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eXtended EudraVigilance Medicinal Product Dictionary (XEVMPPD) product export tool

User manual

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1. Introduction

The Agency has introduced a tool by which registered users of the Eudravigilance system with permissions to view and submit xEVMPD data may extract the current data held within the xEVMPD for their products at the headquarter level. This document describes the use of this export tool by system users other than the European Medicines Agency (EMA).

This document is divided into eight main sections, which reflect the flow of use of the tool, as follows

- Section 2. describes how to [access the export tool](#).
- Section 3. provides an [overview](#) of the use of the tool.
- Section 4. describes in detail the process of [setting query filters](#) in preparation for making an export request.
- Section 5. describes the export formats available and [how to submit a request](#).
- Section 6. describes how to [monitor the progress of a pending request](#).
- Section 7. describes how to deal with [downloading a completed request](#).
- Section 8. deals with the use of [Excel format exports](#).
- Section 9. is a [quick reference guide](#) and answers frequently asked questions.

2. Accessing the export tool

2.1. User access requirements

The export tool is open to any user fulfilling all of the following criteria:

- Is a member of an Organisation registered by the EudraVigilance Registration Team in the production environment; if the user's organisation has been able to submit product messages successfully this must already be the case.
- The registered organisation is a member of the EV Human xEVMPD community; if the user's organisation has been able to submit product messages successfully this must already be the case.
- The user must be a recognised user associated with the registered organisation and must be in possession of a EudraVigilance user name and password.
- The user must have permission to send and view xEVMPD data in the EudraVigilance system.

2.2. System Requirements

The export tool is designed to work on machines operating under Windows 7 using Internet Explorer 8 (IE8) or above. Earlier versions of Windows, Internet Explorer and other operating systems/browsers will not receive support for the export tool should issues arise.

Note that if the export tool is used in IE8, it is necessary to disable compatibility mode for the browser as described here:

<http://windows.microsoft.com/en-gb/internet-explorer/use-compatibility-view#ie=ie-8>

2.3. Locating the export tool

The export tool can be accessed directly via an IE browser at the following url which may be bookmarked: <https://eudravigilance.ema.europa.eu/evmpdex/>.

Alternatively, the application may be accessed via the main [EudraVigilance secure home page](#) where a link will be found in the "EV Services" frame in the top left hand corner of the page.

Figure 1: The EV Services frame

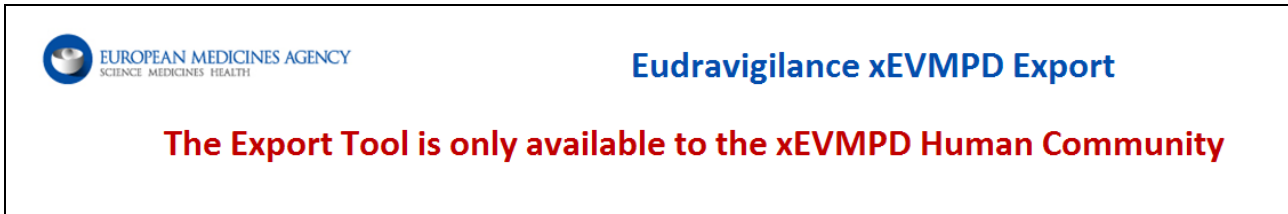


No matter which means of accessing the tool is used, the user will be presented with a standard password entry screen in which ones EudraVigilance user name and password must be entered exactly

as supplied/set. Note that if one already has an EV WEB session active on the same computer, the authentication from this session is carried forward to the export tool; thus this step is omitted.

If the user or organisation does not fulfil the access criteria described in the [user access requirements section](#) then one of a number of messages will be displayed and access to the tool will be denied.

Figure 2: Typical entry denial message



Assuming authentication is successful the user may proceed as described in the following sections.

3. Overview of the export tool

The tool is presented in a single screen and contains four functional areas:

Figure 3: The export work screen

The screenshot shows the 'Eudravigilance xEVMPD Export' interface. On the left, four functional areas are identified with brackets: 'Query Building' (filters), 'Requesting' (Active Filters and buttons), 'Request Monitoring' (table header), and 'Downloading' (table rows). The interface includes the EMA logo and version 'Human Production V. 7.8.1'. The filters section lists various criteria like Start Date, End Date, and Authorisation Procedure. The Active Filters section has checkboxes for 'xEVMPD' and 'Excel', and buttons for 'Count', 'Request', and 'Refresh List'. The table below shows a list of requests with columns for 'Request Title', 'Size', and 'Status', and 'Download' and 'Archive' buttons for each row.

The purpose of each of these areas is described in more detail in the following sections.

- The [query building area](#) is used to set a series of criteria which will limit the products to be exported.
- The [requesting area](#) is used to set the format of the export required, identify the request and obtain a count of the number of products to be exported as well as submitting the export request.
- The request [monitoring area](#) is used to advise the user of the progress towards completion of the request, and can be used by the user to cancel outstanding requests.
- The [downloading area](#) is used to download the files generated when the request is fulfilled.

