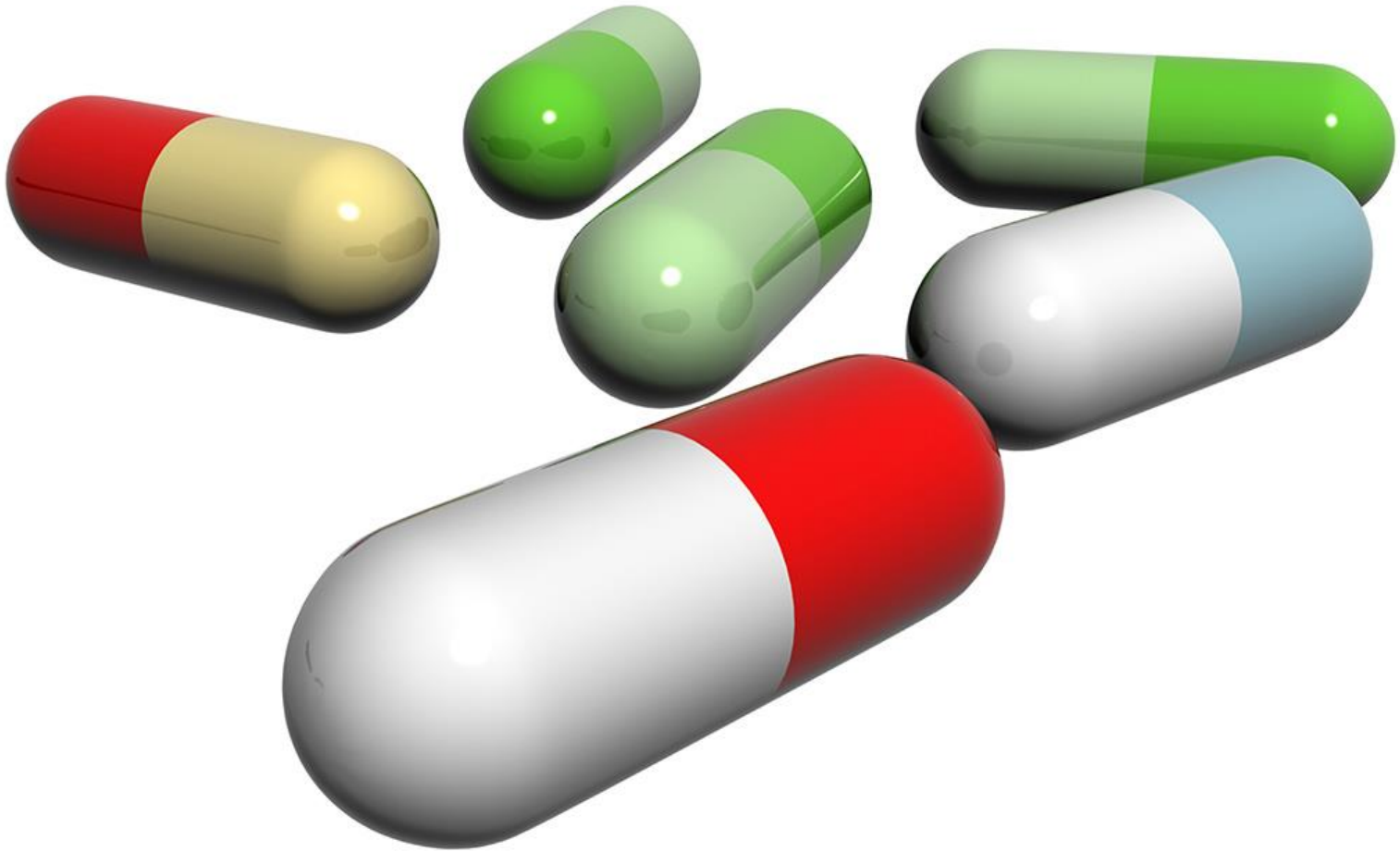
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UAE Pharmacovigilance System Updates

Dr. Katya Nabeel Ailabouni

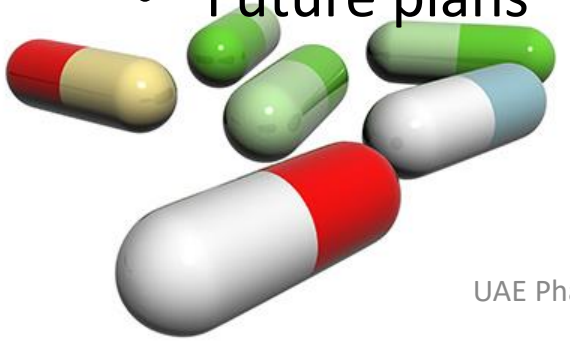
Pharmacovigilance officer

Drug Department / UAE MOHAP

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Content

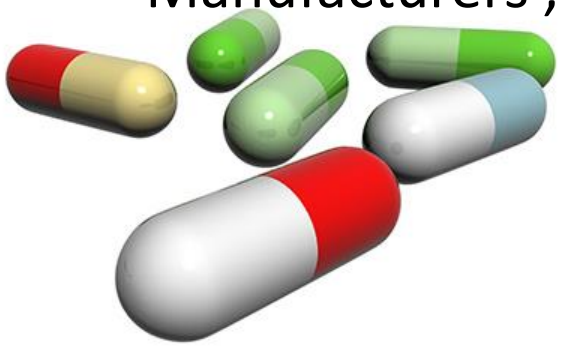
- Summary of PV System in UAE
- PV officer Approval and Renewal Requirements
- Updated PV Statistics
- Online Submission:
  - Current Feature
  - New launched features:
    - PV Officer Submission
    - ADR Online Submission
- Future plans



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Summary of PV System in UAE

- MOHAP PV activities started year 2007 with the collaboration of local Health Authorities in UAE and Military services and Academia all over UAE.
- The National PV committee was formed in year 2008.
- Several Guidelines were issued regarding the PV practice, PV officers, ADR reporting in UAE.
- February 2018 the new UAE Good Pharmacovigilance Practice Guidelines was issued targeting the Pharmaceutical Manufacturers , MAH, Healthcare Providers and the Public.



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Summary of PV System in UAE

- 2018 the Online submission of PV plan (PSMF), RMP , PSUR(PBRER) and officer details through Drug Registration and Pricing System/DRPS was launched
- 2023 additional Features of PV Officer approval, ADR reporting was added to Drug Registration and Pricing System/DRPS and the process is active from March 1/2023



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Good Pharmacovigilance Practice in UAE

Content of Good PV Practice Guidelines

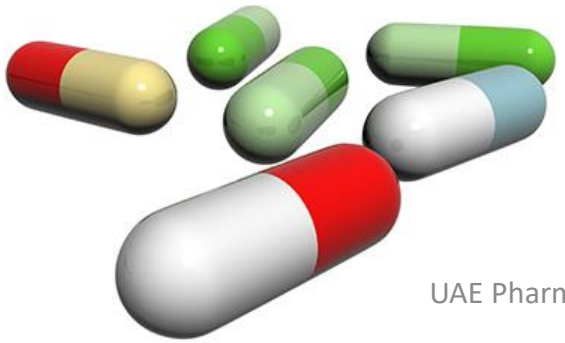
- Pharmaceutical Manufacturer/ Marketing Authorization Holder (MAH) and *qualified Person Responsible for Pharmacovigilance (QPPV) responsibilities*.
- Pharmacovigilance System Master File (PSMF).
- Risk Management System (RMS).
- Reporting of adverse reactions to medicinal products .
- Periodic Safety Update Reports (PSURs)
- Post-authorization Safety Study (PASS).
- Signal Management.
- Safety communication.
- Risk Minimization Measures (RMM).



