Produk

6. *Permohonan/Penilaian Pendaftaran Produk Baru*
7. *Permohonan/Penilaian Produk Kombo*
8. *Permohonan/Penilaian Tambahan Indikasi*
9. *Penjanaan Malaysia Drug Code*
10. *Penggantungan / pembatalan produk berdaftar*
11. *Permohonan Rayuan Produk*
12. *Permohonan Perakuan Produk Farmaseutikal (CPP)*
13. *Permohonan/ Penilaian Change of Holder*
14. *Permohonan / Penilaian Pembaharuan Pendaftaran Prdduk (Renewal)*

Pasca Pendaftaran

15. *Permohonan Variasi*
16. *Pemohonan Pertukaran Tapak Pengilang (COS)*

Pelesenan dan Pemeriksaan GMP

17. *Permohonan/Penilaian Lesen/Pembaharuan Lesen/Senarai Tambahan*
18. *Pengeluaran Sijil/Surat Pengesahan*
19. *Pemeriksaan Premis*

Pengujian Sampel

20. *Penilaian Protokol / Data Validasi / API*
21. *Pengujian Sampel*
22. *Pengurusan Stor Sampel*

Kosmetik Notifikasi

23. *Permohonan / pembaharuan Notifikasi Kosmetik*
24. *Program Pemantauan Kosmetik Bernotifikasi*
25. *Pengendalian Aduan Kosmetik*
26. *Permohonan Permit – CFS, Market Sampling and In-House Evaluation*

Admin

BROWSER COMPATIBILITY

QUEST 3+ will be compatible with at least 2 internet browsers such as

Google Chrome

Mozilla Firefox

Internet Explorer
or
Other browser deemed reasonable

UPDATES ON PRODUCT REGISTRATION PROCESS

FOR

QUEST 3+

1) APPLICATION FORMS FOR PRODUCT SCREENING AND PRODUCT REGISTRATION

QUEST 2 & QUEST 3

- There are different forms available for each categories of product.

QUEST 3+

- The same template will be used for all categories of products under human category (except for veterinary products).

- Only relevant field for respective categories will be enabled for filling of data and document submission.

- The same template will be used for all categories of products for veterinar.

2) <u>SCREENING</u>

QUEST 2 & QUEST 3

- Currently done semi-manually.

- Unlimited time to complete the form on Application for product screening.

- Applicant is allowed to apply again for screening if the first screening application was rejected.

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- For one product, only one time screening application is allowed.

- Applicant will be given a maximum of **30 days** from the first day of screening application to complete and submit the form.

2) __SCREENING__ (cont.)

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- Applicant will be able to retrieve the rejected form for resubmission (a new 30 days cycle will be repeated).

- Archived form/documents will only be available for retrieval (and resubmission) within six months from the date of rejection.

3) **<u>PROCESSING FEES FOR SCREENING</u>**

QUEST 2 & QUEST 3

- No processing fees for screening of product registration application.

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- Processing fees for screening/pre-evaluation for product registration application **may** be imposed.
- If the policy is implemented, total ageing of working days for screening will be from the date of payment is cleared.

4) **DOCUMENTS FOR SCREENING**

QUEST 2 & QUEST 3

- Screening only involves documents which will be evaluated by Centre for Product Registration.

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- Screening will be done **concurrently** for registration documents involving evaluation of Active Pharmaceutical Ingredients (API)/Active Complementary Ingredients (ACI), together with screening and evaluation of protocol and validation documents.

5) IMPORT PERMIT & PERMIT TO MANUFACTURE

QUEST 2 & QUEST 3

- Both Import permit & Permit to manufacture are issued manually.

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- The system will be able to allow users to print;

  ❖ Import permit for imported Traditional product

    (for the purpose of laboratory analysis)

  ❖ Permit to manufacture unregistered product for all categories of local product.

    (for the purpose of registration requirements such as; product validation, stability studies, pilot batch, etc.)

5) **IMPORT PERMIT & PERMIT TO MANUFACTURE (cont.)**

QUEST 3+

- The system will only enable the user to print the permits after product screening status is approved (one time printing).
- The permits will have specific individual serial number and validities .

