Work instructions

Title: Documentation of external requests for access to information (from healthcare professionals, patients and the general public) and their responses		
Applies to: Staff in the Medical Information Sector dealing with external queries		
Status: **PUBLIC**		Document no.: WIN/H/3320
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1. Changes since last revision

New WIN.

2. Records

All external requests for access to information as well as their responses are entered into the Queries database.

The Queries database is located on the FileMaker Pro server and can be accessed using the path: fmp7://fmapps.emea.eu.int/Queries_Database_KP5_v2.

The electronic request together with the response is saved as a Word document in DREAM in the appropriately labelled folder corresponding to the year/month the enquiry was received (Cabinets/Old EDMS Structure/Operational Units/Human/Post/MIS/Projects/external queries).

3. Instructions

Background

The purpose of the WIN is to provide instructions for the recording of external requests for access to information as well as the respective responses in the Queries database and in DREAM.

Requirements

- Access to the Queries database. This requires:
    - FileMaker Pro (version 10)
    - valid account and password
    - the client and the host must be on the same local area network.
- Access to Public folder "External Queries"

References

SOP/H/3386 SOP - Handling of external requests for access to information from patients, healthcare professionals and the general public:

User manual to Queries database (EMA/575192/2010)

Response templates (EMA/464669/2010)

Instructions

V-PD-DIS – Documentation Information Services Section (Product Data Management Sector)

DREAM - Document Records Electronic Archive Management

P-MI – Medical Information Sector

Step	Action
A	**Data entering**
1	A new request was received into the public folder "external queries" which was screened and it was decided that the request is suitable and sufficient background was provided (see SOP/EMA/0104 SOP - Handling of external requests for access to information from patients, healthcare professionals and the general public).
2	Open database (fmp7://fmapps.emea.eu.int/Queries_Database_KP5_v2)

Enter account name and password.

The database opens: Three panes are visible – "general Information", "Background" and "Analysis/ Answer". Choose which content pane to view by clicking the respective tab