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PV Officer Approval Requirements in UAE

- The MAH shall have permanently and continuously at its disposal an appropriately QPPV resident in UAE. For multinational MAHs a local safety responsible (LSR) may be accepted Based in UAE. For local MAHs there should be a dedicated QPPV and he/she should be resident in UAE. The names and 24 hours contact details of the nominated QPPV and his alternate during absence should be submitted to PV section /Drug Department (third party QPPV is not accepted as per MOHAP Regulations)



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PV Officer requirements in UAE

- Following documents should be provided:
  - ✓ Letter of appointment from the company not the agent
  - ✓ Proof Of residency IN UAE
  - ✓ Qualification proof (B. Pharm, Medicine etc.)
  - ✓ Training certificate in PV
  - ✓ Experience certificate in PV
  - ✓ List of products covered by the company
  - ✓ ADR case reports submitted in UAE. (Local companies to report ADR cases of their products to the department within one year of the appointment)
  - ✓ SOP of the PV officer.



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PV Officer Approval Renewal requirements in UAE

- Following documents should be provided:
  - ✓ New updated Letter of appointment from the company not the agent
  - ✓ Qualification proof (B. Pharm, Medicine etc.) whenever changes is available.
  - ✓ Updated Training certificate in PV
  - ✓ Experience certificate in PV
  - ✓ Updated List of products covered by the company
  - ✓ Minimum of 15 Domestic ADR case reports submitted in UAE. Mandatory requirement in renewal .
  - ✓ SOP of the PV officer whenever changes is available.



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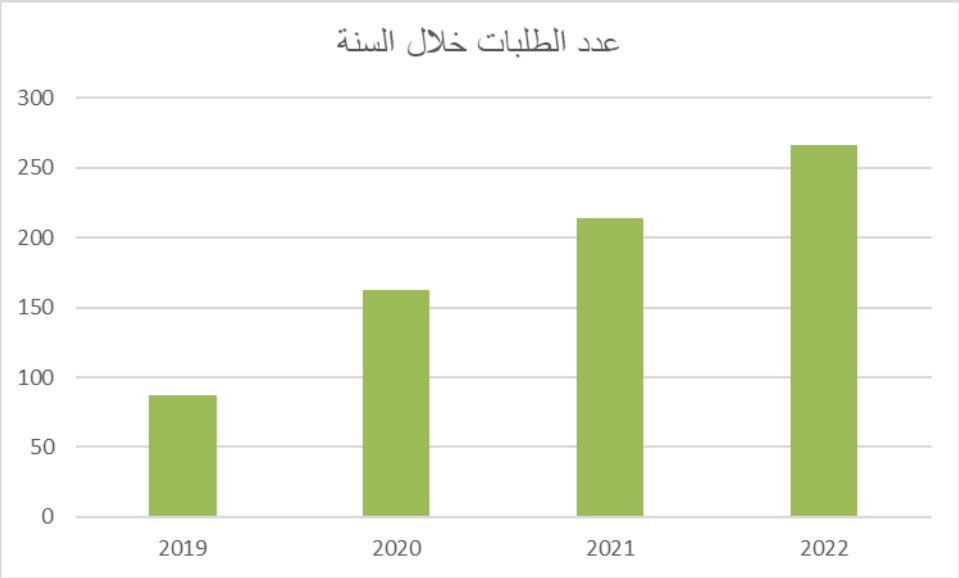
PV Officers Statistics in UAE/1

Total No. of PV Officers Applications	Total : 995
Approved	198
Approved conditionally	496
Delayed	258
Rejected	43



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PV Officer Statistics in UAE/2



السنة	رقم ضباط اليقظة الدوائية
2019	87
2020	163
2021	214
2022	266



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Risk Minimization Measures (RMM).

- Risk reduction measures are interventions aimed at preventing or reducing the occurrence of adverse reactions associated with exposure to the drug, or to one of them is dangerous or affects the patient. Planning and implementation of risk reduction and effectiveness evaluation are key elements of the risk management plan. Risk reduction measures include routine or additional risk mitigation measures. Reduction actions routine risks apply to all medical products.



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Risk Minimization Measures (RMM).

Routine risk minimization is applicable to all medicinal products, and involves the use of the following tools.

- Summary of Product Characteristics (SmPC);
- Package Leaflet (PL);
- labeling;
- pack size and design;
- legal (prescription) status of the product.

Year	Approved	Under review
2019	14	0
2020	34	0
2021	25	0
2022	39	0



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Reporting of adverse reactions to medicinal products

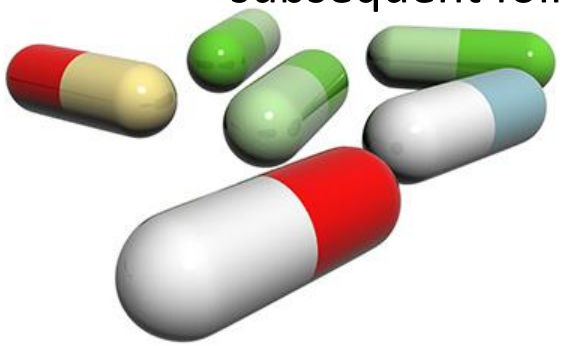
UAE Good PV Practice Guidelines, addresses the requirements which are applicable to the PV Section , Drug Department, MOHAP, UAE, as regards the collection, data management and reporting of suspected adverse reactions (serious and non-serious) associated with medicinal products for human use authorized in UAE. However, this guide does not address the collection, management and reporting of events or patterns of use, which do not result in suspected adverse reactions (e.g. asymptomatic overdose, abuse, off-label use, and misuse or medication error) or which do not require to be reported as individual case safety report or as Emerging Safety Issues. This information may however need to be collected and presented in periodic safety update reports for the interpretation of safety data or for the benefit risk evaluation of medicinal products.



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Reporting of adverse reactions to medicinal products ./1

- Reporting time frames:
  - In general, the reporting of serious valid ICSRs is required as soon as possible, but in no case later than 15 days after initial receipt of the information by any personnel of the marketing authorization holder, including medical representatives and contractors. This applies to initial information while follow-up information should be submitted within 15 calendar days. Where a case initially reported as serious becomes non-serious, based on new follow-up information, this information should still be reported within 15 days; the reporting time frame for non- serious reports should then be applied for the subsequent follow-up reports.



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Reporting of adverse reactions to medicinal products ./2

- Reporting time frames:
  - Reporting of non-serious valid ICSRs is required within 90 days from the date of receipt of the reports by marketing authorization holders.
  - Reporting of international cases is required to be reported through the PSUR/PBRER



