FREQUENTLY ASKED QUESTIONS (FAQ) ABOUT THE IMPLEMENTATION OF ELECTRONIC LABELLING (E-LABELLING) ON PHARMACEUTICAL PRODUCTS

Q1: What is e-labelling?
A1: E-labelling refers to the electronic delivery of product information such as the package insert (PI) and/or Consumer Medication Information Leaflet (RiMUP) that have been approved, through a QR code.

This QR code will be affixed on the product packaging. When users scan this QR code using a mobile device, the latest PI and RiMUP information contained in the QUEST3+ NPRA system will be displayed.

Q2: When is the implementation period of e-labelling?
A2: The Drug Control Authority (DCA) at its 383rd meeting on 6 April 2023 agreed to the proposal for e-labelling voluntary implementation on pharmaceutical products from 1 May 2023 to 31 December 2026.

Q3: Which products are involved in the e-labelling implementation?
A3: The implementation of e-labelling applies to biologics, new drug products, and generic products containing scheduled poisons for human use.

Q4: How is e-labelling implemented?
A4: The Directive for the implementation of e-labelling was issued by the Senior Director of Pharmacy Services on 11 April 2023. The implementation of e-labelling during the voluntary phase is described in the 'Guideline on Electronic Labelling (e-Labelling) for Pharmaceutical Products in Malaysia' which can be downloaded from the NPRA website.

Product Registration Holder (PRH) who intend to use e-labelling on existing products need to submit variation under 'Minor Variation Notification (MiV-N): E-labelling Verification' category in a staggered manner.

For new products seeking registration, the PRH can submit an e-labelling application along with the product dossier. However, variation application shall be submitted immediately after the product is approved by the Drug Control Authority (DCA) or latest before the product is launched into the market. This is to ensure that that the product marketed has a QR code connecting to the latest Package Insert (PI)/ Consumer Medication Information Leaflet which is readily accessible in the QUEST3+ system when the QR code is scanned by the user.

Before variation submission, PRH shall communicate with one of the pharmaceutical industry associations, namely the Pharmaceutical Association of Malaysia (PhAMA), The Malaysian Organisation of Pharmaceutical Industries (MOPI) and Malaysian

Association of Pharmaceutical Suppliers (MAPS). The person(s) in charge are as follows:

(a) PhAMA
Name : PhAMA Secretariat
E-mail : phama@phama.org.my
Contact no. : 03-7960 8322/23

(b) MOPI
Name : Mr. Mike Lee
E-mail : admin@mopi.org.my
Contact no. : 03-7931 9003

(c) MAPS
Name : Ms. Chong Siew Mei
E-mail : maps_smchong@hotmail.com
Contact no. : 012-3878386

This is because the list of products selected for e-labelling implementation has been jointly finalised by NPRA and the Joint Industry Task Force before the implementation. Such communication is necessary to ensure the variation is submitted systematically, as required in section 3.3.4 of the e-Labelling Directive.

Q5: Is the Product Registration Holder (PRH) required to obtain variation approval for e-labelling before implementing the changes?
A5: PRH does not need to wait for approval from NPRA and can proceed with implementing the changes after submitting the notification.

Q6: How is e-labelling implementation communicated to the healthcare facilities and healthcare professionals?
A6: As stated in section 3.3.5 of the e-labelling directive, the Product Registration Holder (PRH) will issue a Dear Healthcare Provider (DHCP) Letter as a communication tool to inform healthcare facilities and healthcare professionals on the use of e-labelling. The DHCP Letter shall be provided along with printed copies of the package insert (PI) and/or Consumer Medication Information Patient Information Leaflet (RiMUP).

The DHCP letter shall also include the contact information of the person in charge if printed PI and RiMUP are required.

The PRH is responsible for providing printed PI and/or RiMUP when requested by healthcare facilities/professionals.

