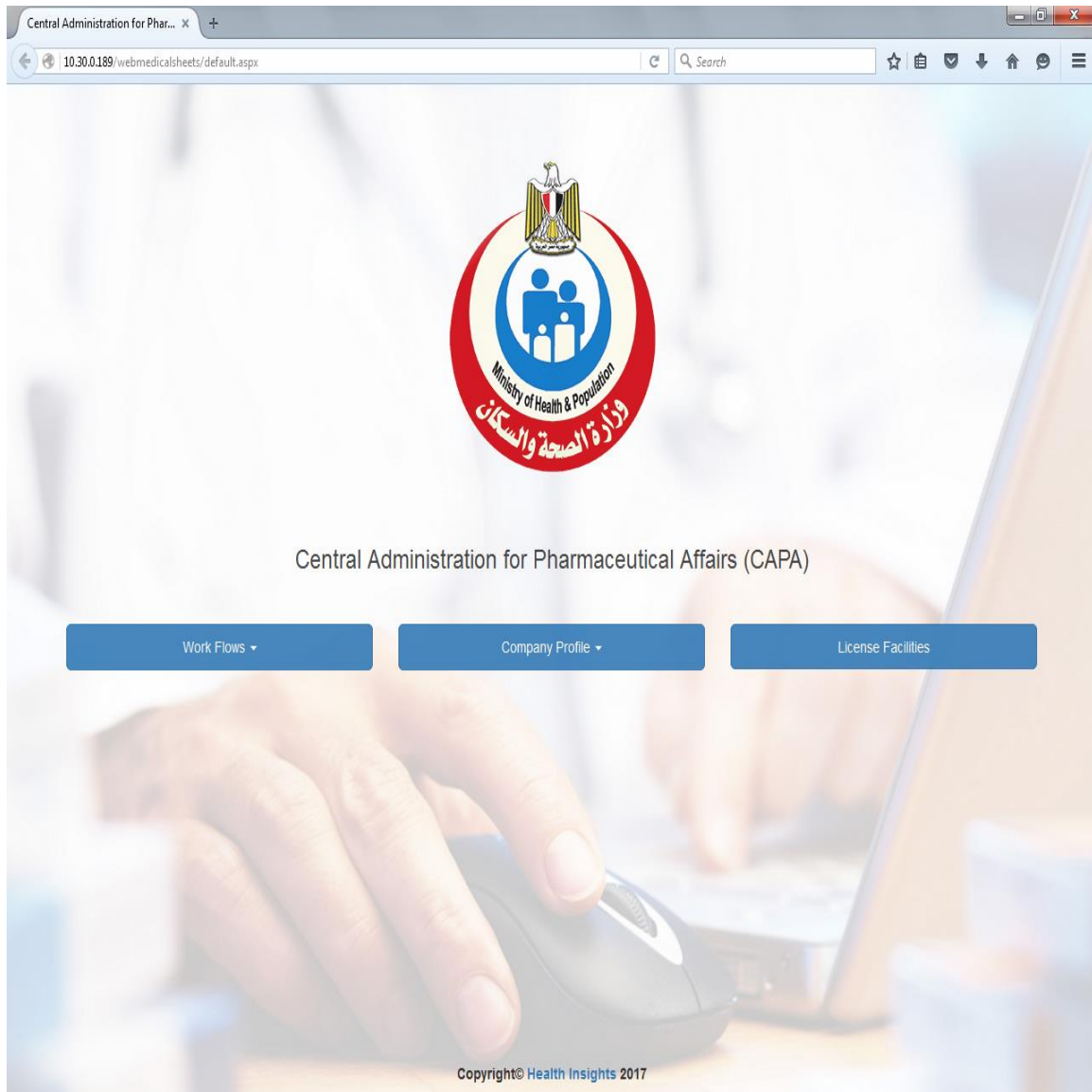


The Manual for the submission of the Naming Request for a new human drug Via the automated Naming Program

1. A program was developed to inquire about the names submitted for testing in accordance with the decisions of the Minister Decree (٤٢٥ - ٢٩٧ - ٨٢٠)
- 2-The naming program has been linked to the program for Request Inquiry in accordance with the requirements of automated operations in the central administration for pharmaceutical affairs.
- 3- The name screen is accessed through the website of the Central Administration for Pharmaceutical Affairs www.eda.mohp.gov.eg
- 4-Press **Open here**