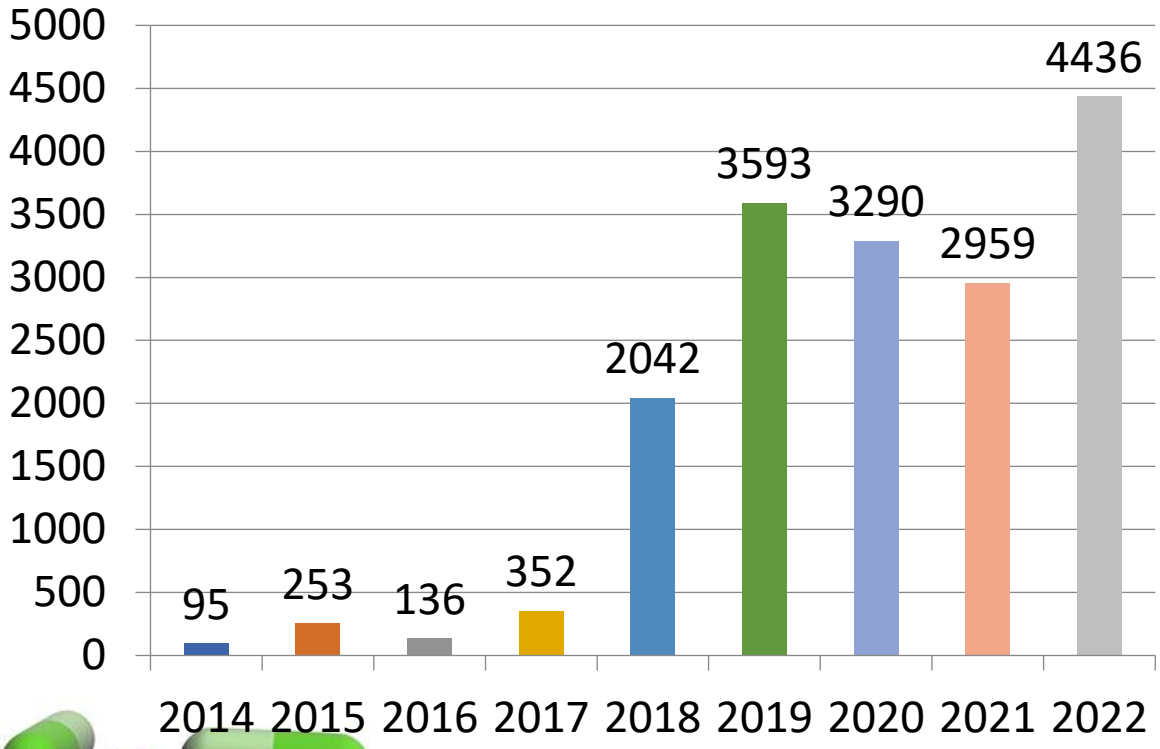
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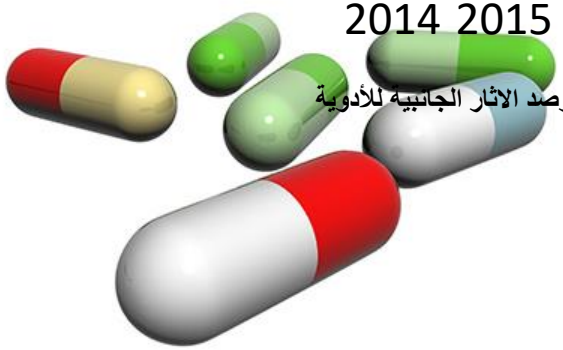
	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	TOTAL
ADR 2022	248	237	952	319	305	294	261	354	311	370	393	363	4436
PSUR 2022	46	32	25	35	53	85	36	58	48	56	29	33	517



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No. Of ADR reports sent from UAE to Upsala Monitoring Centre UMC/WHO (2014-2022)





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Online Submission/ Current available features

- Listing QPPV/PV Officer in the Drug Registration and Pricing System
- PV Plan /PSMF Approval
- RMP Submission
- PSUR Submission
- All above submissions and approval are related to new Drug Application or Renewal of Product Registration



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Online Submission/ New Launched Features

- ADR Submission
- PV officer/QPPV Submission for Approval



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Online Submission/ New Launched Features

- Announcement March 2023

- The Drug Department in the Ministry of Health and Prevention is pleased to announce the availability of MOHAP portal for submitting Individual Case Safety Reports (ICSRs) (to be submitted as XML files) & approvals of pharmacovigilance officers.

- Kindly visit the following links:

Approval of Pharmacovigilance Officer:

- https://smartservices.moh.gov.ae/wps/myportal/mohap/application/#/pv/registration/pva

Individual Case Safety Reports:

- https://smartservices.moh.gov.ae/wps/myportal/mohap/application/#/pv/registration/pvrp

- For any further clarification, please email: SmartServicesSupport@mohap.gov.ae



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Online Submission/ New Launched Features/ ADR / ICSR Submission

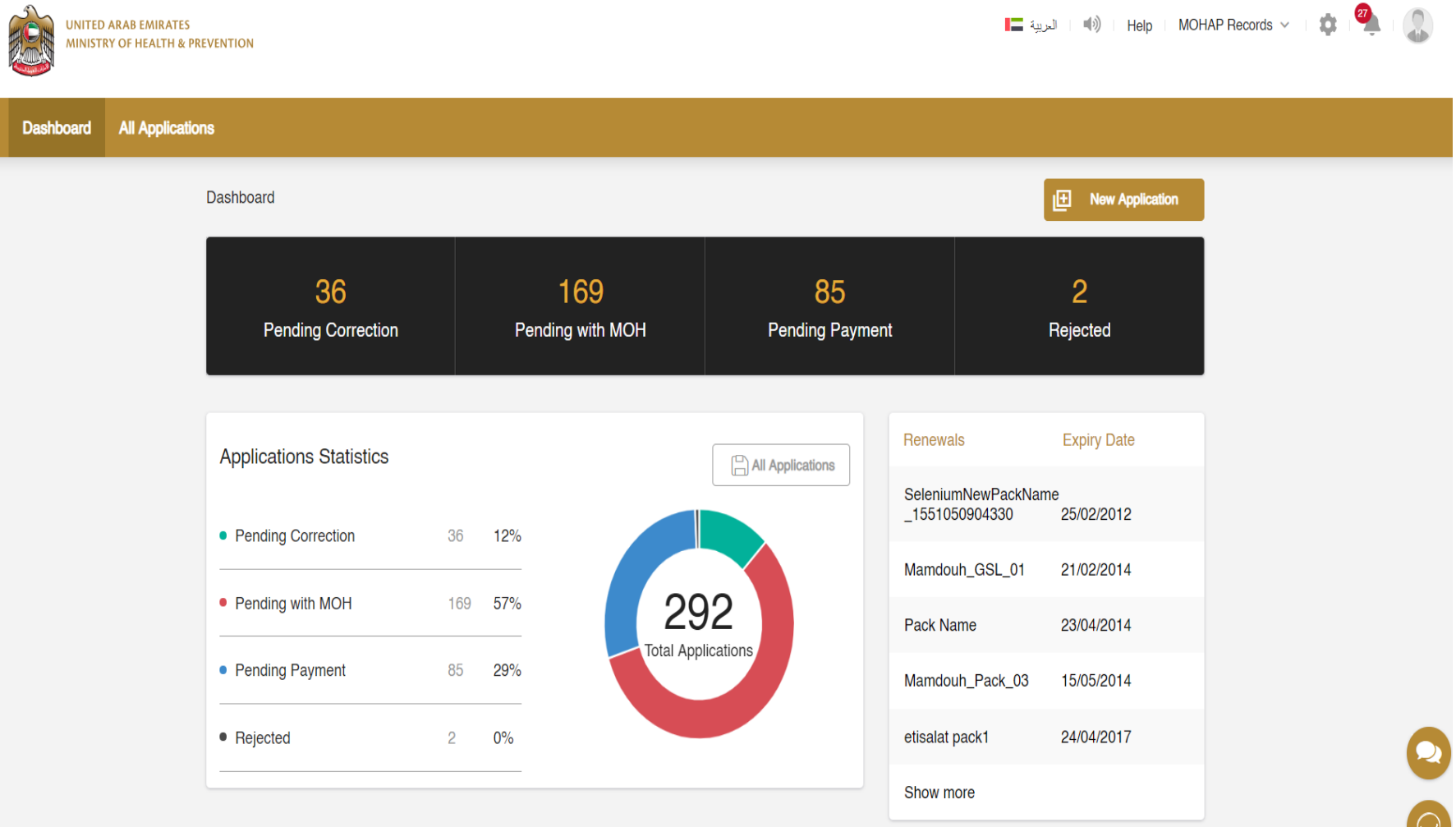
In order to start this service you have to request access to the System , access will be granted to :

- **Local Manufacturers**
- **Medical Store**
- **Scientific Office (MAH as per the products Registration Certificates)**