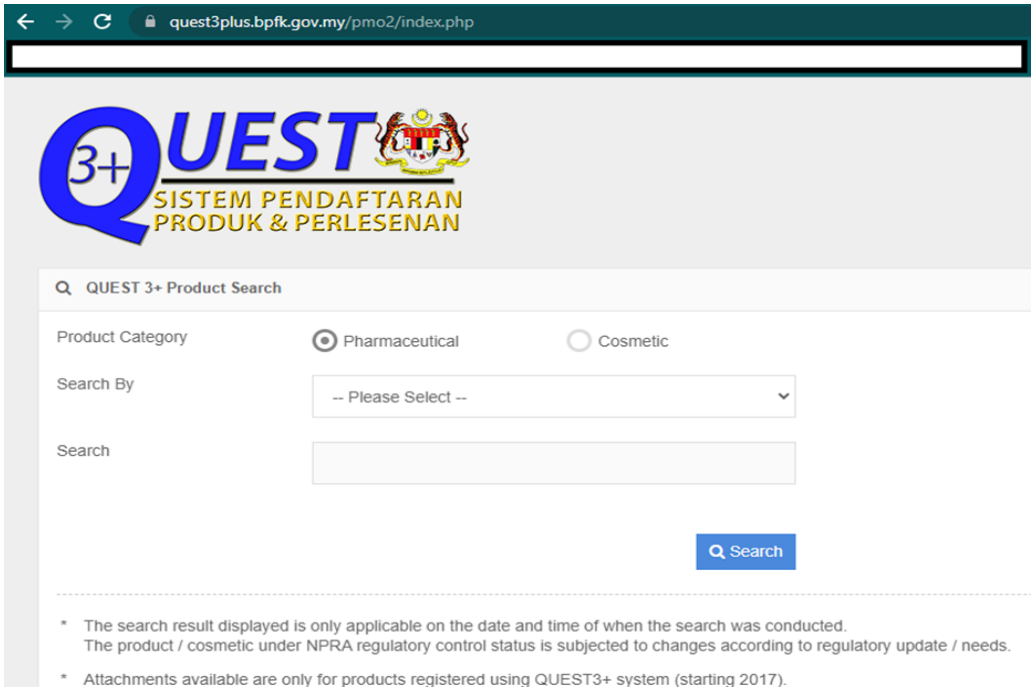
Should the printed PI and/or RiMUP is maintained in the packaging, PRH may distribute the DHCP Letter without the printed PI/RiMUP attached to the DHCP Letter.

Q7: Does the Dear Healthcare Provider (DHCP) Letter requires approval from NPRA prior to issuance to the healthcare facilities/professionals?
A7: Product Registration Holder (PRH) does not need to submit the draft DHCP Letter to NPRA for review prior to issuance because a DHCP letter template has been provided to the Joint Industry Task Force. Kindly liaise with the person in charge listed under question number 4.

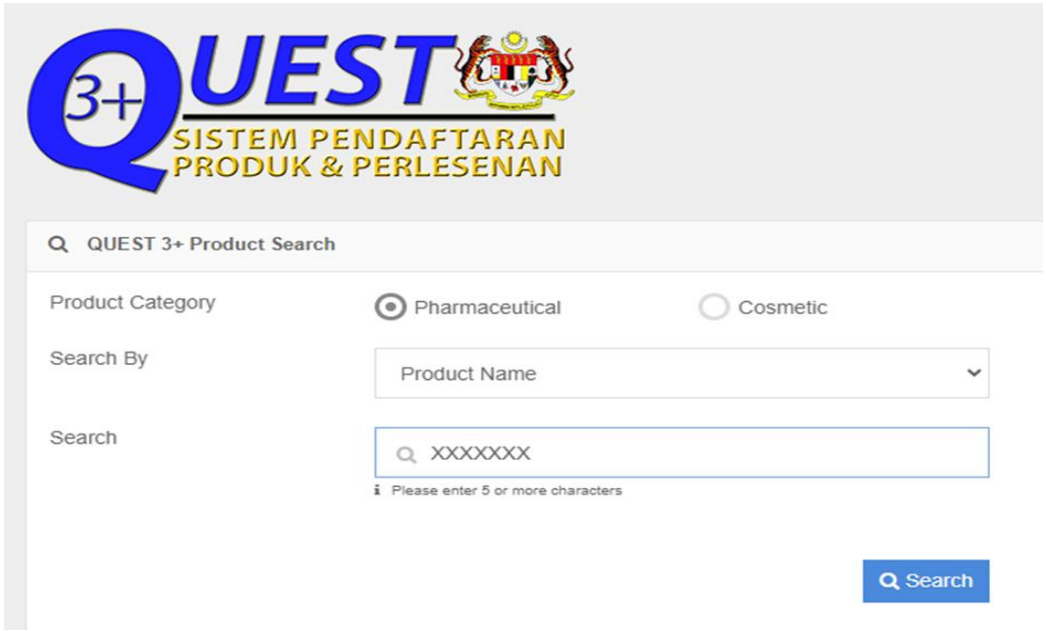
Q8: Can the industry use their company's hosting site for e-labelling implementation?
A8: As stated in section 3.3.2 of the e-labelling directive, the QUEST3+ system will be used as the hosting site during the voluntary phase.

Q9: What will be displayed when the QR code on the product packaging is scanned?
A9: When the QR code on the product packaging is scanned, the same display will be shown when searching for product information using the 'Product Search' through NPRA website. The information displayed includes product name, registration number, registration holder information, manufacturer information, importer information (if applicable), active ingredients, packaging details, Consumer Medication Information Leaflet (RiMUP), label for immediate container, label for outer carton and package insert.

