Barcode Requirements

Frequently Asked Questions (FAQs)

Q: Is this announcement and requirement, to include product barcode, limited to devices for layperson only? Or is it for ALL devices?

A: It is currently required for devices that are intended to be used by Lay Person and Home Use devices only

Q: What levels of packaging does this apply to? Only the unit of sale, or also to the shippers and units of use?

A: It is applicable for the unit of sale as minimum.

Q: What type of barcode format does Saudi FDA require? On our devices there are multiple barcodes and each contains different information.

A: SFDA barcode preferences are in the following order:

1. If the device comes with UDI Compliant Barcode:

   The applicant should enter the information for Static (Fixed) part only; which is known as DI= Device Identifier, as shown in the following example:

Fixed Device Identifier
(Human Readable Format)

2. If the device is not tagged with a UDI Compliant Barcode:

   The applicant should use the EAN-13/UPC barcode (if available)

3. If the device is not tagged with any of the above 2 Barcode types,

   Any other type of Barcode is acceptable

Q: Does SFDA require specific barcode format? Are both Linear OR 2D DataMatrix barcode acceptable?

A: Yes, both are acceptable.

Q: Is there any specific barcode size requirements?
A: No.

Q: How can we provide barcode information for Software only medical devices? Usually there is no barcode on the product labeling

A: If the software is intended to be used by layperson or home use device and no barcode available for this type of products. The applicant can provide a justification for exemption.

Q: Can some products be exempt from the bar code requirements because of their small container / box size or their container material (e.g. foil/ polythene wrap?)

A: All devices for layperson and home use shall be provided with barcodes. If it is not technically possible, the applicant should provide a clear justification for exemption to SFDA for review and give the final decision.

Q: What about the current applications for the Medical Devices which under process now? Is adding Barcode artwork required for it?

A:

- If the first SFDA review after payment was conducted on 7-June-2015 or later the applicant will be required to submit barcode information through the application.
- If the first SFDA review after payment was conducted before 7-June-2015, it is optional to the manufacturer to submit barcode information through the application (Recommended) or to submit the barcode after the application is issued through the new barcode module.

Q: Does this announcement effect immediately?

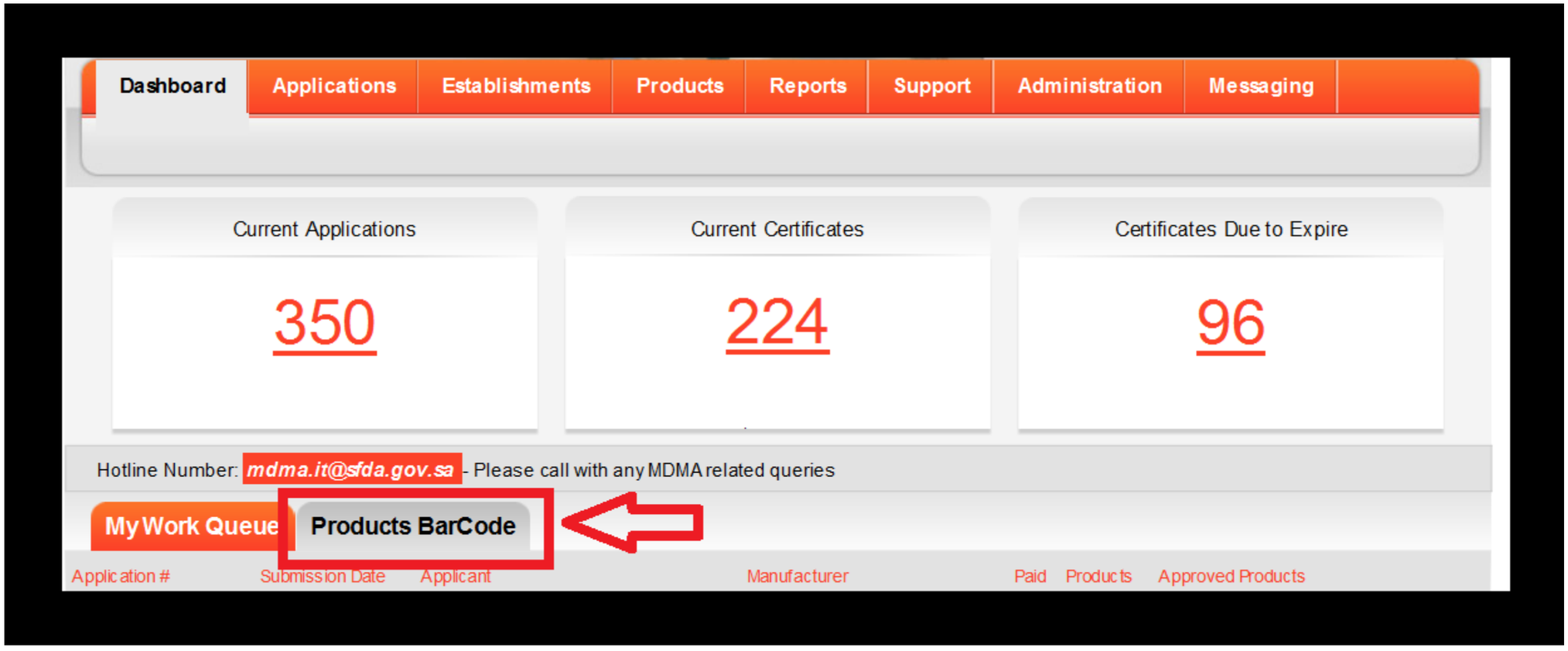
A: Yes, this announcement is effecting immediately.