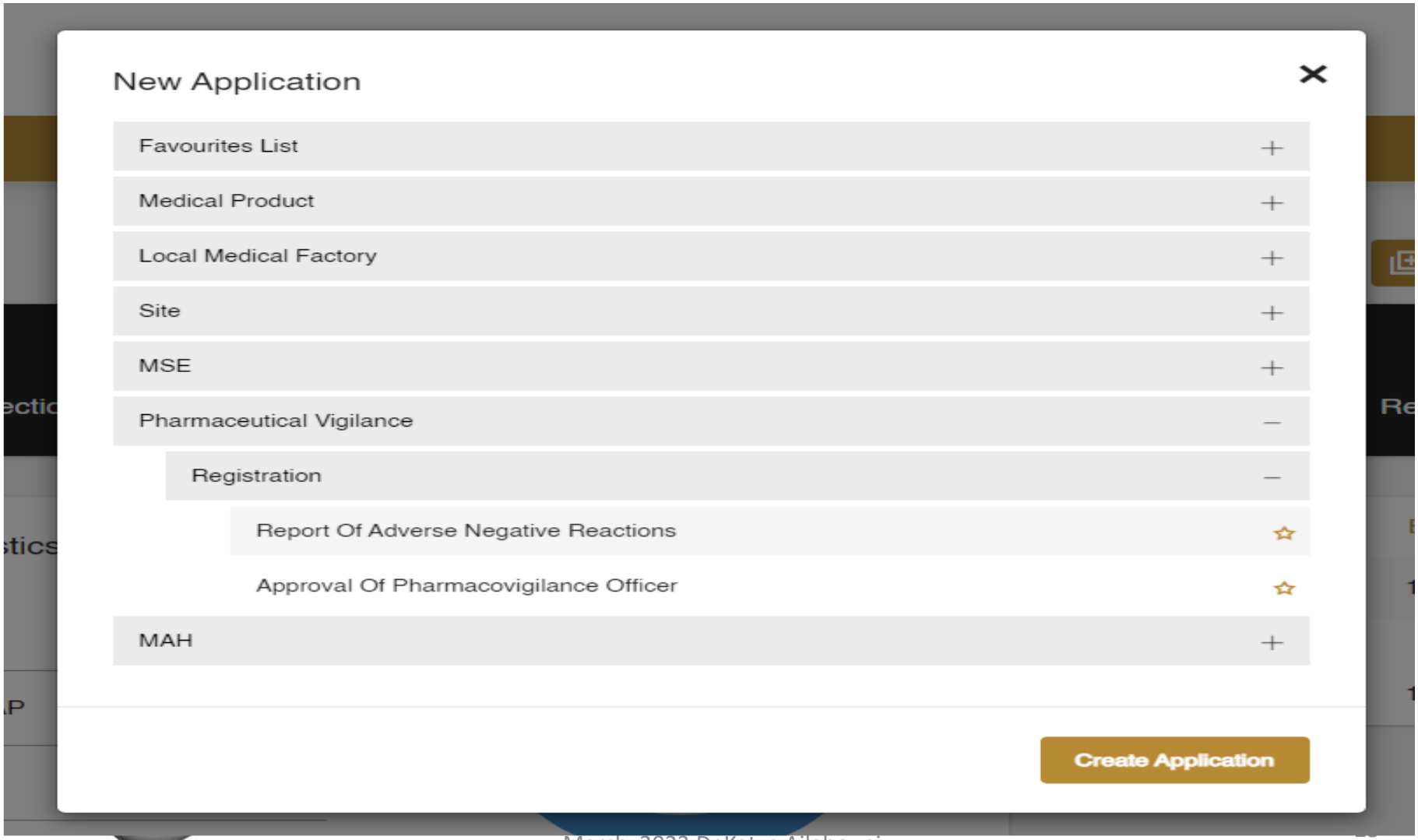
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Online Submission/ New Launched Features/ ADR / ICSR Submission



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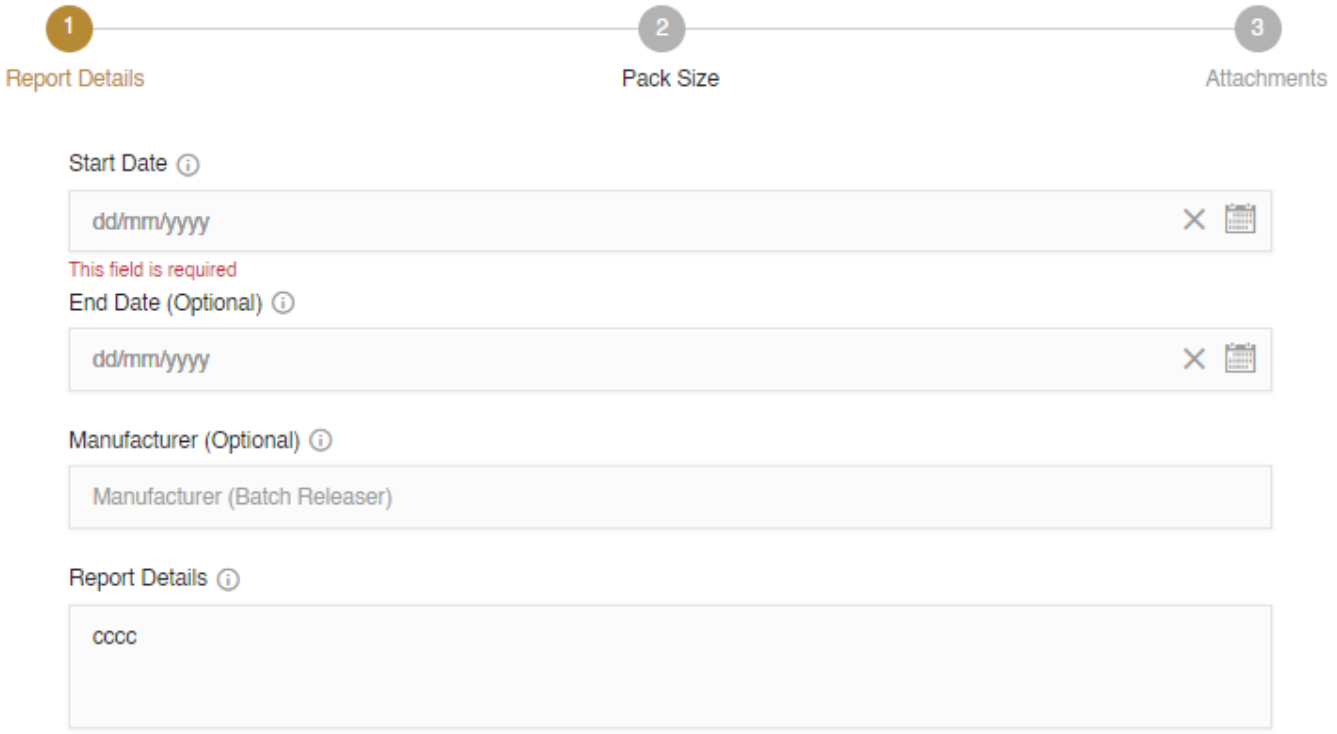
Online Submission/ New Launched Features/ ADR / ICSR Submission



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Online Submission/ New Launched Features/ ADR / ICSR Submission

