

UPDATES ON QUEST 3+



National Pharmaceutical Control Bureau (NPCB)
Ministry of Health, Malaysia
26 Apr 2016

AGENDA

9:00 am	Registration
9:30 am	Opening remarks by Mr Tan Ann Ling, Director of Regulatory Pharmacy,NPCB
9:45 am	Updates on QUEST 3+ Cik Nurulfajar Mohd Jamid, Project Manager of QUEST 3+, Centre for Organisational Development,NPCB
10.30 am	Updates on Registration Milestone Dr Azizah Ab Ghani, Senior Principal Assistant Director, Centre for Product Registration,NPCB
11:00 am	Discussion on the Implementation of QUEST 3+ & Moratorium Periods
12:30 pm	Outcome of the Discussion
1:00 pm	Adjourn

Outline

Background on QUEST3+

Minimum Requirement for QUEST3+

- Hardware Specification
- Browser Compatibility

QUEST3+ Integration

- Smart Card
- Online Payment

QUEST Moratoriums

- Cosmetic Notifications
- Product Application Submissions
 - Variation Submissions

Rationale for QUEST3+

- 1) Technology platform for Q2 and Q3 is getting obsolete.
 - E.g. Q3 is best viewed in IE 8.0 which is only available in Window XP and Window 7.
- 2) Increasing number of submission and thus workload of evaluation works.
- 3) A need for a new system to consolidate and replace legacy systems i.e. Q2 and Q3

Q3+ Development Project

- Started in March 2015
- 1 year of development of system plus 1 year of technical support (warranty) services.
- Q3+ is anticipated to go LIVE in 2nd Quarter of 2016

Q3 & Q3+ Comparisons

	Q3	Q3+
Payment method	Manual -Banker's draft/bank cheque, postal order	Online payment -B2B (Multi Authorization) -B2C (Single Authorization) -or Credit Card (Master/Visa issued by local/oversea bank)
Security Features	USB token System user identification Provider : Digicert Sdn Bhd	USB token System user identification Digital Signature Provider : MSC Trustgate Sdn Bhd
Web Browser Compatibility	IE 8.0	IE 9.0 and above Mozilla Firefox 38 and above
New Modules Included	-	API,Licensing,Surveillance & Complaints,Lab modules

PC / Laptop Requirement

	Minimum	Optimum
Operating System	Windows XP	Windows 7,8,10
Hardware	Processor : Intel Core i3 or AMD A10 RAM : 2GB Hard Drive : 10 GB	
Internet Service Provider	IE 9.0 Mozilla Firefox 38	Internet Explorer 10 (with No Compatibility View Mode) Mozilla Firefox v43
Internet connection speed	2 Mbps /user wired broadband	More than 2 Mbps /user wired broadband

Browser Compatibility

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

Mozilla Firefox



Internet Explorer



QUEST3+ Integration

	Integrated System	Provider	Features
1.	MSC Trustgate www.msctrustgate.com	MSC Trustgate.com Sdn. Bhd.	Certification Authority for e-business <ul style="list-style-type: none">❖ Allows to apply for forgotten passwords online❖ Allows for renewal of membership online
2.	myGovXchange (MGX) http://mygov.malaysia.gov.my	MAMPU	Online Payment through internet banking <ul style="list-style-type: none">❖ Secured by MyClear, a subsidiary of Bank Negara Malaysia
3.	MasterCard Internet Gateway Service (MiGS)	MasterCard	Online payment gateway provides fast and secure electronic credit card processing

Security Features Enhancement

- Existing Digicert will be supported until the certificate expires
- Option for USB tokens 1,2 or 3 years
- Digital signature concept will be applied
- More user friendly :
 - validity period of the certificate during authentication process
 - online PIN unblocking
 - online renewal of certificate

Q3+ Component I : Smart Card

Application type	Duration (year/s)	Retail price (RM)	
		Without GST	With GST
New User (Token + Certificate)	1	260.00	275.60
	2	290.00	307.40
	3	335.00	355.10
Supplementary User (Token + Certificate)	1	245.00	261.50
	2	275.00	291.50
	3	320.00	339.20
Renewal (Certificate only)	1	48.00	50.88
	2	95.00	100.70
	3	140.00	148.40