Q: All oue Medical Devices obtained the MDMA license, how update barcode will be in this case? Shall we do it through update authorization?

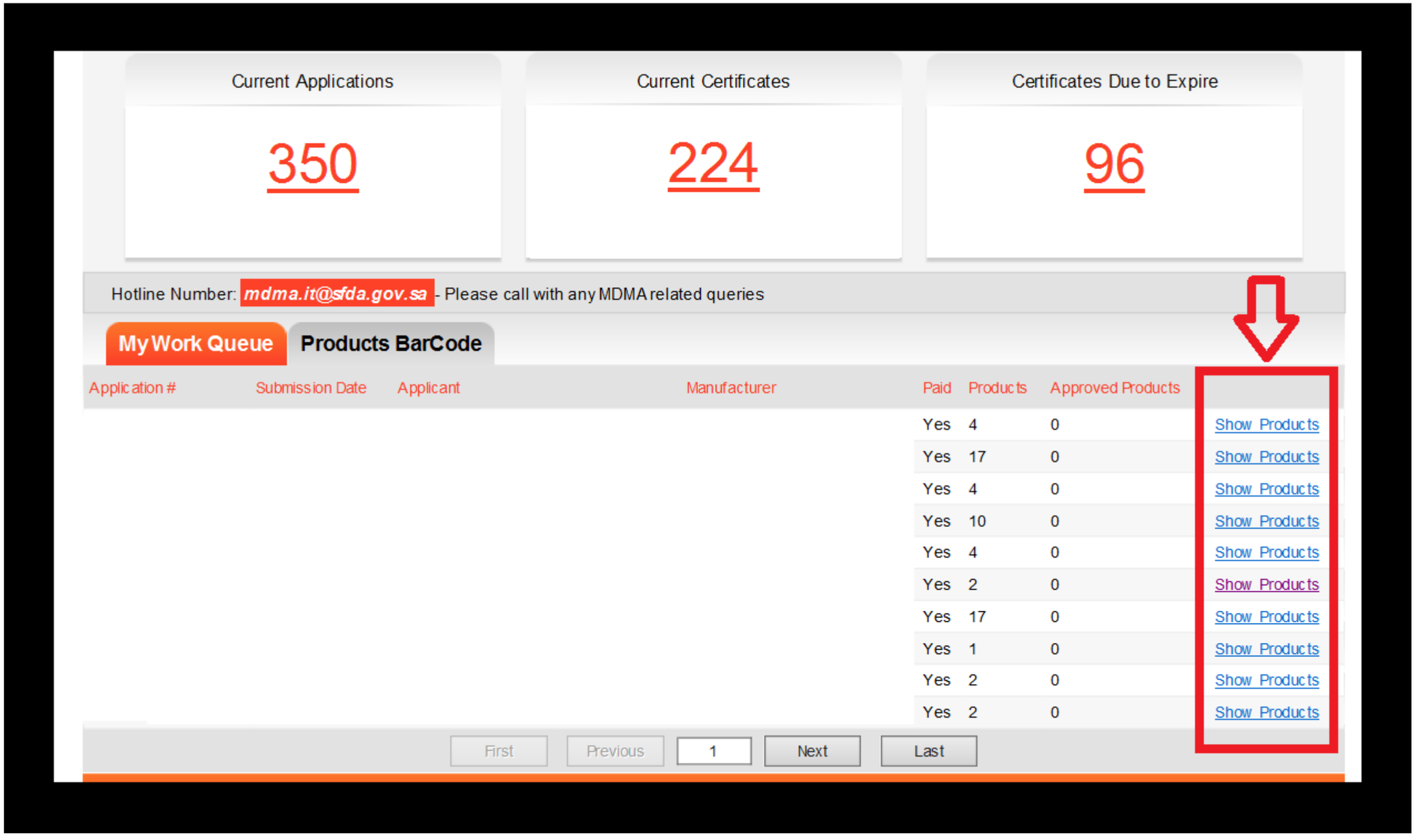
A: No, no need to use update authorization option. The applicant can submit barcode for products included in an issued authorization through the new Product Barcode module and for free.