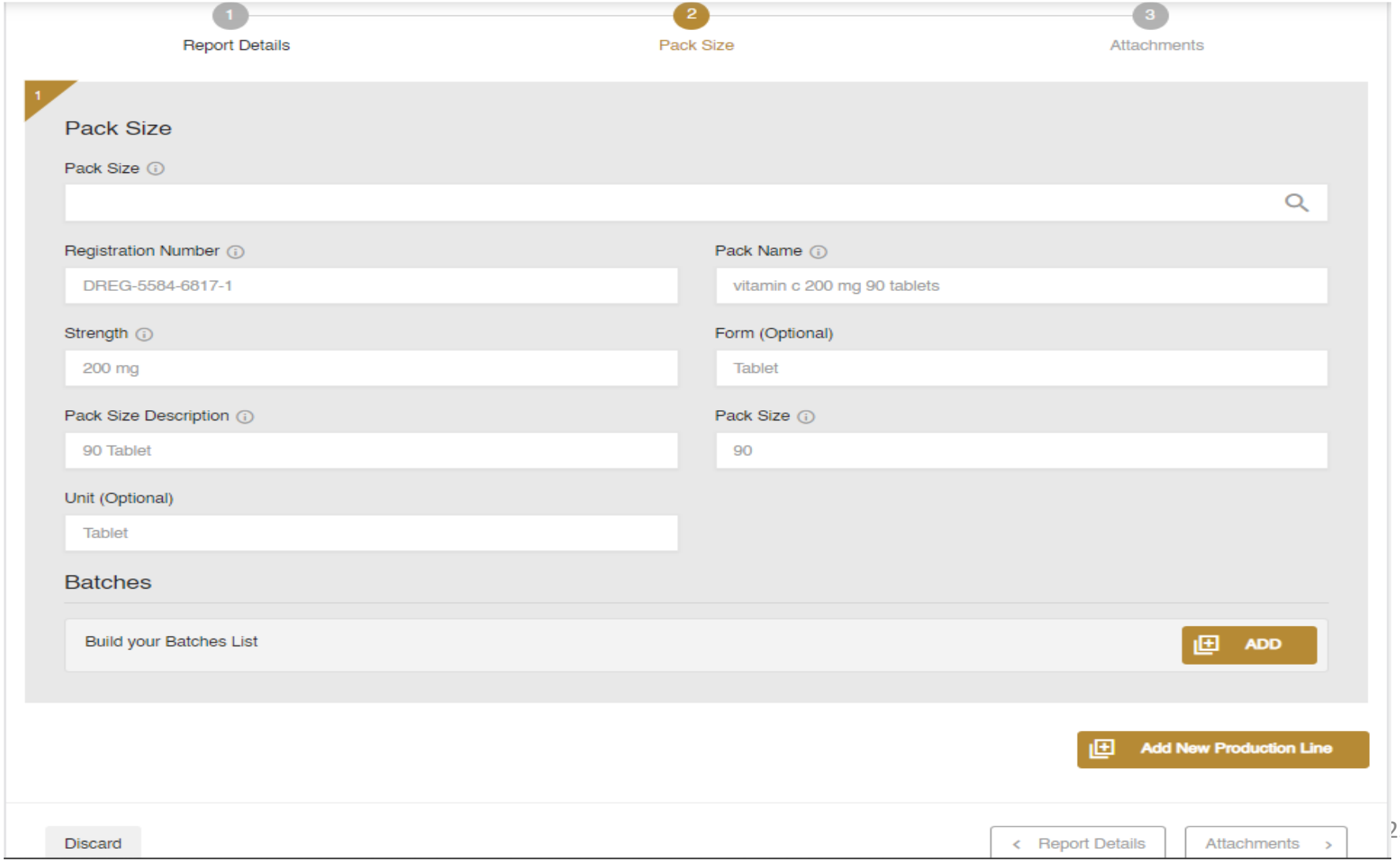
- Report Details



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Online Submission/ New Launched Features/ ADR / ICSR Submission

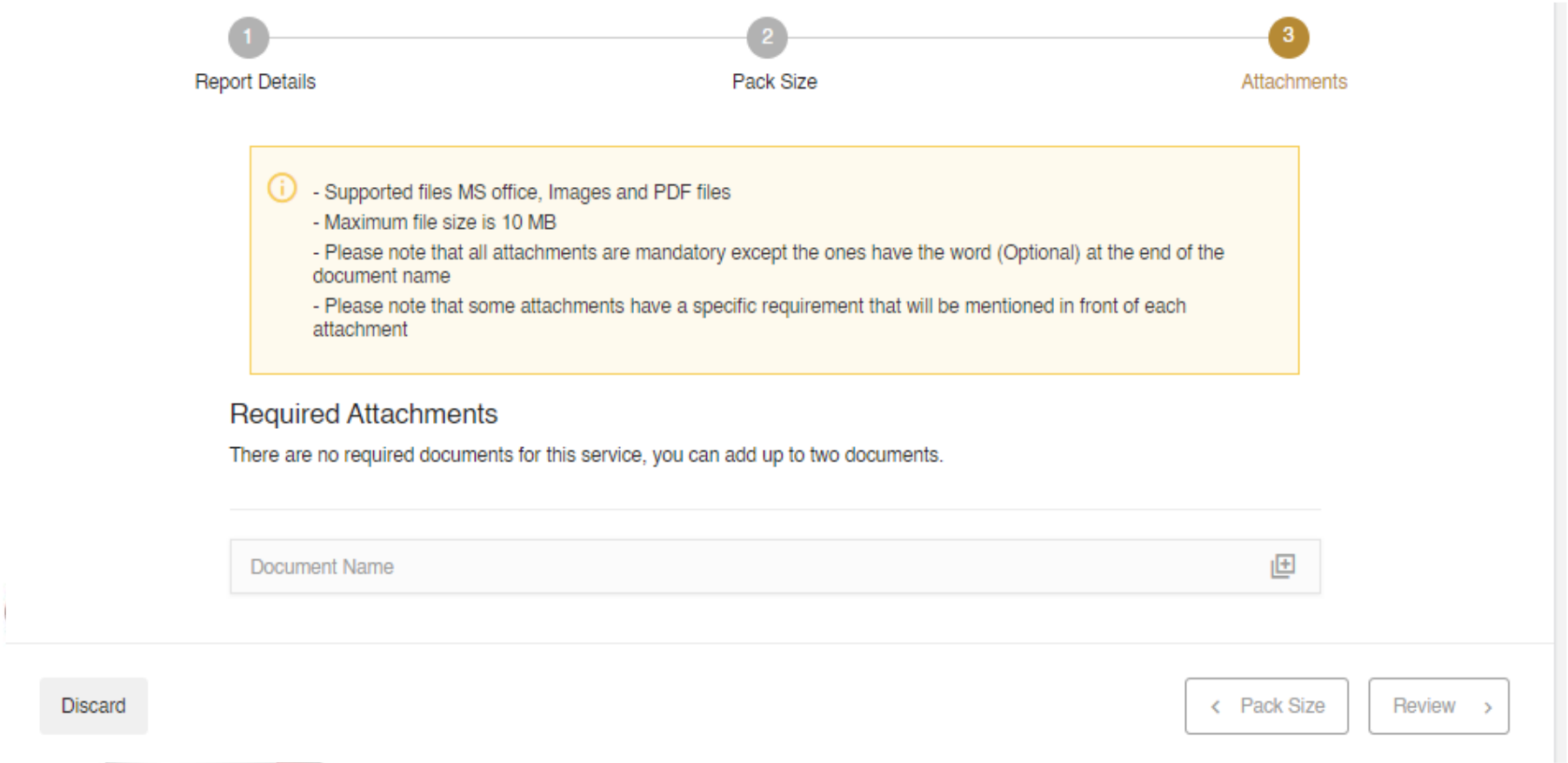
- Pack Size



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Online Submission/ New Launched Features/ ADR / ICSR Submission

- Attachments



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Online Submission/ New Launched Features/ ADR / ICSR Submission

- ## Review Application

Review Application After the applicant completes filling all application details, they must click on the Review button to proceed with application submission. Once the applicant clicks the Review button, they will be redirected to Review screen where they are able to perform the following actions:

a. Edit Application
b. Discard Application
c. Read & Accept General Terms & Conditions
d. Submit Application



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Online Submission/ New Launched Features/ QPPV PV Officer Submission

