UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

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Tatmeen

A. GENERAL

Q.1 What is Tatmeen?

Tatmeen is a digital platform from the Ministry of Health and Prevention that enables the tracking and tracing of all pharmaceutical products in the United Arab Emirates.

Q.2 What is serialization?

Serialization is the application of a GS1-approved 2D Matrix barcode and human readable information onto all drug secondary packing.

Q.3 When was the legislation issued by the ministry of Health and Prevention?

The legislative decree was issued on June 14, 2021.

Q.4 Where can I find the serialization legislation

You can view the Serialization Legislation in Arabic here and in English here.

Q.5 When will Tatmeen become operational?

The go-live date for Tatmeen is December 13, 2022.

Q.6 What is the period to comply with the legislation?

There is a 6-month period to install the 2D matrix barcode and human readable format, as well as comply with serialization, the deadline for this is December 13, 2022.

Q.7 What is the timeline of the Go Live?

Partners will start receiving the registration invitation emails from the month of July. This will be done as a phased approach to register in the pre-production environment. You will receive another registration invitation email by September that contains the Live Environment address (URL) to switch to the Live Environment before the "Go Live" date. The "Go Live" is scheduled for December 13, 2022, as per the official announcement.

Q.8 What if we are not ready on time before the Go Live date on 13 of December 2022, what will be the consequences?

The Go Live date is issued by the government 18 months before the Go Live date, so there is no reason to not abide by the Go Live date. The government will enforce the implementation of the Tatmeen program as per the law.

Q.9 What is meant by Supply Chain Partners, and what is the role of each of them?

Supply Chain Partners are entities that produce, transport, store, or dispense pharmaceutical products. They are classified as either:

- Marketing Authorization Holders (MAH) who own the medicine and either manufacture it directly or use a manufacturing subcontractor and are supposed to handle commissioning messages to Tatmeen. MAH can have Scientific Offices in the country or in the free zone as well.

- Licensed Agents (local distributors): These are companies that are allowed to import products into the country, and are responsible for obtaining an import permit from MoHAP and including it in the commissioning messages sent by MAH or by them directly.

- 3PL: are companies that store and distribute medicines whether in the UAE mainland or in the Free Zone. They are responsible of sending shipping messages into and out of their warehouses.

Dispensaries: These include pharmacies, hospitals, clinics, or rehabilitation centers that dispense products to final consumers (patients) and are responsible for dispensing messages on Tatmeen.

Note: Some partners may have more than one role in the supply chain, and in that case, they need to handle all the messages associated with all these roles.

Q.10 When should dispensaries start reporting to Tatmeen?

Dispensaries are required to connect to Tatmeen in parallel to the rest of the supply chain partners, there is no special timeline for dispensaries.

Q.11 What about our warehouse operations? Should we change our warehouse software?

Tatmeen is all about serialization data and tracking these serial numbers of products. Having a Warehouse Management System (WMS) will make it easier to send these details to Tatmeen. However, some updates are needed before your WMS can communicate with Tatmeen. If you don't have a system, then Tatmeen will provide a portal and mobile service to perform these transactions. There is no need to have any track and trace system since Tatmeen will be the tracking tool.

Q.12 Can we use an external service provider to onboard us on Tatmeen?

Any supply chain partner can share their credentials with any external service provider (for example IT companies) to handle the connection process on Tatmeen. However, partners (MAHs, Licensed Agents, 3PL, Dispensaries) would still be responsible for all the activities that is performed using their credentials. We recommend that only the technical user credentials be shared (if required) with an external party and not the SPOC credentials. We recommend that you share the technical user credentials (if necessary) with an external party and not the SPOC credentials.

Q.13 What if our B2B connection was not ready before the Go Live date?

Any partner can use the portal and mobile views to upload all sorts of events if their B2B is not ready.

Q.14 How much will the Tatmeen platform cost partners?