4. Setting the filters for an export request

4.1. General principles

In preparing an export, the user should limit the request to only those products which are required to meet a particular need; please note that requests that involve large numbers (1000 +) of products will cause delays for all other users of the system.

Limiting a request is achieved by setting a series of filters in this section of the application. If no filters are set then, by default, the following products will be exported upon processing of the request;

- The current version of all authorised products last submitted or updated on or after 5th March 2012 (under Article 57 business rules) that is the responsibility of the logged on user's organisation headquarter organisation;
PLUS
- The current version, regardless of submission date, of every development product that is the responsibility of the logged on user's organisation headquarter organisation.

When filters are applied, each product that is returned must fulfil the criteria set in **all** of the fields with filters set, however some fields offer the opportunity to prepare one or more lists of values in which case **within this field only** a product only needs to fulfil one of the selected criteria (plus all the criteria set in the other filter fields) in order to be included in the export.

Expansion and contraction of individual filter controls is toggled by clicking on the relevant field label. If values have been set within a field, then the label will be blue, and the label (or a shortened version of it) will appear in the active filters area of the requesting area. This sequence of events is shown for various filter fields below:

Figure 4: Different views of a filter field

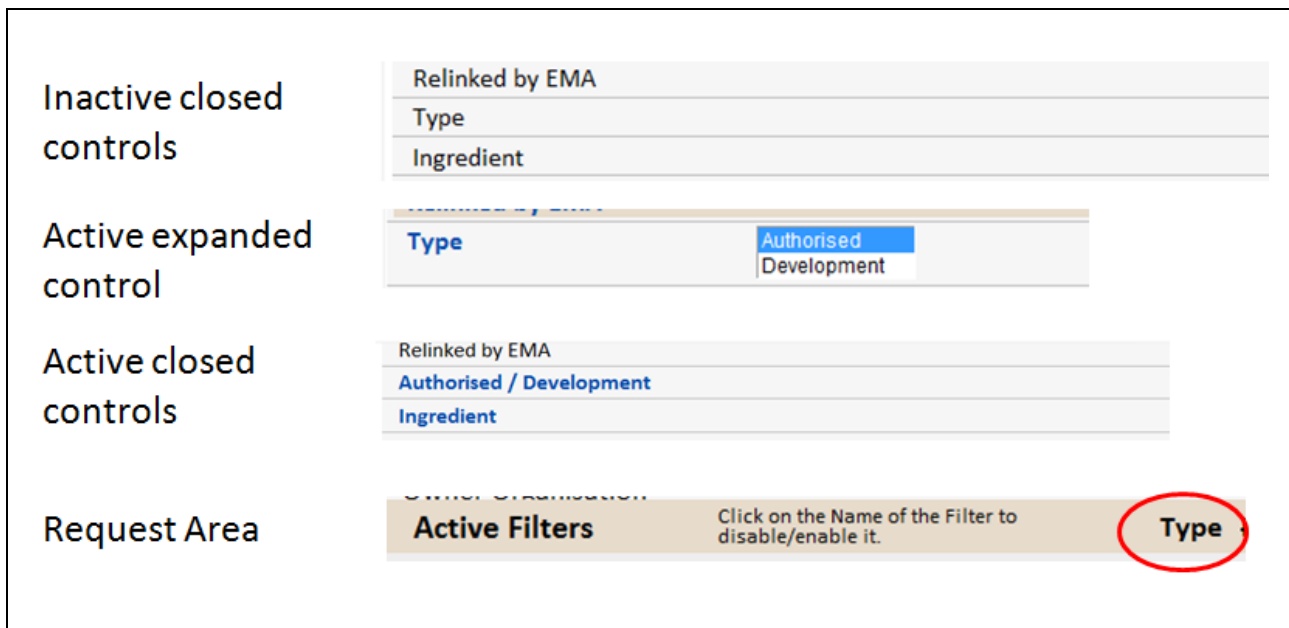


Table 1 shows the filter fields available and key facts about these fields.

4.2. Types of query building control

As will be seen, there are a number of different fields that can be set as filters, the type of filter presented differs between fields, but is one of the following types:

4.2.1. Date controls

Calendar controls are used where appropriate; the control is accessed by clicking in the box when the field is expanded.

Figure 5: Use of a calendar control

The screenshot shows a web interface with a list of filter fields on the left and a date selection calendar on the right. The calendar is for February 2014 and is currently open over the 'Start Date' field. The 'Start Date' field has a 'Clear' button next to it. The calendar has navigation arrows and a '[Close]' button. The calendar grid shows the following dates:

Sun	Mon	Tue	Wed	Thu	Fri	Sat
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	

To select a date, click on the number in the calendar, to change the year use the double arrows, and to change the month use the single arrows. If a date is selected and appears in the box above the calendar, then this may be cleared by clicking the "clear" button to the right of the expanded section.