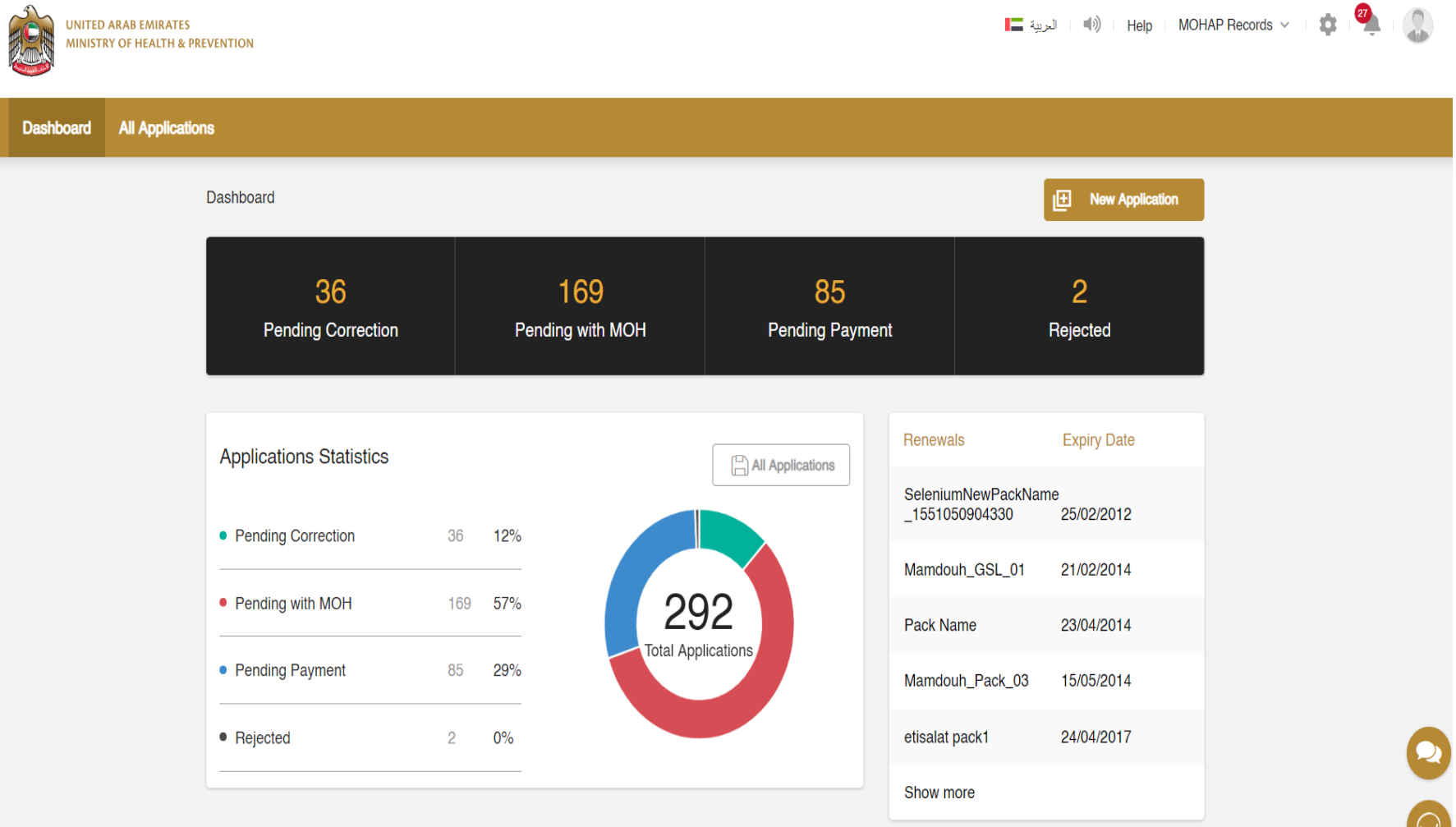
In order to start this service you have to request access to the System , access will be granted to :

- **Local Manufacturers**
- **Medical Store**
- **Scientific Office (MAH as per the products Registration Certificates)**



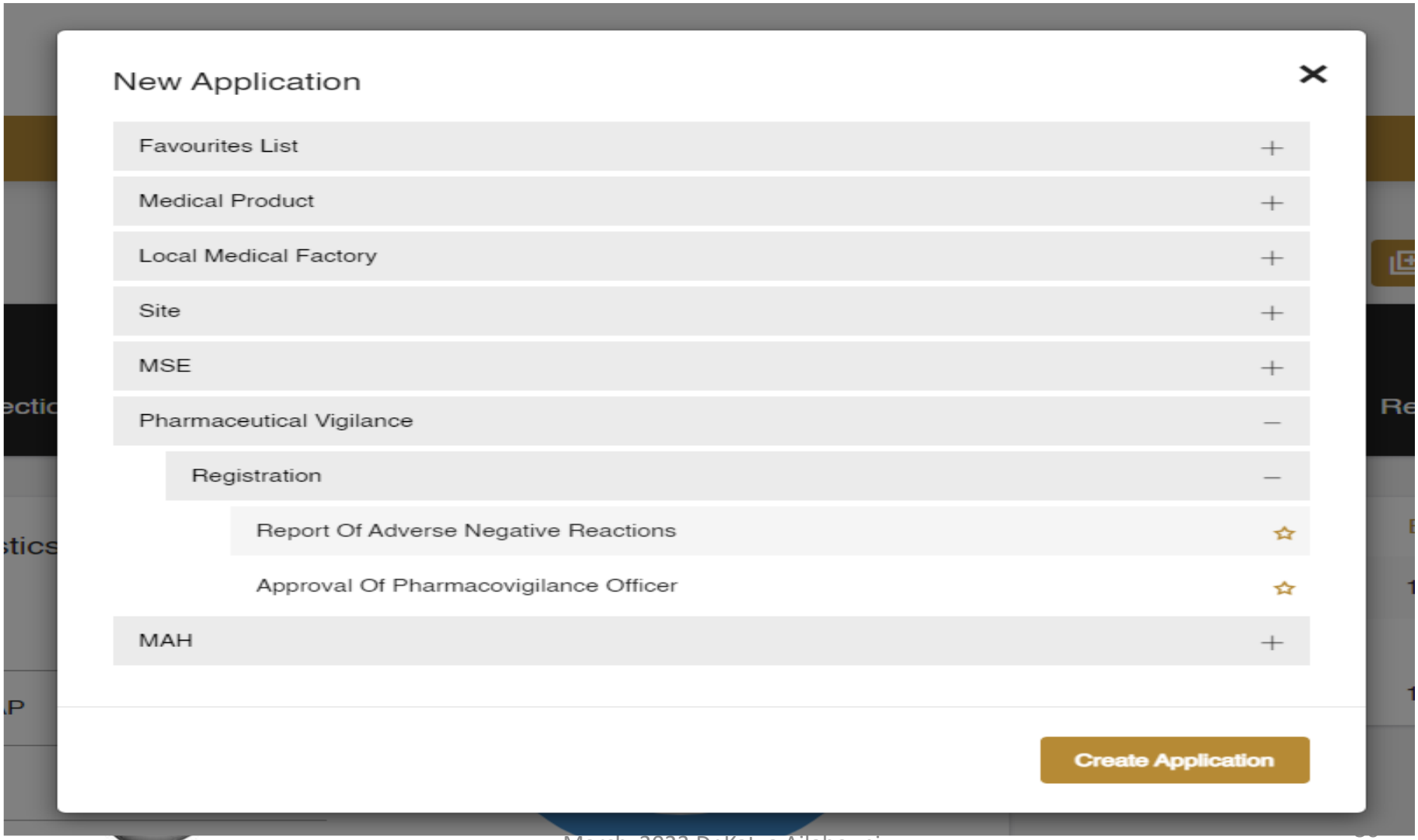
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Online Submission/ New Launched Features / QPPV PV Officer Submission