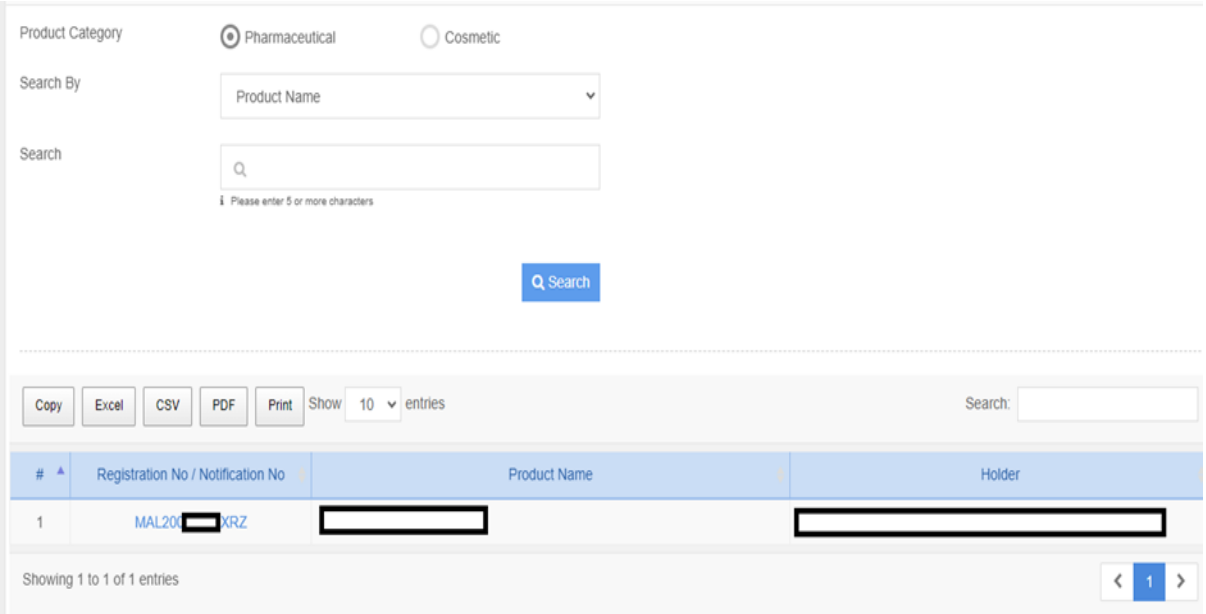
The method to generate QR code is explained in the diagram below
EXAMPLE:
1. Please click on this link https://quest3plus.bpfk.gov.my/pmo2/index.php



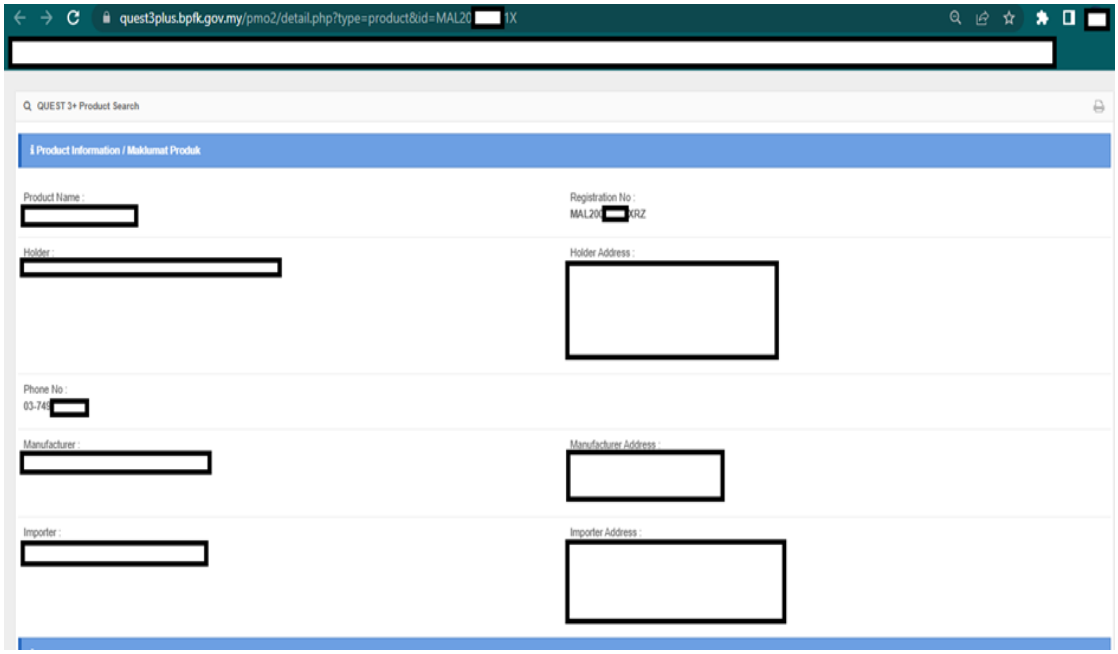
2. Enter the product name / registration number of the approved product to generate QR code.