4.2.2. Simple drop down list

In cases where the values appear as simple lists of values in the EV system i.e. authorisation status, then the available data is presented as a simple drop down list;

Figure 6: Use of a simple drop down filter control

The screenshot shows a web interface with a list of filter fields on the left and a simple drop down list on the right. The list is for 'Authorisation Status' and is currently set to 'Valid'. There are 'Refresh' and 'Clear' buttons to the right of the list. The list is described as 'Authorisation Statuses of Products. Lookup automatically executed. Multiple selection list.'

Notes for use of simple drop down lists;

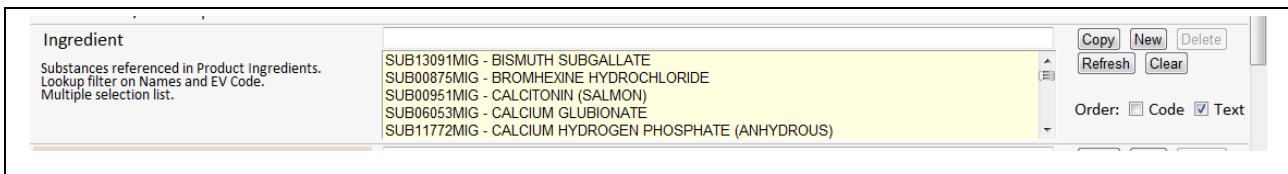
- The list is automatically filtered to contain only those values in use within the products of the logged-in user's organisation HQ.
- The list of values presented takes no account of the values selected in any other filter control.
- These lists can be refreshed using the button to the right of the control but by default contain all values used in the logged-in user's (and all other users' belonging to the same HQ) products.
- Selections in the list are cleared using the button to the right of the control.
- Selections can be made as follows:
 - To select a single item click the item;

- Use shift + click to select a continual range of items;
- Use control + click to select a range of items with gaps in.
- If all values in a control are selected, then it is more efficient to clear the control and make the search field inactive, as using no filter for a field gives better system performance than setting all of the values within the field.
- In some cases the control may appear empty even after using the refresh button, when this occurs the background of the list will appear yellow -the situation arises when the logged-in user's Organisation HQ does not have any products, which contain one of the values that could be in the list, i.e. if an organisation only has development products in the xEVMPD and the authorisation status filter is being used.
- Some fields are exclusive to authorised products and as such, these should not be used if development products are expected in the import, as there is no circumstance where the use of these filter can yield development products. Where this is the case it is indicated in Table 1.

4.2.3. Compound search fields

In cases where the values represent entities in the xEVMPD i.e. pharmaceutical form and for all product name fields, then the compound search controls are used to set filters;

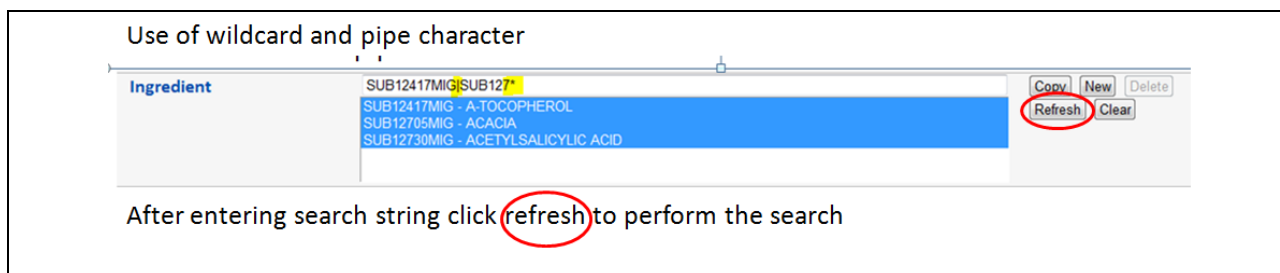
Figure 7: Use of a compound search control



Notes for use of compound search controls:

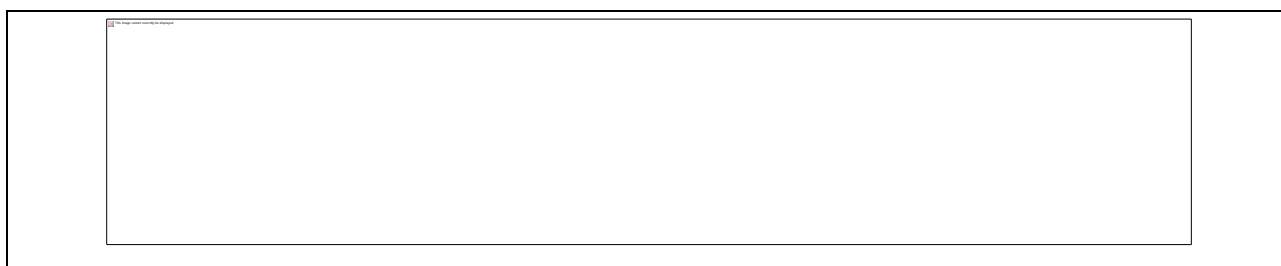
- The list is automatically filtered to contain only those values in use within the products of the logged-in user's organisation HQ but refresh must be clicked in order to show the values;
- The list of values presented takes no account of the values selected in any other filter control;
- There is a limit of 50 values presented in each list whether the search box contains a value or not, if this number is exceeded, then the background colour of the list becomes yellow as shown in the example above;
- Once loaded, the list may be ordered by either EV Code or text value using the order boxes to the right;
- The list presented can itself be filtered using the search box at the top of the control area (see Figure 8):
 - The search can be based on either names or EV Codes;
 - Multiple values can be separated by use of the pipe (|) character;
 - Any value can use the wildcard character in any position in the string.