Ministry of Health and Prevention will announce the fees associated with Tatmeen at a later stage, the final decision pertaining to the fees is still pending.

Q.15 Can I use the information loaded onto other government sites for Tatmeen (European medicines verification organization, Saudi Arabia, and so forth)?

No, the United Arab Emirates requires you to follow the decrees and regulations issued by the Ministry of Health and Prevention in relation to drugs serialization and the Tatmeen platform.

B. REGISTRATION

Q.1 How to register with Tatmeen?

The process begins once the partner master data and the product master data are both updated in BrandSync. After that, Tatmeen will receive the master data and release the registration email to the single point of contact, kickstarting the process. There are manuals and guidelines on tatmeen.ae that will help all partners register and connect with Tatmeen.

Q.2 Do we need to get a GLN?

Yes. All supply chain partners: MAH, Licensed Agents, 3PL, and Dispensaries need to get a GLN from BrandSync, as part of their master data registration. This enables the government to track the routing and location of any medicine.

Q.3 We see that we must upload for product on BrandSync, could you please tell me how I can do this?

GS1 provide support for the BrandSync platform, in conjunction with Tatmeen. Press on the link to access BrandSync support. [Homepage (brand-sync.com)]

Q.4 If our products are already on BrandSync, do we need to enter our details again to Tatmeen?

No. The data is getting automatically synchronized with Tatmeen. There are no actions required from partners.

Q.5 What if my drug has not been registered with the Ministry of Health?

The application of 2D Matrix barcodes applies to both registered and non-registered drugs and is mandatory for all drugs imported or produced in the UAE.

Q.6 What are the product types that are required to be registered in Tatmeen?

Any conventional medicines and biological medicines need to be commissioned by Tatmeen. Supplements are not part of Tatmeen at this stage.

Q.7 Do I have to still register my company and our drug portfolio for the UAE to the Ministry of Health and Prevention?

Yes, all protocols for the registration of scientific offices, medical stores, registration of drugs will remain as they are today.

Q.8 Do I have to register my production site, clinical site, pharmacy on the system?

Yes, all sites that are licensed to dispense drugs will be required to be registered with a Global Location Number. For more information, click on this link.

Q.9 Which MAH GLN should a foreign manufacturer use while registering a product?

The MAHs can choose to use the original manufacturer GLN or the local Scientific Office GLN. Both GLNs can be used.

Q.10 The Manufacturer has a BrandSync account and registered products, do we need to do that again?

If the manufacturer has already uploaded the master data for products, then the distributor is not required to create products again on BrandSync.

Q.11 Will more information be issued to help the industry onboard the Tatmeen platform?

Yes, the Tatmeen website will carry all updates related to the introduction of the Tatmeen platform and the Ministry of Health and Prevention will issue any decrees or regulations for the UAE.

Q.12 Will training be provided for the implementation of Tatmeen for my company?

Yes, Tatmeen will provide support and training to ensure you are able to access and work with the Tatmeen platform.

Q.13 Are 3PL required to register with BrandSync?

The 3PLs are not currently registered with MoHAP, however the master data of the 3PLs should be present in Tatmeen; therefore, the 3PLs need to register with BrandSync to get a GLN.

Q.14 Will I still have to report issuing of controlled drugs and opioids to the other government entities?

Yes, there will be no changes in any reporting of information to those government entities you currently have to mandatorily report to.

C. FUNCTIONAL PROCESS

Q. 1 We source products from local manufacturers, how does the Tatmeen process flow for local products?

Locally manufactured products follow similar process but instead of the import permit they have to apply for local sales permit.

Q.2 How can we get the import permit number?

The process starts with the Licensed Agents (distributors) applying for the Import Permit, which indicates the intention to import a certain medicine - this usually does not have a validity period. Once the product is ready to be shipped, the Licensed agent should apply for a Shipping Permit Number or SHP, that should also contain one or more import permit numbers. Once approved, it becomes a Shipping Permit that is valid for three months only. After the deadline, another permit should be applied for.