Q3+ Payment Mode

- 2 types of online payment:
 - (i) **Internet banking**
via Financial Process Exchange (FPX)
(all bank accounts - Corporate/business & personal)
 - (ii) **Credit Card**
via MasterCard Internet Gateway Service(MiGS)
(all visa & master cards)

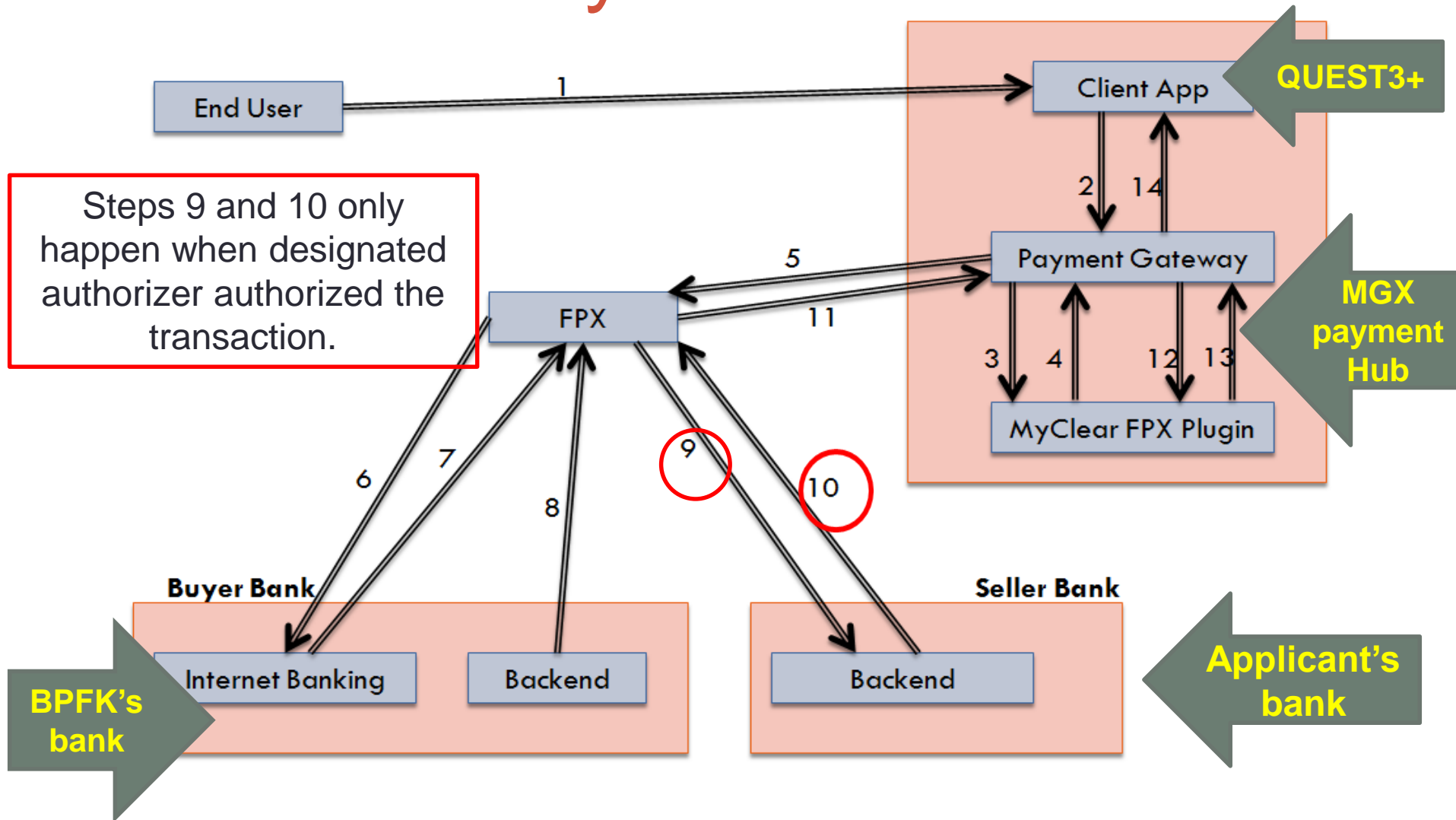
FPX - B2B

- Transaction requires at least 2 personnel from product holder to make payment.
- ❖ Role of maker (eg: applicant)
- ❖ Role of authorizer (eg: applicant's superior)