5- When pressed, you are converted to the next screen

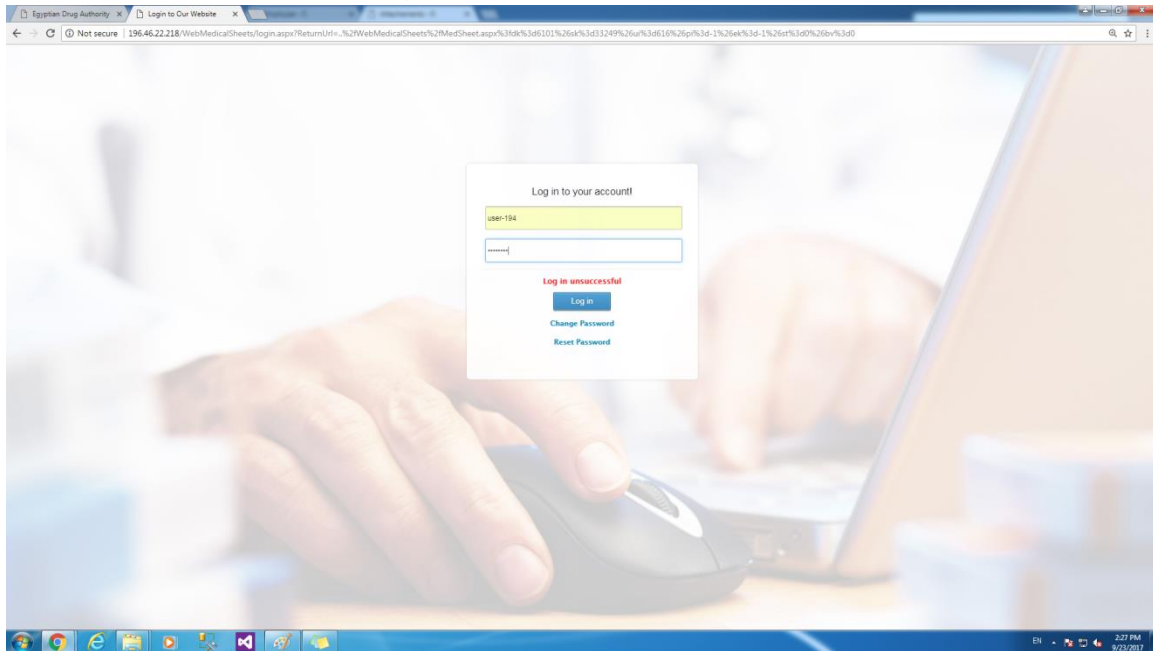


6 . Select Work Flow , the Dropdown List appears. Click Naming

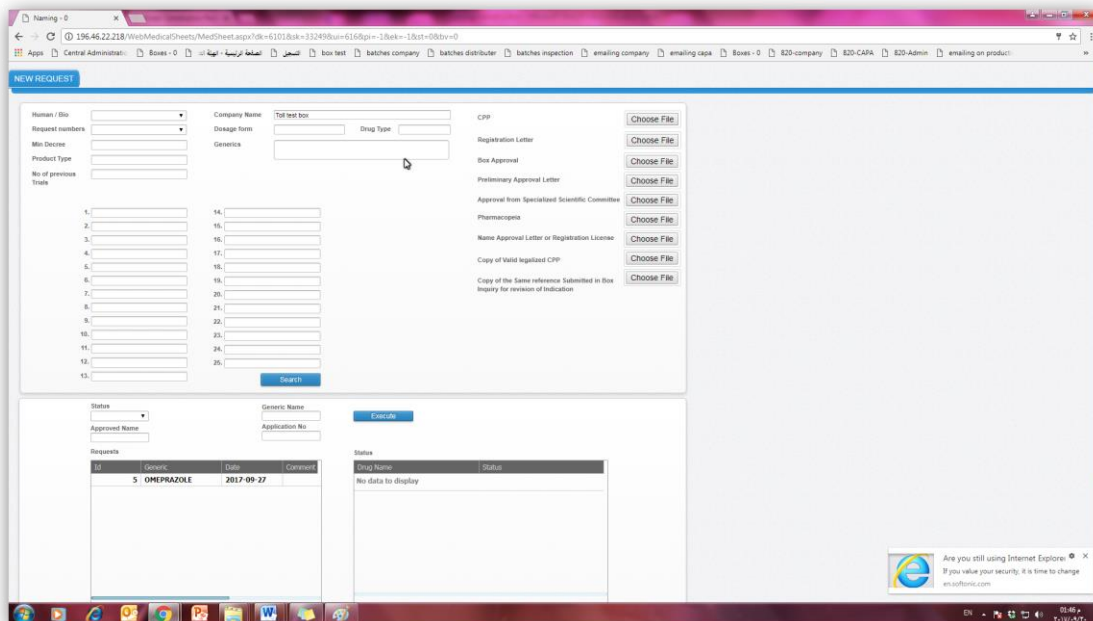
The screenshot shows a web browser window with the URL `10.30.0.189/webmedicalsheets/default.aspx`. The page features the logo of the Ministry of Health & Population, which includes the national emblem and Arabic text. Below the logo, the text "Central Administration for Pharmaceutical Affairs (CAPA)" is displayed. There are three main navigation buttons: "Work Flows", "Company Profile", and "License Facilities". The "Work Flows" button is expanded into a dropdown menu with three items: "Boxes Inquiry", "Naming" (which is highlighted), and "820". At the bottom of the page, there is a small copyright notice: "Copyright © Health Inspector 2017".