Q.3 Are there any guidelines that explain the import permit process?

On the ministry website, there is a Services section that explains the process of getting an import permit and shipping permit.

Q.4 Would the new Import Permit process have any effect on the timeline of Tatmeen's Go Live?

No, the import permit process will not cause any change in the Go Live of Tatmeen.

Q.5 What if the product that was shipped to the UAE did not have the same serial number that was commissioned to Tatmeen?

These products will be rejected by customs, and receive a decommission status, and the MAH will have to do a new commissioning process for the correct serial numbers.

Q.6 Where can we get serial numbers if our manufacturer cannot provide them?

Serial numbers must be generated by the manufacturer or MAH, and then reported to Tatmeen. However, Tatmeen can generate serial numbers for Serial Shipping Container Codes (SSCC) that are used for aggregation messages through a connection with GS1.

Q.7 When importing from a Scientific Office in the free zone to mainland, who is the Licensed Agent in this case?

The Licensed Agent will always be the supply chain partner who is attributed to the specific medicine in the drug administration database, regardless of whether the product is coming from a Free Zone or from overseas.

Q.8 Do we need to report products that we receive in our warehouse in the Free zone if they are not going to be shipped to the UAE market?

No, only products that are destined for the UAE need to be reported to Tatmeen.

Q.9 Our products get shipped from overseas to the free zone and then to the UAE, when should we send commissioning messages?

Only the products that enter to UAE mainland should be reported to Tatmeen, anything that happens in the Free Zone is out of Tatmeen's program scope. Therefore, once the products get segregated, you will then be able to send the commissioning messages.

Q.10 We have several locations around the globe. Our factories, hubs, distribution centers, and our local scientific office are in UAE. Which GLN should we use?

The MAH has the flexibility to use any GLN for their product master data. The manufacturer MAH is the most preferred GLN, however the scientific office can also be used for commissioning.

Q.11 Can the Licensed Agent handle commissioning instead of the MAH?

Yes, if the Licensed Agent GLN is associated with the product in the drug department master data, then either that specific licensed agent or the MAH can send commissioning messages.

Q.12 Can the 3PL handle commissioning?

For any product, it's either the MAH or the Licensed Agent that can handle commissioning, provided that their GLN is linked to the product master data. If MAH or LA want to delegate this role, then these supply chain partners can share their credentials with the 3PLs but they remain responsible for the data.

Q.13 What messages should the distributor produce?

Any action that the distributor takes on the products should be reported, including packing, unpacking, receiving, shipping, loss or damage, etc.

Q.14 If upon importing products to the country, the local distributor decided to return / reject the products, then how can these products be treated on Tatmeen?

These products must be decommissioned, and in this case the reason will be export.

Q.15 What will happen to a product when it gets sold to a patient?

Products that are sold to patients from dispensaries will receive a status changed: "Decommissioned" - "Dispensed" and will be automatically decommissioned from Tatmeen.

Q.16 Are we required to report Free Samples to Tatmeen?

If these are Conventional Medicines or Biological Medicines, then yes. There are clear message types on Tatmeen for free samples.

Q.17 What is product verification?

Product verification will show the status of the product, and whether it is registered on Tatmeen or not, and if there is any aggregation on this product.

Q.18 How can Tatmeen verify unregistered drugs?

Unregistered drugs details will go to the import permit system, and then to Brandysnc before they get sent to Tatmeen as well. The difference is that more details must be added on Brandsync before they get reflected on Tatmeen.

Q.19 What are the required actions for warehouse and delivery?

The warehouse has to share receiving messages with Tatmeen whenever they receive goods, in addition to any other activities that they perform including “Packing”, “Unpacking”, “Ship out”, “Sample Out”, “Damage”, and “Lost”. Please refer to the Logistics Technical Guide for more information.

Q.20 If we need to ship any product out of our warehouse on an urgent basis, do we need to get any approval from Tatmeen?