Figure 8: Search tips for compound controls (using special characters in searching)



- For situations where it is not possible to create a single list within a field, for example where more than fifty values are required or when it is not possible to create a single search to list the values required; the control can be duplicated to perform an “or” search within this particular field. In order to do this; use the “new” (creates an empty control) or the “copy” (duplicates the values in the current control) button to the right (see Figure 9):

Figure 9: Search tips for compound controls (searching using multiple copies of the same field)



- The control may be emptied using the “clear” button to the right.
- Each repeat (except the last remaining) may be deleted.
- Each repeat may be cleared, refreshed or duplicated as before by using the appropriate button within the control.
- Selections can be made within each control in a field as follows:
 - To select a single item click the item;
 - Use shift + click to select a continual range of items;
 - Use control + click to select a range of items with gaps in.
- If all values in a control are selected, then it is more efficient to clear the control and make the search field inactive as using no filter for a field gives better system performance than setting all of the values within the field.
- If either more than fifty (or zero) values are returned by the refresh action, then the background colour of the list is yellow.
- Some fields are exclusive to authorised products and as such these should not be used if development products are expected in the import, as there is no circumstance where the use of these filter can yield development products. Where this is the case, it is indicated in Table 1.

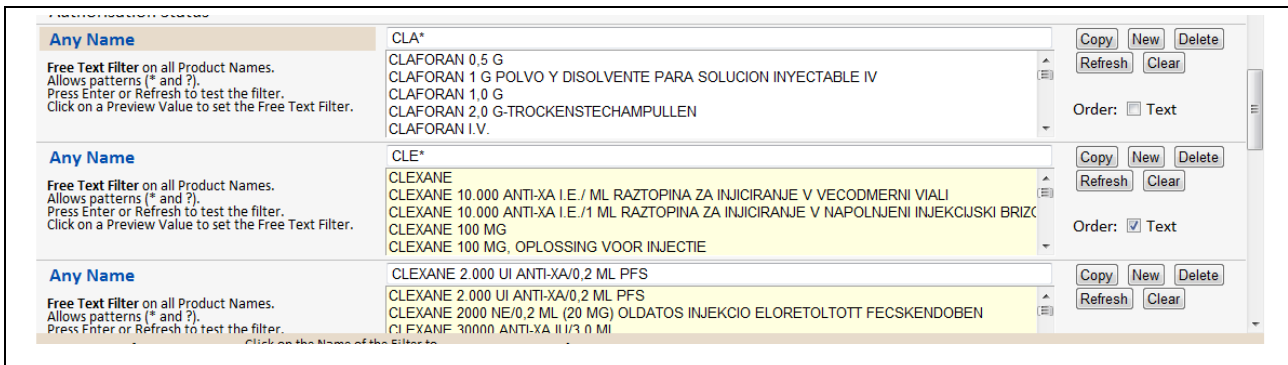
4.2.4. Free text compound controls

There are a number of filter controls where the only value searched is the value in a text box but a results list below the control previews the values that would be found by the typed filter condition. In the example in Figure 10, the user has prepared a filter which returns every product with any name beginning with CLA, a second filter with the text CLE* (any name beginning with CLE) and a third which was prepared using the same CLE search and then clicking on one particular result in the list after clicking refresh.

In this case, the combined filters set for any product name would be "any name starting with CLA OR any name starting with CLE OR CLEXANE 2000 UI ANTI-XA/0.2ML PFS".

NOTE: Only the value in each clear text box is used for the filter. To search for a specific term use the text box to enter a term (using wild cards [* or ?] if necessary) and click the refresh button. The preview list may be ordered by text by use of the text box to the right. If the specific term is seen in the preview list then that value can be transferred to the text box by clicking on it in the list.