Step	Action
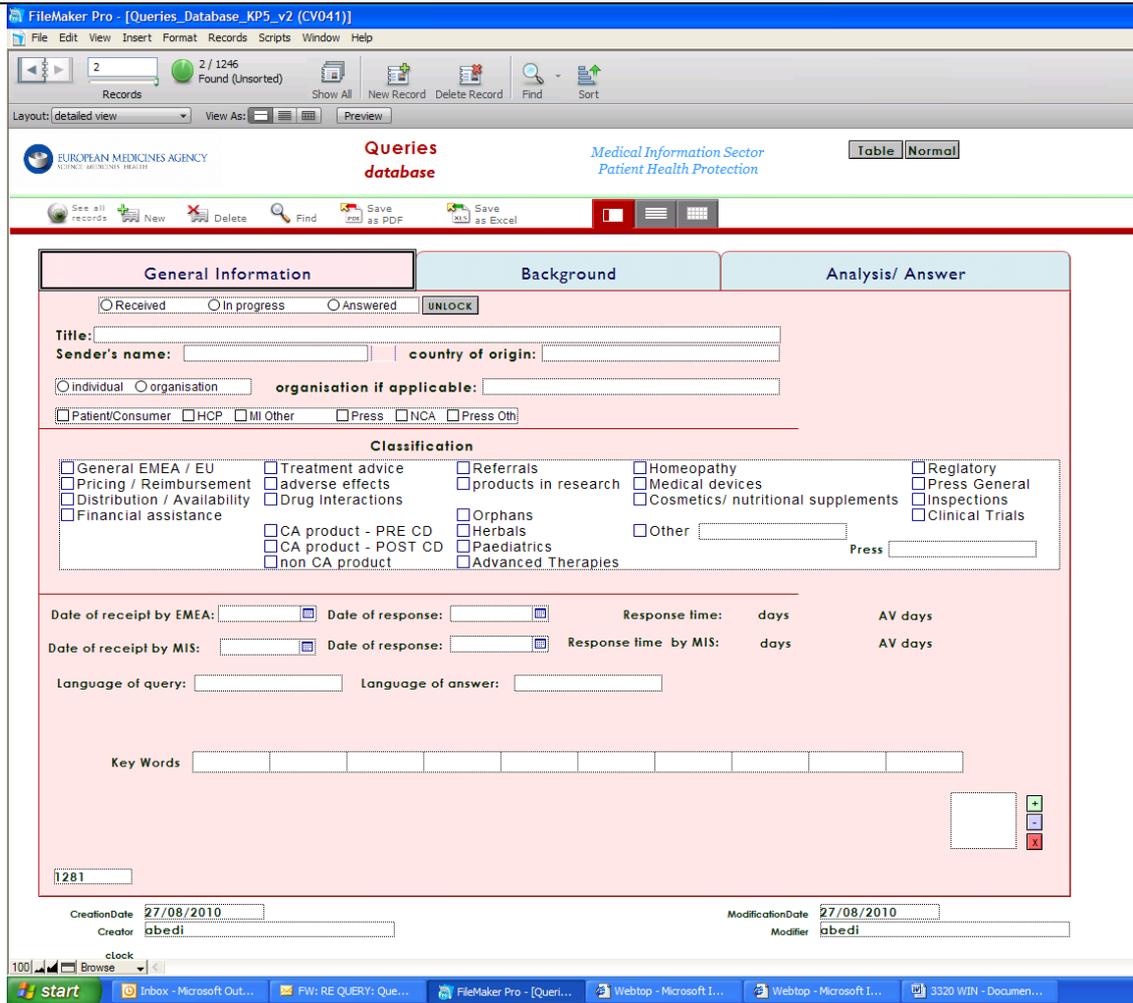
Click on "New record" or "New" to enter a new enquiry
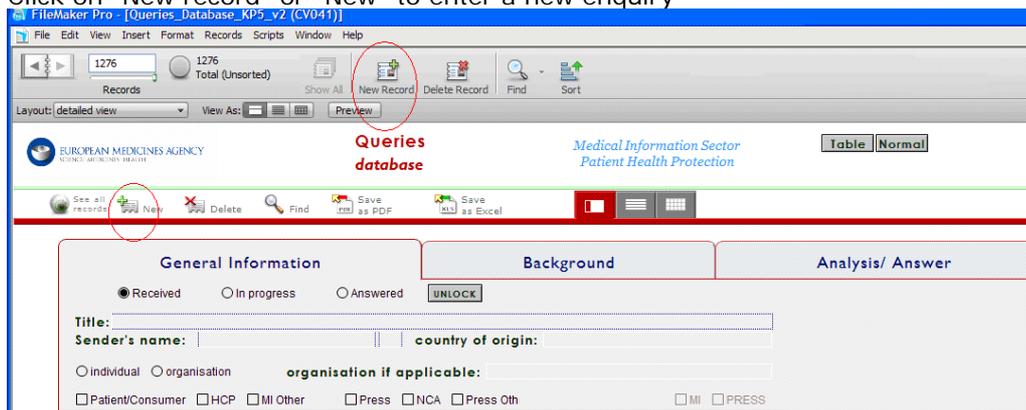
3	Start entering the data in the "general Information" pane: 1) Status of enquiry will default to "received"

Step	Action
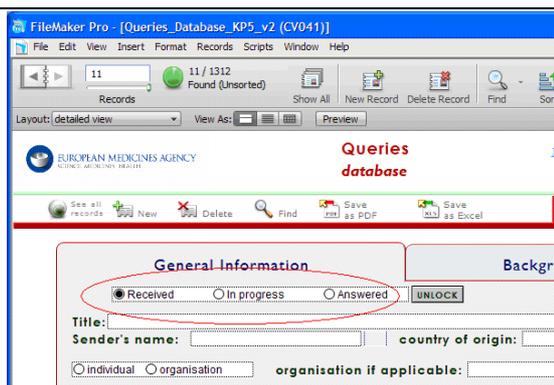
2) Enter title of request. Only use the subject of the email sent if it is relevant. Otherwise change to a relevant description of request.

3) Enter senders name and select country of origin if known (if the enquirer does not mention his origin use country IP location of email address)

4) Select whether the requester is an individual or asking on behalf of an organisation (only use organisation if patient/consumer organisations or healthcare professional organisation). Enter organisation name if applicable.

