World Health Organization

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In reply please refer to: PQT-PM/ha (2021-124)

Your reference:

Mr Anil Jose
Abu Dhabi Medical Devices Co. L.L.C
P.O. Box 30485
Abu Dhabi
Emirates Arabes Unis

7 June 2021

Dear Mr Jose,

Notice of revalidation for single use injection devices and safety box

Thank you for having submitted the complete dossiers for revalidation during the 2021 annual review (AR) of your products:

PQS No	Product description	Your product reference
E008/004	AD syringe 0.5 ml	MEDECO® INJECT AD 0.5 ml
E008/069	0.05ml AD BCG syringe	MEDECO INJECT AD 0.05ml BCG
E008/070	0.1ml AD BCG syringe	MEDECO INJECT AD 0.1ml BCG
E013/099	RUP syringe 3ml	Medoco® Inject RUP 3ml
E013/100	RUP syringe 5ml	Medeco® Inject RUP 5ml
E10/016	5L Safety box	Medeco Safety Box 5L

We are pleased to inform you that these products are revalidated until 31 May 2022 and will be published accordingly on the Prequalification (PQ) WHO website page:

http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/

We will formally notify you of the date of next year's review in due course.

If any of your time-bound certificates expire before May 2022, you are requested to provide us with the new documents at their time of issue, or in the case that renewal is pending in the following three months, to communicate to PQS the expected renewal date. Please note, the product will not be revalidated until PQS receives the renewed certificate. Any products covered by an ISO that has not been renewed in the previous year will be automatically suspended.

Kindly note that although PQ does not explicitly request active monitoring of product performance, we do require notification of all adverse events and device failures of which you are aware in accordance with our agreement under the terms and conditions of the PQ initiative.

Kindly note:

- The focus of the PQ initiative is progressing from a qualification process based on certificate and license reviews, towards the improvement of products through manufacturing change transparency, CAPAs with more detailed failure reports and risk mitigation.
- A pre-review of submissions will take place four weeks before the Annual Review (on or shortly after the submission deadline). Should the manufacturer be required to provide further information or to complete documentation, they will be advised two to three weeks prior to the AR.
- As of the 2022 AR, resellers submitting dossiers for product revalidation will be required to provide complete information and certification for the original product manufacturer. This change will be explained fully in the pre-submission package of documents.

- Reminders:
  - *Confidentiality*: all information provided by the manufacturer will be treated in the strictest confidence.
  - *Completeness*: manufacturers are reminded that incomplete submissions cannot be revalidated and will require further action on their part. A checklist of required submission documents will be included in the Manufacturer Declaration as of 2022.
  - *Licence/certificate renewal*: manufacturers are requested to ensure business licences and manufacturing certificates are valid, are accompanied by a notarised translation and, when renewal is required, to ensure that valid documents are provided to the PQS Secretariat in line with the AR submission deadline.
  - *Certification validation*: manufacturers are reminded that they are obliged to provide a specific web link to a certificate authentication page for each mandatory certificate. (A general web link is not sufficient.)
  - *Manufacturer declaration*: manufacturers are reminded of the requirement to sign and date the Manufacturer Declaration form in order to validate their submission. Products cannot be recommended for revalidation in the absence of this signature.
  - *Taxonomy*: E003 manufacturers are reminded that PQS requires that the product performance Taxonomy (released 2020) be used to report all performance failures of PQS prequalified products – including as a part of the Annual Review requirement.
  - *Fees payment*: Payment of the previous year's fee is also required for a manufacturer to have its products revalidated in the subsequent AR. Payment of fees is verified

Thank you for your continued collaboration.

Yours sincerely,

Paul Mallins

Mr Paul Mallins
Technical Officer, Vaccines & Immunization Devices Assessment Team(VAX)
Prequalification Unit (PQT)
Regulation and Prequalification Department (RPQ)
Access to Medicines and Health Products Division (MHP)