Figure 10: Use of the free text filters



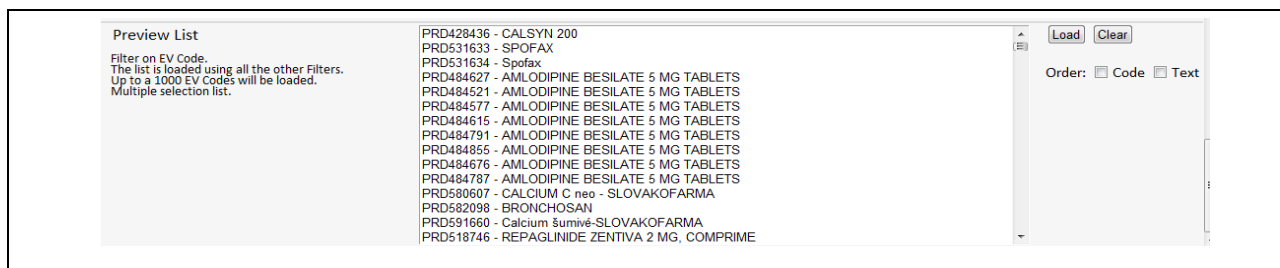
- The control may be emptied using the "clear" button to the right.
- Each repeat (except the last remaining) may be deleted.
- Each repeat may be cleared, refreshed or duplicated as before by using the appropriate button within the control.
- The searched value is the value in each text box.
 - To transfer a preview value to the text box click on the value required.
- If either more than fifty (or zero) values are returned by the refresh action, then the background colour of the list is yellow.
- Some fields are exclusive to authorised products and as such, these should not be used if development products are expected in the import, as there is no circumstance where the use of these filter can yield development products. Where this is the case it is indicated in Table 1.

4.2.5. The preview field

This is a special filter field which, unlike all the other filter fields, can be updated to show a preview of the first 1000 products that fulfil all of the criteria set in the other fields and its own filter text. This list

is used in a similar way to a compound field but without the opportunity to replicate the field. The field functions as a preview or final filter before requesting the export.

Figure 11: Use of the preview list field



If more than one thousand (or zero) values are in the preview, then the background of the list is shown in yellow.

Required products can be selected from the preview list using the standard selection methods:

- To select a single item click the item;
- Use shift + click to select a continual range of items;
- Use control + click to select a range of items with gaps in.

4.2.6. List of filter fields available

Table 1 below shows a list of all of the filter fields available along with key information about each field.

Table 1. Filter fields reference

Filter Label	Product Attribute Searched	Control Type	Specific to Authorised Product	Data Displayed	Notes
Start Date	All Products: Loading date	Calendar	NO	Current date	For authorised products the start date is overridden to the 5 th March 2012 if the date supplied is before this date or is omitted from the filters.
End Date	All Products: Loading date	Calendar	NO	Current date	If no date is supplied; the end date defaults to the date the request is processed.
Relinked by EMA	All Products: EMA specific data	Simple List	NO	List: Yes / No	A product is defined as “re-linked by the EMA” if it has been updated by the EMA as a result of data cleaning activities since it was last submitted by the product owner.
Authorised / Development	All Products: Is development product or is authorised product	Simple List	NO	List: Authorised / Development	
Ingredient	All Products: Any substance in any role	Compound Search	NO	List of substances: EV Code + current preferred name	On clicking refresh, the list is restricted to the first 50 substances that are used in any product which is owned by any organisation with the same HQ as the logged-in user and which fulfils the search criteria in the control text box.

Filter Label	Product Attribute Searched	Control Type	Specific to Authorised Product	Data Displayed	Notes
Pharmaceutical Form	All Products: Pharmaceutical form at pharmaceutical product level	Compound Search	NO	List of pharmaceutical forms: EV Code + current pharmaceutical form name	On clicking refresh, the list is restricted to the first 50 pharmaceutical form values that are used in any product which is owned by any organisation with the same HQ as the logged-in user and which fulfils the search criteria in the control text box.
ATC Code	All Products: Any referenced ATC code	Compound Search	NO	List of ATCs: ATC Code + current ATC name	On clicking refresh, the list is restricted to the first 50 ATC values that are used in any product which is owned by any organisation with the same HQ as the logged-in user and which fulfils the search criteria in the control text box.
Indication MedDRA code	All Products: Any referenced MedDRA code in the indications section	Compound Search	NO	List of MedDRA Codes: MedDRA code + most recent MedDRA code description	On clicking refresh, the list is restricted to the first 50 MedDRA values that are used in any product which is owned by any organisation with the same HQ as the logged-in user and which fulfils the search criteria in the control text box.
MAH / Sponsor	Authorised product: MAH Development Product: Sponsor	Compound Search	NO	List of MAHs/Sponsors: EV Code - Name - Country -City	On clicking refresh, the list is restricted to the first 50 values that are used in any product which is owned by any organisation with the same HQ as the logged-in user and which fulfils the search criteria in the control text box.