- Number of authorizers depend on conditions set by product holder with their respective bank.

- No limit time for authorization from time of submission of payment request / initiation, determined by product holder .

B2B Payment Workflow



Simplified Version

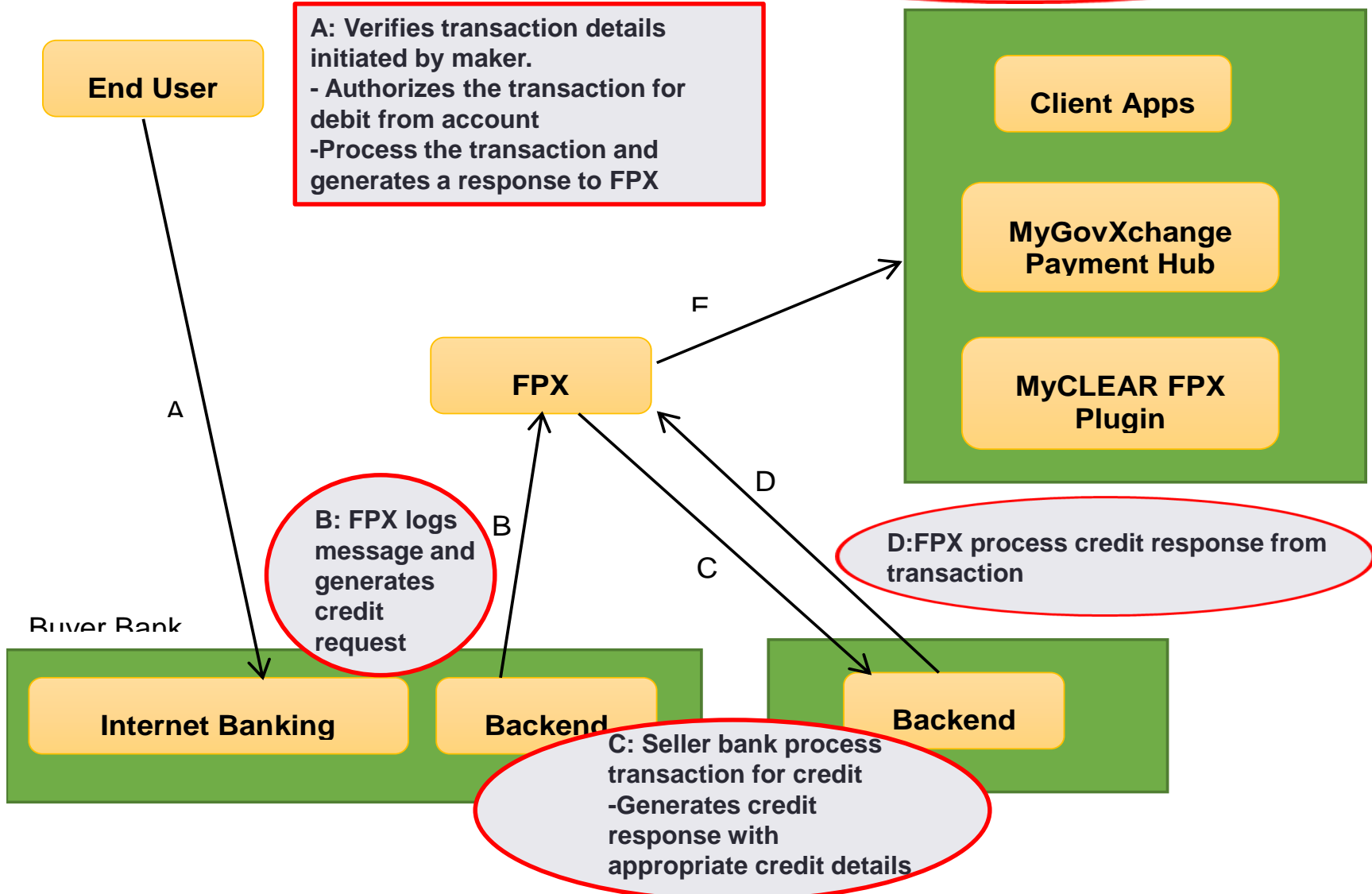
E: Direct Message. Once response message received, the same is appropriately decrypted and response / status handled accordingly in MyGov Portal