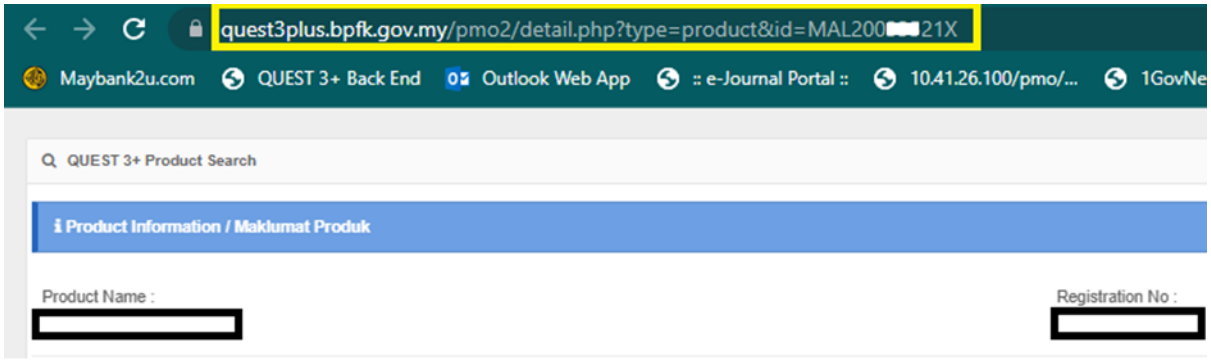
3. Choose the intended product by clicking the link of the registration number of the product in the list.



4. Once the link of the registration number clicked, a separate page will be opened with the information stated below.



5. The link in the URL (*Uniform Resource Locator*) address bar should be used to generate QR code from any QR Code Generator software. The URL is highlighted in the yellow box:



6. The information displayed which includes product name, registration number, registration holder information, manufacturer information, importer information (if applicable), active ingredients, packaging details, Consumer Medication Information Leaflet (RiMUP), label for immediate container, label for outer carton and package insert should be exactly the same in the URL page in the yellow box & the generated QR code. An example of the displayed information is as follows:

Ingredients Information / Maklumat Bahan Aktif

No	Active Ingredient
1	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE

Packaging Information / Maklumat Bungkusan

No	Quantity
1	14Tablet Tablets

Consumer Medication Information Leaflet / Risalah Maklumat Ubat Pesakit

No	Attachment
1	MY-PIL-RiMUP-Nexium Tab 20mg, 40mg-BM Doc ID-004792674 v3 - clean - 20230417.pdf
2	MY-PIL-Nexium Tab 20mg, 40mg-Doc ID-003067303 v11 - clean - 20230417.pdf

Label (mock-up) for Immediate Container / Label Terdekat

No	Attachment
1	D1 Nexium MUPS 40mg - Gov pack_IL - P955061A-V1R0.pdf
2	D1 Nexium MUPS 40mg - Private pack_IL - P955047B-A02.pdf

Label (mock-up) for Outer Carton / Label Luar

No	Attachment
1	D2 Nexium MUPS 40mg - ePI QR code - 20230502.pdf

Proposed Package Insert / Sisipan Bungkusan

No	Attachment
1	MY-PI-Nexium-Tab-20mg-40mg-MS Doc ID-002254254 v23 - clean â€“ 20230221.pdf

Q10: For Influenza vaccines, there are bi-yearly seasonal changes that affect the stock for the Northern Hemisphere (NH) and Southern Hemisphere (SH) in the market. Can the package insert (PI) for both stocks be maintained in the QUEST3+ system at the same time?

A10: Influenza vaccines with NH and SH stocks have the same MAL registration number but different PIs.

The PI for NH and SH stocks can be retained in the QUEST3+ system at the same time as the scanned QR code will direct users to the QUEST3+ Product Search for that particular vaccine. Users can click on the relevant PI to select the package insert for either NH or SH stock. Product Registration Holder (PRH) shall ensure the PI for the specific stock is accurately labelled in the QUEST3+ system.

Q11: Will the implementation of e-labelling be expanded to other product categories such as the Over the Counter (OTC) products?

A11: The implementation of e-labelling applies to biologics, new drug products and generic products containing scheduled poisons for human use only. Extension of e-labelling to other product categories will need to be reviewed further.

A study on the effectiveness of e-labelling will be conducted during the voluntary phase. This study aims to assess the effectiveness and acceptance of e-labelling by the public and healthcare professionals.

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22 February 2024