Filter Label	Product Attribute Searched	Control Type	Specific to Authorised Product	Data Displayed	Notes
QPPV	Authorised product: QPPV	Simple List	YES	List of QPPVs: QPPV Code + Name	Presents a list of the QPPVs that are registered for organisations with the same HQ as the logged-in user, and used in any authorised product which is owned by any organisation with the same HQ as the logged-in user.
Master File Location	Authorised product: Master File Location	Simple List	YES	List of Master File Locations: EV Code - Country –City – Postcode - Street	Presents a list of the MFLs that are used in any authorised product which is owned by any organisation with the same HQ as the logged-in user.
Owner Organisation	All Products: EudraVigilance message sender ID	Simple List	NO	List of Registered Organisations: SenderID + Name	Presents a list of sender IDs for organisations (message sender IDs) that have submitted products and which have the same HQ as the logged-in user.
Authorisation Country	Authorised product: Authorisation country	Simple List	YES	List of Countries: Country Code + Name	On clicking refresh, the list is restricted to the first 50 countries that are used in any authorised product which is owned by any organisation with the same HQ as the logged-in user.
Authorisation Procedure	Authorised product: Authorisation procedure	Simple List	YES	List of Authorisation Procedures: Procedure name	On clicking refresh, the list is restricted to only those values that are used in any authorised product which is owned by any organisation with the same HQ as the logged-in user.

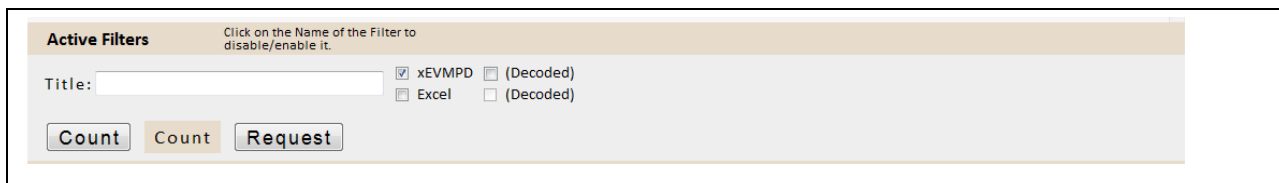
Filter Label	Product Attribute Searched	Control Type	Specific to Authorised Product	Data Displayed	Notes
Authorisation Status	Authorised product: Authorisation status	Simple List	YES	List of Authorisation Statuses: Status name	On clicking refresh, the list is restricted to only those values that are used in any authorised product which is owned by any organisation with the same HQ as the logged-in user.
Any Product Name	All products: Any name	Free Text + Compound Search	NO	List of Names	On clicking refresh, the list is restricted to the first 50 values that are used in any product name field for any product which is owned by any organisation with the same HQ as the logged-in user and which fulfils the search criteria in the control text box.
Full Name	Authorised product: Full presentation name Development. product: Name	Free Text + Compound Search	NO	List of Names: Authorised Product Name Development Product Name	On clicking refresh, the list is restricted to the first 50 values that are used in the product name field for any product which is owned by any organisation with the same HQ as the logged-in user and which fulfils the search criteria in the control text box.
Short Name	Authorised product: Short name	Free Text + Compound Search	YES	List of Names: Authorised Product Short Name	On clicking refresh, the list is restricted to the first 50 values that are used in the authorised product short name field for any authorised product which is owned by any organisation with the same HQ as the logged-in user and which fulfils the search criteria in the control text box.

Filter Label	Product Attribute Searched	Control Type	Specific to Authorised Product	Data Displayed	Notes
Generic Name	Authorised product: Generic name	Free Text + Compound Search	YES	List of Names: Authorised Product Generic Name	On clicking refresh, the list is restricted to the first 50 values that are used in the authorised product generic name field for any authorised product which is owned by any organisation with the same HQ as the logged-in user and which fulfils the search criteria in the control text box.
Company Name	Authorised product: Company name	Free Text + Compound Search	YES	List of Names: Authorised Product Company Name	On clicking refresh, the list is restricted to the first 50 values that are used in the authorised product company name field for any authorised product which is owned by any organisation with the same HQ as the logged-in user and which fulfils the search criteria in the control text box.
EV Code	All Products: EV Code	Free Text + Compound Search	NO	List of Products: EV Code + Product Name	On clicking refresh, the list is restricted to the first 50 values that represent any product which is owned by any organisation with the same HQ as the logged-in user and which fulfils the search criteria in the control text box.
Preview	All Products: EV Code	Searchable Simple List	NO	List of Products: EV Code + Product Name	On clicking refresh, the list is restricted to the first 50 values that represent any product which is owned by any organisation with the same HQ as the logged-in user and which fulfils the search criteria in the control text box AND all of the other criteria set in the preceding filter fields.

5. Submitting an export request

Having set a series of filters as described in section 4. Above, the user may now proceed to submitting an export request using the requesting area of the page. This area is shown in the figure below:

Figure 12: The export request area



The screenshot shows a web interface for submitting an export request. At the top, there is a section titled "Active Filters" with a subtitle "Click on the Name of the Filter to disable/enable it." Below this, there is a "Title:" input field. To the right of the input field, there are four checkboxes: "xEVMPD" (checked), "(Decoded)" (unchecked), "Excel" (checked), and "(Decoded)" (unchecked). At the bottom of the interface, there are three buttons: "Count", "Count", and "Request".