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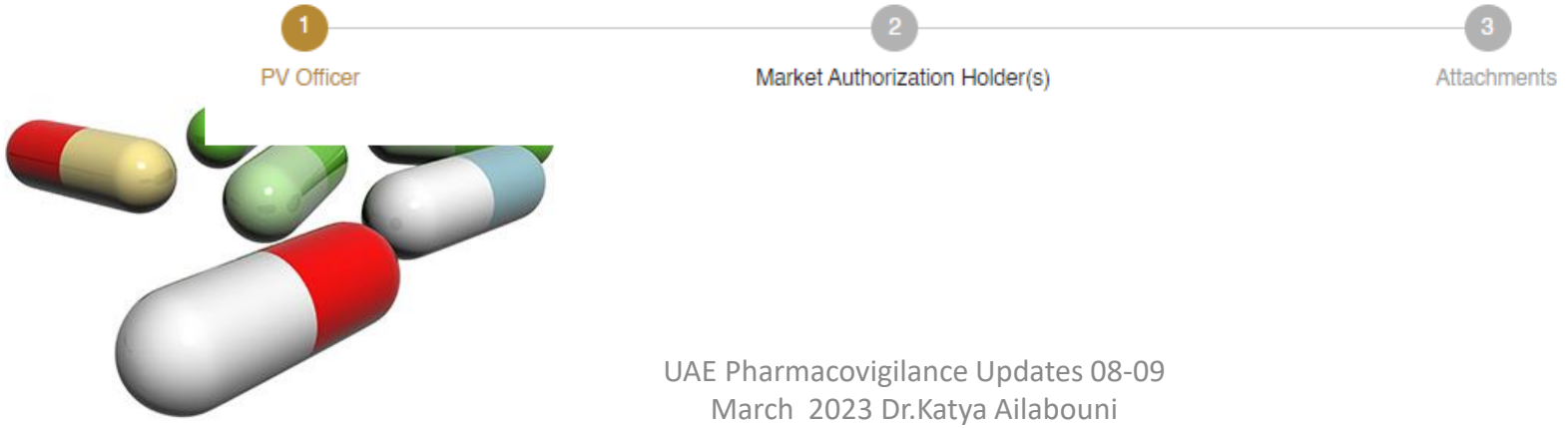
Online Submission/ New Launched Features / QPPV PV Officer Submission



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Online Submission/ New Launched Features/ QPPV PV Officer Submission

- To complete the **Approval of Pharmacovigilance Officer**, the applicant must fill the following sections:
- PV Officer
- Market Authorization Holder(s)
- Attachments

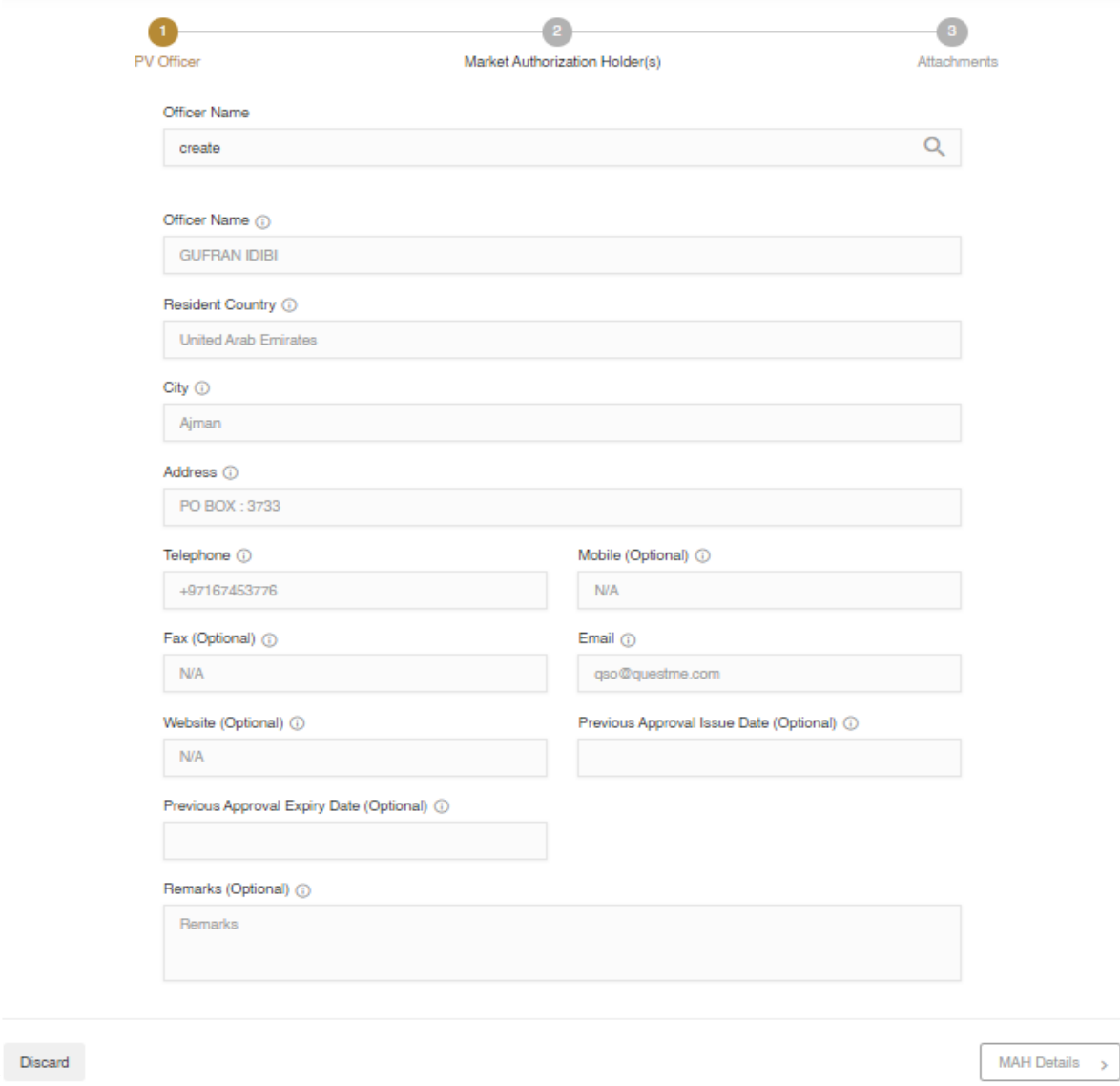


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Online Submission/ New Launched Features/ QPPV PV Officer Submission

- PV Officer
  - Officer Name
  - Resident Country
  - City
  - Address
  - Telephone
  - Mobile (optional)
  - Fax (Optional)
  - Email
  - Website (Optional)
  - Previous Approval Issue Date (Optional)
  - Previous Approval Expiry Date (Optional)
  - Remarks (Optional)





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Online Submission/ New Launched Features/ QPPV PV Officer Submission

- Market Authorization Holder(s)

50% Completed

1 PV Officer — 2 Market Authorization Holder(s) — 3 Attachments

Market Authorization Holder(s)

MAH Name	Country	City	Address	ACTIONS
waymade Plcs	United Kingdom	Basildon	sovereign house , miles gray road basildon , essex , united kingdom	
i.com medical GmbH	Germany	Munich	Kaflerstr. 15, Postal Code 81241, Munich	