10.30.0.189/WebMedicalSheets/login.aspx?ReturnUrl=../WebMedicalSheets/MedSheet.aspx?dk=6101&sk=33249&ui=616&pi=-1&ek=-1&st=0&bv=0

7- you will be converted to the Log in screen



8- Register The user name and Password of the company and press Log in , you will be converted to the screen of naming Program.



9- The Company has to fulfill all the following fields as the following:

- Choose the Type of the Product (Human or Biological)
- According to the Registered User Name ,The Company Name will be Inserted Automatically
- Choose the request number of the product which is approved with the automated box program

Notes

- Inquiries about the Names of The Products are only made after the approval of the Box Request Inquiry.

○ **ملاحظة هامة:** في حالة الاستعلام عن المستحضرات الحيوية يمكن تقديم الاستعلام عن الاسماء بمجرد تسجيل الشركة لطلب الاستعلام عن صندوق المائل و لا يتطلب ذلك اصدار موافقة صندوق المائل حيث يتم اصدار موافقة موحدة لصندوق المائل و الاسماء

- 10- After choosing the Request Number, The Data (Dosage form - Minister Decree- Product type – Drug Type - Generics- Number of previous - Number of previous trials) will be Inserted Automatically According to the data of Box Request inquiry.

11-Upload the Following Attachments according to the table :

CPP	Under-license – Imported
Registration license	Line extension in case of registered product
Preliminary approval letter	In case of tender or export
Naming approval	Line extension in case of Under-registration product
Box Approval (stamped copy from CAPA with date)	Mandatory field - In all cases
Reference	In All Cases
Approval from specialized scientific committee (stamped copy from CAPA with date)	In non-reference products
Pharmacopeia	In Pharmacopeial products

- * In case of Local Products : Insert 25 trade Names
- * In case of imported Products : only one name Is required according to The CPP
- * In case of Line extension Products : a screen will be opened to choose from the registered and under registration Products of The Company

١٢ - After inserting the Names, Press **Search**

*If the Inserted names are matched with names provided before and included in the program: A message is displayed stating that a number of the names submitted are actually listed and that it requires modification or change of the name so that the program can save the data (in order to facilitate the company and save time and effort For each of the companies and pharmacists of the Central Administration for Pharmaceutical Affairs)

- * The Inquiry for the product will be recorded on the application screen with the date and time, and the Result of the Inquiry of each submitted name (Initial acceptance - Initial Refusal).

**The result of the Inquiry automatically shown from the program is an initial result where the name submitted is subject to two other phases of testing before final approval is issued.*

) ۳ -In the case of rejection of the first list of the Product , you can restore the previous steps and Re-Insert the second, third and fourth lists.

** The company can inquire about the applications submitted through 4 Filters :*

- Status*
- Generic Filter*
- Approved Name*
- Application Number*

** The names provided by the company are reviewed by the priority of the order in the list of names and the name approved by the Naming and labeling department is a final name and is not subject to modification.*