The requesting area is divided into two areas; the Active Filters area and the main active area.

5.1.1. Examine the preview and prepare a count

In order to prepare a count of the number of products to be exported click the count button in the active area - this action causes a count of the number of products to be exported to be displayed in the count field to the right of the count button. If the count of products is not as expected, then the user may perform several actions, these are:

- Examine the Preview List to check the products being exported;
- Re-enter or clear data in one or more of the filter fields – the filters in use will be coloured blue and will appear in the active filters list;
- Explore the effect of temporarily removing filters on the counts and preview by using the Active Filters area as described in the following section.

Having obtained the required number of products for export; the user should proceed to setting the output format as described in 5.1.3.

5.1.2. Temporarily remove filters

The active filters area is supplied to allow users to experiment with the filters that are applied without recourse to clearing filter field values; it achieves this by listing all active filter fields and allowing the user to toggle whether or not each field is used in the preview list, count and final submission.

To deactivate or activate any active filter simply left click on each word in the active filter list as required.

If the active filter list text relating to a field is shown in normal text then it is active (being applied to the count, Preview List and final export), conversely, if it shown in strikethrough text then all filters in this particular field are not applied to these three functions.

Note that all of the selected values in a deactivated filter are ignored even if the filter has many repeats in the case of a complex search filter.

Note also that for the purpose of saving space, some names are abbreviated.

In the example below, the user has set filters for Authorised/Development (abbreviated to type) and ingredient (as indicated by the filter field labels in blue text) and chosen to disable the ingredient filter as indicated in the strikethrough text (~~ingredient~~) in the Active Filters area. Note that the ingredient filter field label text remains blue.

Figure 13: Activate or deactivate set filters.

The screenshot shows a web application interface with several filter sections. At the top, there are two filter fields: 'Authorised / Development' with a dropdown menu set to 'Authorised' and 'Development', and 'Ingredient' with a dropdown menu showing a list of ingredients including 'SUB11842MIG - COD-LIVER OIL (TYPE B)', 'SUB11845MIG - COPOVIDONE', 'SUB11847MIG - COPPER SULPHATE, ANHYDROUS', 'SUB21071 - ETANOLO', and 'SUB03087MIG - MANNITOL'. Below these are fields for 'Pharmaceutical Form', 'ATC Code', 'Indication MedDRA Code', 'MAH / Sponsor', 'QPPV', 'Master File Location', and 'Owner Organisation'. The 'Active Filters' section is highlighted in orange and contains a table with two columns: 'Name of the Filter' and 'Type'. The 'ingredient' filter is currently disabled, indicated by a strikethrough over the word 'ingredient' and a red circle around it. The 'Type' filter is active. Below the filters, there are checkboxes for 'xEVMPD', 'Excel', and '(Decoded)', and a 'Count' field showing '9'. Buttons for 'Request' and 'Refresh List' are also visible.

To reactivate the ingredient filter the ~~ingredient~~ text should be left clicked once.

Having decided on the active filters to apply for the export; the user should proceed to setting the output format as described in 5.1.3.

5.1.3. Setting the output format

The export tool offers two alternative export formats each with or without decoding of reference values requesting area and are described below;

- xEVMPD: an export in this format supplies the data in the xEVMPD
 - A format that **is compliant** with the xEVMPD product message schema.
 - In cases where data is not present in the xEVMPD for the product exported then the entire element/field will be omitted; this should be taken into account where data is to be exported, edited and resubmitted since elements/data which is required by new business rules (e.g. rules published in Version 5.0 of Chapter 3.I: Extended EudraVigilance product report message (XEVPRM) technical specifications) may not be present in the exported data.
- xEVMPD + decoded: As above but with the name attributes present on coded fields as described in version 4.1 of Chapter 3.I: Extended EudraVigilance product report message (XEVPRM) technical specifications.
- Excel: This is an xEVMPD product message **NON COMPLIANT** format which is designed to be imported into an Excel template supplied with the export (see section 8. for further details).
- Excel + Decoded: As above but with the name attributes present on coded fields as described in version 4.1 of Chapter 3.I: Extended EudraVigilance product report message (XEVPRM) technical specifications.

5.1.4. Making an export request

Having set all required active filters and setting the output format; the user may optionally set a title for the export (to make it easier to identify later) and proceed to submitting the request by clicking the request button in the requesting area.

If the title is not set then it will default to the user name and date.

Upon clicking the request button, the system previews the number of products that will be exported and if this number is zero the request will be rejected, if the number is not zero then the request joins the export queue and may be seen in the Request Monitoring Area described in section 6.