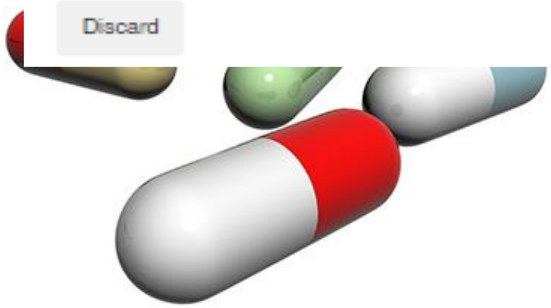
2

Select MAH

Discard

< PV Officer

Attachments >



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Online Submission/ New Launched Features/ QPPV PV Officer Submission

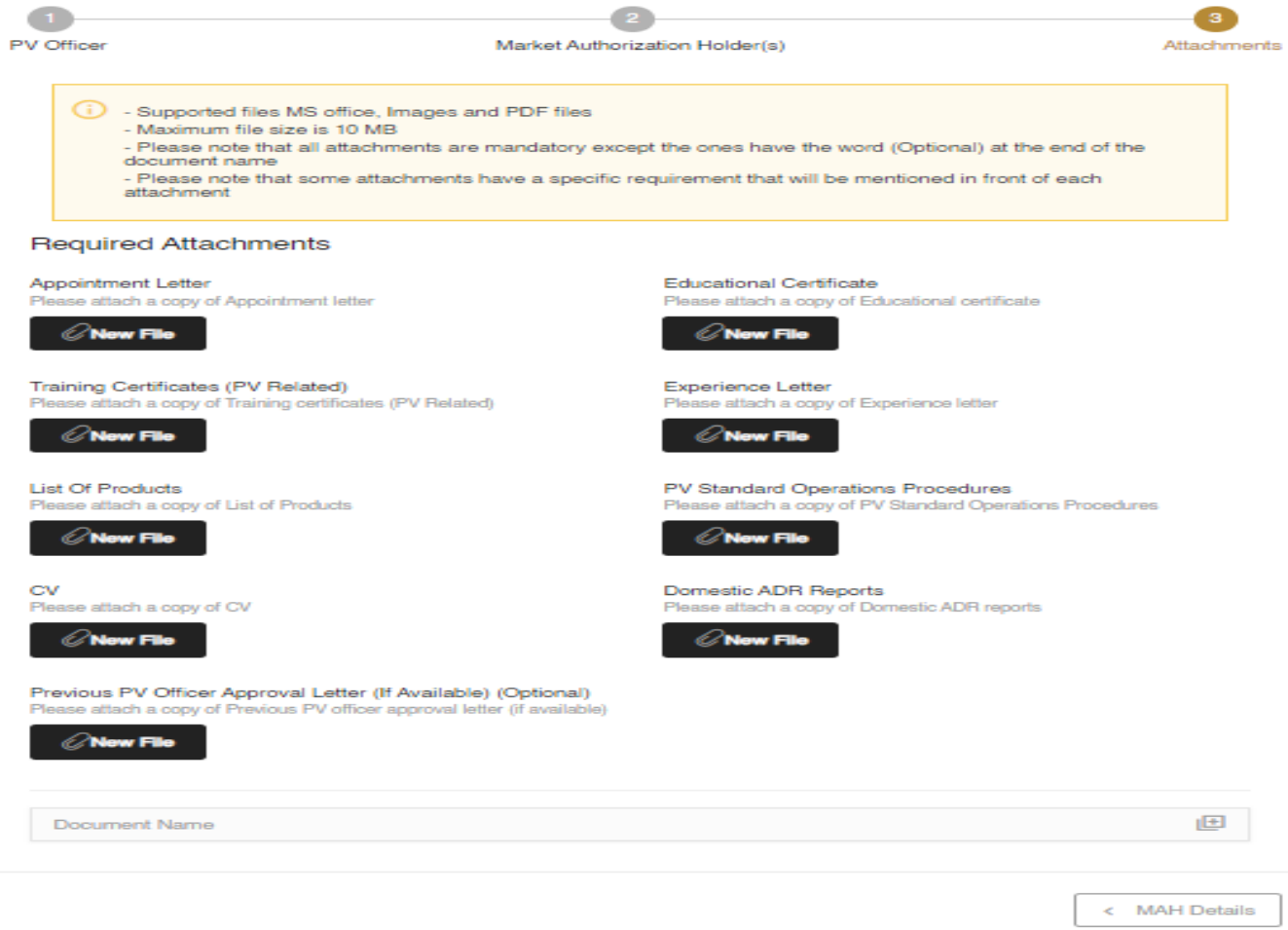
- Attachments
  - Below are the attachments the applicant must upload before moving to the next section.
    - Appointment Letter
    - Educational Certificate
    - Training Certificates (PV Related)
    - Experience Letter
    - List Of Products
    - PV Standard Operations Procedures
    - CV
    - Domestic ADR Reports
    - Previous PV Officer Approval Letter (If Available) (Optional)
    - Proof Of Residency IN UAE



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Online Submission/ New Launched Features/ QPPV PV Officer Submission

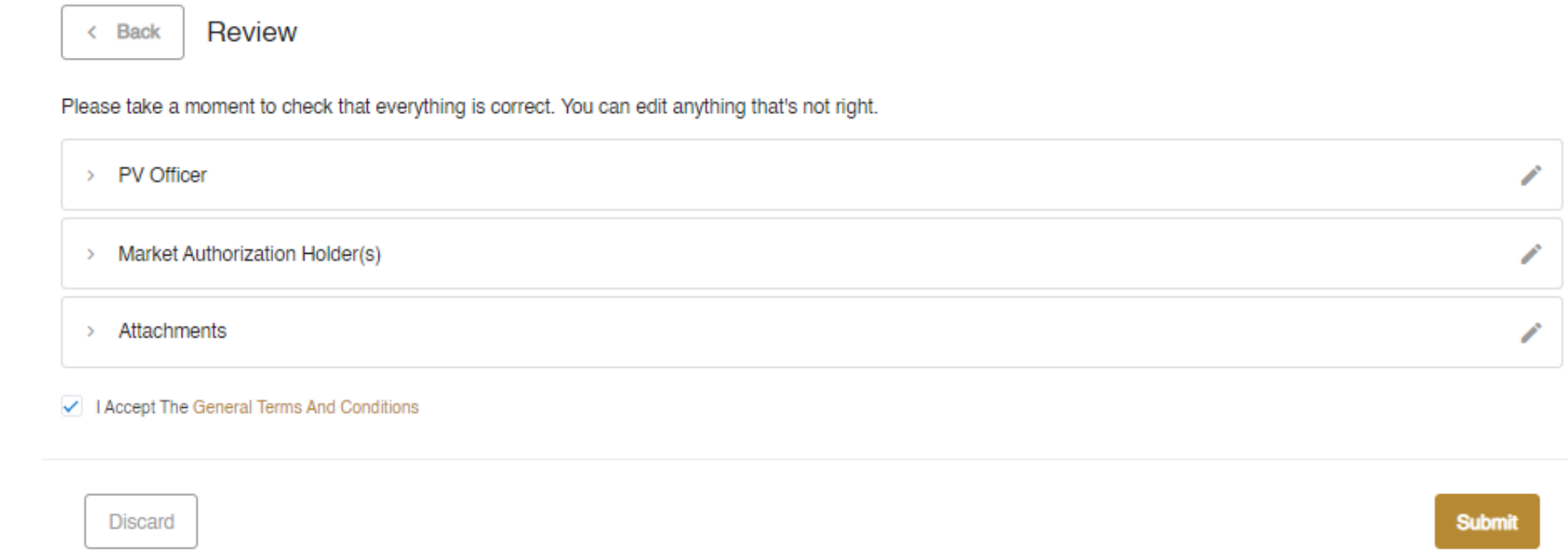
- Attachments



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Online Submission/ New Launched Features/ QPPV PV Officer Submission

- Review Application





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Future Projects

- ✓ Addendum to UAE Good Pharmacovigilance Practice Guidelines for Different Product registration classes . By June 2023



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Thank You