5) Enter status of enquirer (Patient/consumer, healthcare professional or other)(only use three tick boxes on the left hand side – the tick boxes on the right are reserved for the press office)
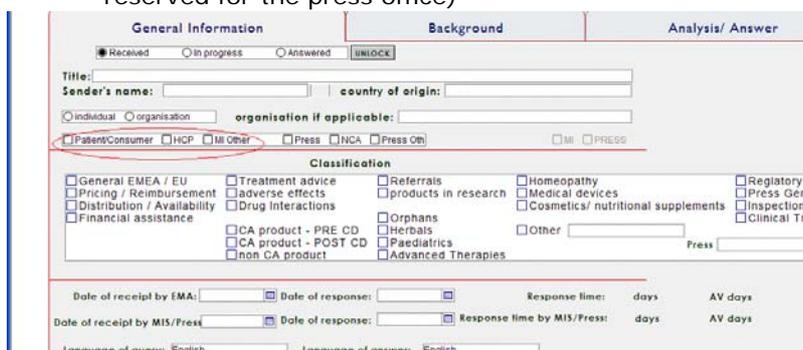
6) Choose classification of request – more than one may apply.

7) Select date of receipt by EMA and date of receipt by P-MI. For the date of receipt by the EMA use the actual date of receipt of email (irrespective of working hours/ working days). For the date of receipt within P-MI use the date when the email was forwarded to the sector but take into account working hours and working days (if the email was forwarded on Friday at 18:00, the date P-MI received it would be the following Monday).

Step	Action

8) Select language of request. The language always defaults to English but can be manually changed. The language of response will always be by default the same as language of request. This is in line with EMA policy, whereby a request that is formulated in an official language of the European Union will be followed up with a response in the same language.

9) The enquiry will be assigned a unique identifying number by the system which can be found at the bottom left hand corner of the general information pane. Take note of this number.

4	Move to "Background" pane: Copy and paste content of email into "background" pane. Remove standard communication by V-PD-DIS but leave relevant internal correspondence. If the enquirer sent a document please attach it using the "+"icon at the bottom right hand corner of the general information pane. Use "−" to view the document and "x" to remove the pdf file again.
5	Now save a copy of the request in DREAM Copy and paste email (this time leave all correspondence – including V-PD-DIS) into Word document (use Agency template "blank report") and save in DREAM folder (see records). It should be saved in the folder of the corresponding year/month and more particularly within the subfolder corresponding to its status i.e. "new" (Cabinets/Old EDMS Structure/Operational Units/Human/Post/MIS/Projects/external queries/queries) Use the following file name: "unique identifier as per Queries database - date request received by P-MI DD/MM/YYYY- Title of request as per database". This document will be used to record the response, track changes as well as being a back-up to the record in the Queries Database.
B	**Drafting and finalising response**
1	Open request in Queries database:
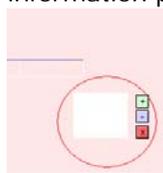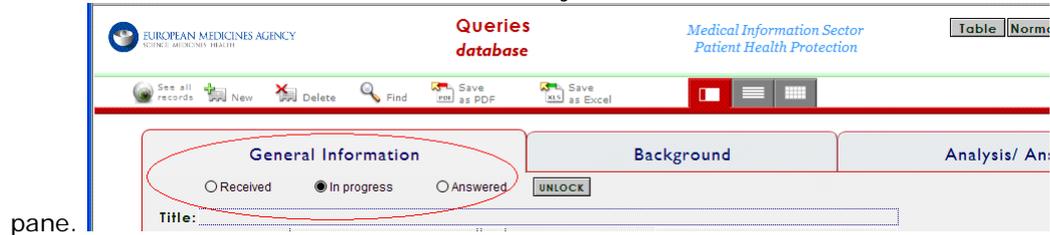
Step	Action
2	In the "analysis/answer" pane document all the resources that have been used (i.e. website, date accessed) and document the relevant information they provide. Note that the status of enquiry will automatically move from "received" to "in progress" once documentation has been entered in the "analysis/answer" pane.
3	Draft response in the same Word document containing request (response should precede the request) and save in DREAM.
4	Move document (current version with all pre-existing versions) from "new" to "in-progress"
5	When drafting a response refer to standard response templates and use if appropriate. These can be found in DREAM (see records)
6	When response is finalised, then update database by copying and pasting the response email into database, in the pane called "Analysis/Answer". Enter 2-3 keywords for enquiry in general Information pane. Select date of response (use the same date for both boxes - "Response time" and "Response time by P-MI "). Mark request status as "answered". Record the names of all members of staff who commented and were involved in the drafting of the response in the analysis/answer pane. Move Word document (current version with all pre-existing versions) in DREAM from "in-progress" to "completed".
7	For any modifications in the database after the query is completed and the "answered" button is marked the button "unlock" must be pressed first.