A: Verifies transaction details initiated by maker.
- Authorizes the transaction for debit from account
- Process the transaction and generates a response to FPX

B: FPX logs message and generates credit request

D: FPX process credit response from transaction

C: Seller bank process transaction for credit
- Generates credit response with appropriate credit details



Credit Card

- Service provided by **MIGS**. No plug-in, rather a hashing service.
- Card issuing institution adjusts cardholder's credit limit for the funds and returns the result to MIGS.
- MIGS passes result of the transaction on to the MGX Payment Gateway.
- Periodically (normally once a day), records are transferred by MIGS to the seller bank.
- Seller bank settles transaction with the issuing (Cardholder's) bank as part of normal credit card processing.
- The issuing bank adds an entry to the cardholder's statement for subsequent payment by the cardholder.
- The acquiring bank deposits the funds into the seller bank account.

Moratorium of QUEST submission

- **There will be three sets of moratorium in the course of QUEST 3+ implementation :**
 - 1. Cosmetic notifications**
 - 2. Screening & product applications**
 - 3. Variation applications**

QUEST MORATORIUM – COSMETIC NOTIFICATIONS

1st June

1st July

2016

1 MONTH
MORATORIUM

LAUNCH
OF
QUEST3+

SUBMISSION OF
NOTIFICATIONS in
QUEST3+

QUEST MORATORIUM – PRODUCTS APPLICATIONS

1st June

1st July

1st August

2016

1 MONTH
MORATORIUM

LAUNCH
OF
QUEST3+

1 MONTH
MORATORIUM

SUBMISSION
OF
POST REG –
COH/ COS/
RENEWALS
APPLICATIONS in
QUEST3+

SUBMISSION OF NEW
PRODUCT
APPLICATIONS
in QUEST3+

QUEST MORATORIUM – PRODUCTS APPLICATIONS

15th May

1st June

1st July 2016

SCREENING
DEADLINE

PAYMENT
DEADLINE

LAUNCH
OF
QUEST3+

SUBMISSION OF
NEW
PRODUCT
APPLICATIONS/
RENEWALS
in QUEST3

1 MONTH
MORATORIUM

SUBMISSION
OF
NEW PROD
APPS in
QUEST3+

QUEST MORATORIUM – VARIATION APPLICATIONS

8th May

1st July

1st Aug 2016

VARIATION
DEADLINE

LAUNCH
OF
QUEST3+

11 WEEKS
OF
VARIATIONS MORATORIUM

SUBMISSION
OF
NEW
VARIATIONS
in
QUEST3+

THINGS TO NOTE BEFORE MORATORIUM PERIOD

QUEST3

QUEST3+

PRODUCT REGISTRATION
/ NOTIFICATION FOR NEW
PRODUCTS TO BE
LAUNCHED

EXISTING PRODUCTS /
COSMETICS DUE FOR
RENEWAL

 NO CORRESPONDENCE FOR NOTIFICATION
SUBMISSION

THINGS TO NOTE **DURING** MORATORIUM PERIOD

QUEST3

QUEST3+

ABLE TO VIEW & PRINT
NOTIFICATION NOTES

ABLE TO VIEW INFO/
STATUS FOR PRODUCTS

 NO NOTIFICATION / PRODUCT
APPLICATION SUBMISSIONS

THANK YOU