6) SAMPLE SUBMISSION (TRADITIONAL PRODUCT ONLY)

QUEST 2 & QUEST 3

- Processing fee for product registration may be approved prior to acceptance of sample by NPCB's Centre for Quality Control (one time payment of processing fee for product evaluation and sample testing).

QUEST 3+

- The system will require confirmation of sample acceptance by Centre for Quality Control. Otherwise, the system will not allow processing of the fees for sample testing.
- Request to submit payment for product evaluation without the confirmation for sample submission will be rejected.
- The payment of processing fee shall be done within 14 days from the date of screening approved.
- If the Applicant failed to make the payment within specified time, a new application for screening shall be submitted.

7) <u>EVALUATION</u>

QUEST 2 & QUEST 3

- Evaluation of documents for registration dossier, protocol & validation, and data evaluation for API were done separately.

QUEST 3+

- Evaluation of documents as stated above (registration dossier, protocol & validation, and data evaluation for API/ACI) will be done concurrently.

  *ACI = Active Complementary Ingredient (Applicable for TMHS High Claim product)

- Centre/Section with the longest processing time will reflect the final ageing clock.

8) **<u>CORRESPONDENCE FOR EVALUATION</u>**

QUEST 2 & QUEST 3

- Unlimited number of correspondence for evaluation.

QUEST 3+

- Application for product registration under categories of ;
  - ❖ Pharmaceutical full evaluation, Herbal high claim, and Health Supplement high claim will have a maximum of **5x correspondence**.
  - ❖ Pharmaceutical abridge, and TMHS will have a maximum of **3x correspondence**.
  - ❖ The system will be able to capture and track the history of correspondence for easy reference.

9) **ADDITIONAL MODULE/FUNCTIONS FOR PRODUCT REGISTRATION IN QUEST 3+**

Online application and <u>correspondences</u> will be enabled for;

- Application for Certificate of Pharmaceutical Product.

- Application for Change of Holder.

- Application for Renewal of Registration.

- Application for Additional Indication of Registered Product.

- Application for Registration of Combination Product.

10) RENEWAL OF REGISTRATION (RE-REGISTRATION)

QUEST 3+

- Product holder will receive online notifications or reminders within 3 months from the date of registration expiry.

- The system will enable correspondence between applicant and evaluating officer in charge.

- Applicants will have to comply to the current re-registration requirements such as;

  - Bioequivalence Study Report

  - Zone IVB Stability Study Report

  - GMP PIC/S Inspection Report

  - To fulfill the condition from Letter of Undertakings

11) CHANGE OF HOLDER

QUEST 3+

- Application can only be done by the current product holder instead of the new product holder.
- The existing product registration shall have a remaining validity **period of at least six (6) months**.
- If the period is less than six (6) months, product registration renewal shall be made before the transfer application is submitted.
- No change/s can be made to the technical data or approved pharmaceutical / pharmacological information, including the texts of the product label and leaflet, **except** the name and address of the approved PRH, unless made through variation procedure.
- Application shall be rejected if the applicant fails to provide satisfactory required documents within 30 working days starting from the first correspondence date.

12) DCA MEETING RESULTS

QUEST 2 & QUEST 3

* After the DCA meeting, product registration status can be viewed manually by the Product Registration Holder in the QUEST system, or downloaded from NPCB's website.

QUEST 3+

* After the DCA meeting, an email notification will be sent to respective product registration holders to view the meeting results such as product registration status, result for appeal, result for Change of Holder, Registration Renewal, and etc.

13) APPEAL

QUEST 2 & QUEST 3

- After the DCA meeting, applicant may submit a written appeal for the Minister within fourteen days from the date the decision was made known to him.

QUEST 3+

- After the DCA meeting, an email notification will be sent to respective product registration holders.

- Applicants will only be allowed to submit an appeal within 14 days from the date of DCA meeting result notification. Any appeal received later than that will be rejected.

14) **<u>Evaluation of Analytical Method Validation and Protocol Documentation for NCE and Biologics Products</u>**

QUEST 3+

Product Registration Holders applying for registration of NCE and Biologics product will now have to submit the analytical Method Validation and Protocol documentation for evaluation by the Centre for Quality Control (Pusat Kawalan Kualiti).

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