No. Tatmeen is not giving any approval, you just need to report the shipping on Tatmeen.

Q.21 Who can initiate the product recall process?

Product recall will be initiated on Tatmeen, based on product master, the MAH or Licensed agent. The government can do that as well (MoHAP, DOH, and DHA).

Q.22 When should the product and batch recall functionalities be added?

These functionalities will be live before the Go Live date just like all other functions.

D. TECHINCAL

Q.1 Will the Tatmeen system require special software?

No, Tatmeen will work with all partners in the supply chain to give you access to the platform in the easiest manner for your circumstances.

Q.2 We already have a serialization partner, can our partner integrate with Tatmeen directly?

The MAH can create several service users, and authorize each user for a certain number of GLN only, and share the credentials of the service users with their partners. However, by law, the responsibility remains with the SPOC for all the transactions of the sub-users.

Q.3 What is B2B connectivity?

B2B connectivity refers to the integration between two systems, and in Tatmeen's case it is the integration between the supply chain partner's system and Tatmeen.

Q.4 What is an API?

API refers to Application Programming Interface (not to be confused with Active Pharmaceutical Ingredient), and refers to the way two systems interact with each other without human intervention.

Q.5 How to register for API?

Once the SPOC registers with Tatmeen, the latter needs to access Tatmeen developer portal and subscribe to API.

Q.6 What is a SPOC?

SPOC refers to the Single Point of Contact nominated by the company and responsible for all activities on Tatmeen. Every partner, whether a MAH, Licensed Agent, 3PL, or Dispensary will have one SPOC.

Q.7 What is the difference between SPOC, dialogue user and technical user?

A SPOC is the super user who manages all other users and all activities on Tatmeen, and can hence create other types of users. A dialogue user is a username created for any human who wants to access Tatmeen, either via the portal or by mobile. Service user, technical user, or B2B user are created to be used by any system that will be connected to Tatmeen.

Q.8 Is it mandatory that the SPOC creates other users?

Only Service users can create and manage API. So, the SPOC has to create a service user, while the rest of the users are optional.

Q.9 What are the message types that we need to report on Tatmeen?

The types of messages are all listed in the Technical Guide that is published on www.tatmeen.ae. These messages can be commissioning, aggregation, shipping, pack/unpack change in hierarchy etc.

Q.10 Are commissioning and aggregation part of one event?

Commissioning and aggregation messages can be combined in one message, but they can also be sent to Tatmeen separately.

Q.11 Are there different methods of commissioning our products on Tatmeen?

Yes, the best and most efficient way is to use the B2B connectivity (API), however if the MAH does not have the technical capability to do that, they can upload a file to the Tatmeen portal with a certain structure, or the MAH can share their technical user credential with a partner who has this capability. But in this case, the MAH will continue to be responsible for the actions of their partners since they will be using their credentials.

Q.12 Should the import permit number be part of the commissioning message?

Yes, the commissioning message will fail if it does not contain an import permit number or local sales permit number.

Q.13 If a scanned serial number was not available in Tatmeen, what kind of alert messages would the user receive?

In such a case, alerts will be generated and shared with MoHAP Empowerment, starting an investigation for suspected activity. Alerts are for government entities only and not for supply chain partners.

Q.14 How do we test the system before the Go Live?

The SPOC can use the staging environment to start sharing data between partner system and Tatmeen and can finally check the status of the integration. Partners can register to a test case guide to understand the message structure and how to test them.

Q.15 Can we have a sample file that we can use to test the portal?

The portal for manufacturers is still being developed. Once completed, the file structure will be also released.

Q.16 How can we check the status of our messages (success/fail)?

The only way to check the status of B2B messages is through the "Message Query" tool, but there are plans to view message log from portal for B2B in phase 2. However, mobile and portal users can view the status of their messages now.

Q.17 Can we download data from Tatmeen?

No. Users can only view product data and partner data, but they cannot download serial numbers or batches from Tatmeen.