Please follow the below steps to use the new Product Barcode module:

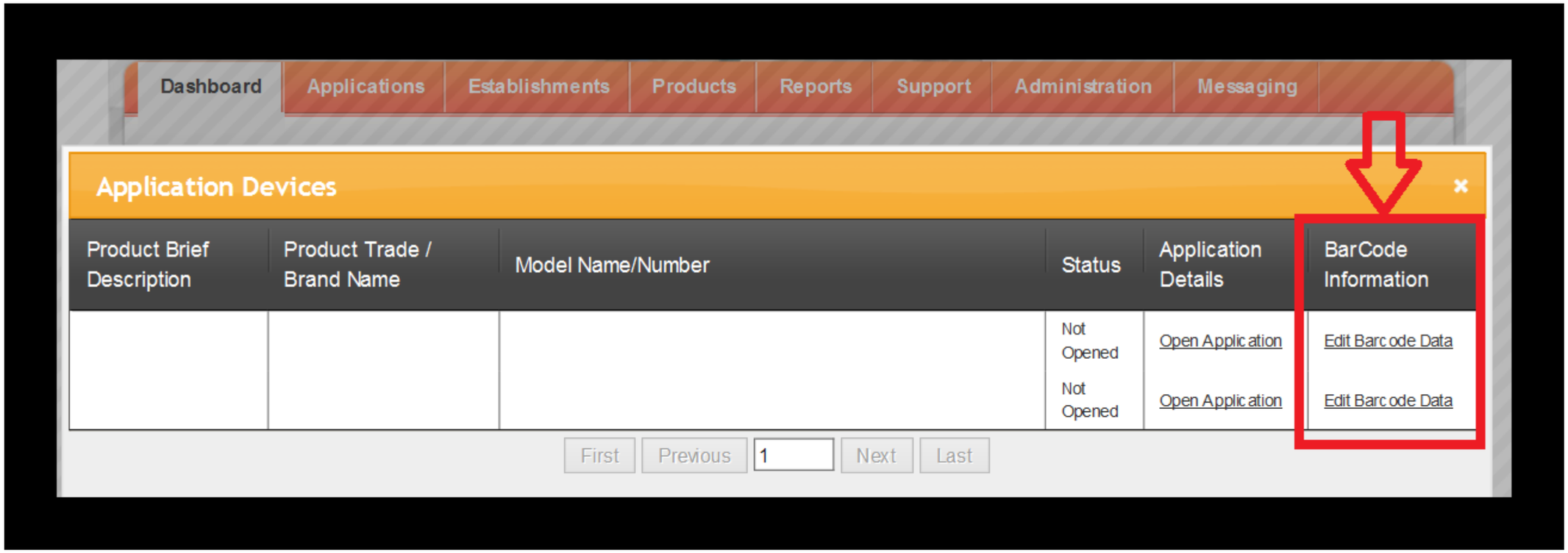
Step 1



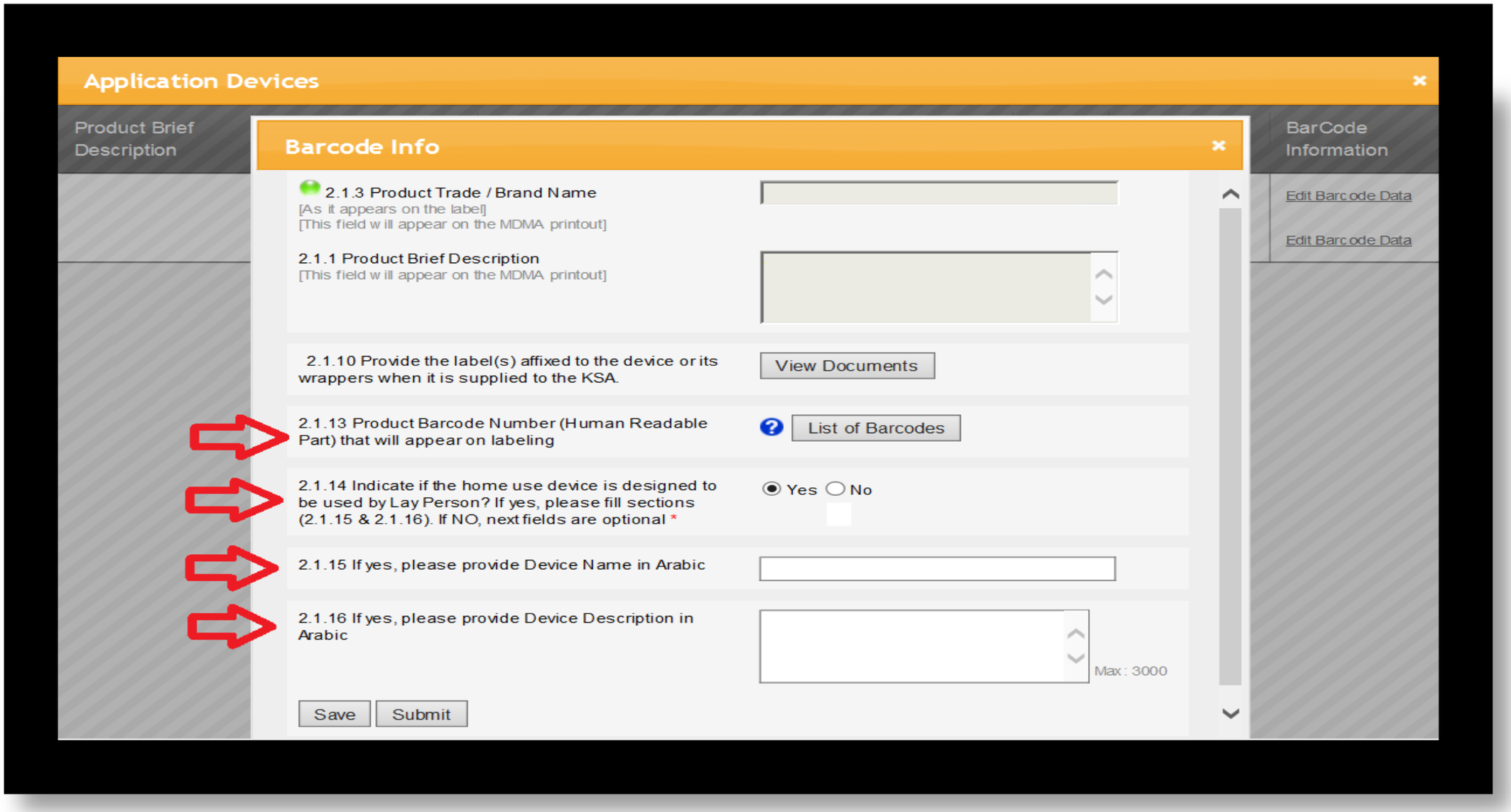
Step 2


Current Applications
350
Current Certificates
224
Certificates Due to Expire
96
Hotline Number: mdma.it@sfda.gov.sa - Please call with any MDMA related queries
My Work Queue
Products BarCode
Application #
Submission Date
Applicant
Manufacturer
Paid
Products
Approved Products
Yes 4 0 Show Products
Yes 17 0 Show Products
Yes 4 0 Show Products
Yes 10 0 Show Products
Yes 4 0 Show Products
Yes 2 0 Show Products
Yes 17 0 Show Products
Yes 1 0 Show Products
Yes 2 0 Show Products
Yes 2 0 Show Products
First
Previous
1
Next
Last

Step 3


Dashboard
Applications
Establishments
Products
Reports
Support
Administration
Messaging
Application Devices
Product Brief Description
Product Trade / Brand Name
Model Name/Number
Status
Application Details
BarCode Information
Not Opened
Open Application
Edit Barcode Data
Not Opened
Open Application
Edit Barcode Data
First
Previous
1
Next
Last

Step 4


Application Devices
Product Brief Description
Barcode Info
BarCode Information
2.1.3 Product Trade / Brand Name
[As it appears on the label]
[This field w ill appear on the MDMA printout]
Edit Barcode Data
2.1.1 Product Brief Description
[This field w ill appear on the MDMA printout]
Edit Barcode Data
2.1.10 Provide the label(s) affixed to the device or its wrappers when it is supplied to the KSA.
View Documents
2.1.13 Product Barcode Number (Human Readable Part) that will appear on labeling
List of Barcodes
2.1.14 Indicate if the home use device is designed to be used by Lay Person? If yes, please fill sections (2.1.15 & 2.1.16). If NO, next fields are optional *
Yes
No
2.1.15 If yes, please provide Device Name in Arabic
2.1.16 If yes, please provide Device Description in Arabic
Max : 3000
Save
Submit