6. Monitor the progress of pending requests

Once a request has been received by the system and until it is ready for download it can be seen in the request monitoring area. This area shows all requests which are pending for all users with the same HQ as the logged-in user. The area is shown below:

Figure 14: The request monitoring area.

Request Title	Size	Status	
Requested on 04/02/2014 14:41, xEVMPD (Decoded) + Excel (Decoded)	12 (0 done)	In Progress: momentarily	<input type="button" value="Cancel"/>

The monitoring (and download) area must be manually refreshed using the refresh lists button in the request submission area.

The table of pending requests contains four columns thus:

- **Request Title:** The name of the request – note this example shows the default name + the formats chosen and demonstrates why it is a good idea to name your requests for easier reference later.
- **Size:** This is a count of the number of products to be exported.
 - If the status is “In Progress” the figure in brackets shows the progress through this number of products.
- **Status:** This is either “In Progress:” or “Queued:”
 - The text after the status provides an estimate of when the export may be complete this estimate takes into account the number of products, the total number of products to be exported in the queue and the average performance of the system for the format of export that each request ahead in the queue requires.

Note: momentarily means within the next minute.
- **Cancel Button:** If a mistake in the filters set or other request parameter is identified please use this button to cancel the request – please remember that each request is dealt with in turn and unnecessary or erroneous requests delay every user’s requests.

When a request is completed (either successfully or because of a failure) then the record is moved to the download area the next time that the Refresh Lists button is clicked, the use of the download area is described in the following section.

On occasions, exports may be queued for some time; this is because each request is dealt with in turn. Figure 14 below shows the monitoring area from two unrelated users point of view – one (MAH 2) has a request for 3000+ products in progress whilst the other (MAH 1) is next in the queue:

Figure 15: The request monitoring area from two different user's point of view.

What MAH 1 sees:

Request Title	Size	Status
MAH1 (on 07/02/2014 10:16), xEVMPD	1	Queued: under 13 Minutes Cancel

What MAH 2 sees:

Active Filters Click on the Name of the Filter to disable/enable it.

Title: MAH 2

xEVMPD (Decoded)
 Excel (Decoded)

Count 3106
Request
Refresh List

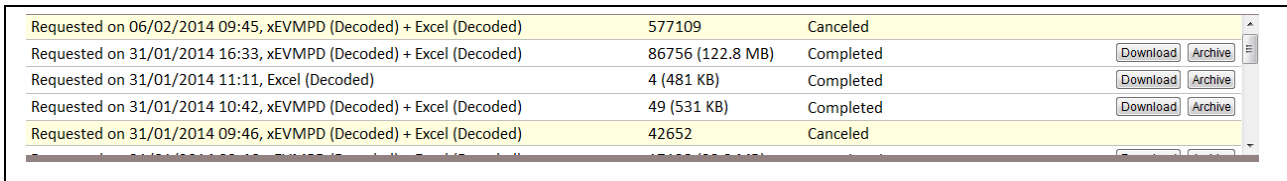
Request Title	Size	Status
MAH 2 (on 07/02/2014 10:16), xEVMPD	3106 (500 done)	In Progress: under 14 Minutes Cancel

Note: Click the "Refresh List" button in the active filters area to update the request monitoring and download areas of the screen.

7. Downloading a completed request

The download area is provided to allow users to manage completed and failed requests and shows all requests for all users with same organisation HQ as the logged-in user. The download area is shown in Figure 15 below:

Figure 16: The download area



Requested on 06/02/2014 09:45, xEVMPD (Decoded) + Excel (Decoded)	577109	Canceled		
Requested on 31/01/2014 16:33, xEVMPD (Decoded) + Excel (Decoded)	86756 (122.8 MB)	Completed	Download	Archive
Requested on 31/01/2014 11:11, Excel (Decoded)	4 (481 KB)	Completed	Download	Archive
Requested on 31/01/2014 10:42, xEVMPD (Decoded) + Excel (Decoded)	49 (531 KB)	Completed	Download	Archive
Requested on 31/01/2014 09:46, xEVMPD (Decoded) + Excel (Decoded)	42652	Canceled		

Note: Click the “Refresh List” button in the active filters area to update the request monitoring and download areas of the screen.

The requests in the list are shown in reverse date/time order of the request date; each request row contains 5 columns.

- **Request Title:** The name of the request – note this example shows the default name + the formats chosen and demonstrates why it is a good idea to name your requests for easier reference later.
- **Size:** This is a count of the number of products to be exported.
 - The figure in brackets shows the file size of the export zip file.
- **Status:** This is either “Completed:” , “Error:” or “Cancelled”.
 - If the value is “Error” then the row will be coloured red.
 - If errors persist with a particular users download, please refer to the FAQs section prior to contacting the Article 57 help desk.
 - If the value is “Cancelled” then the row is yellow and the download and archive buttons are not available.
- **Download Button:** This button allows the export file to be downloaded to the user’s local environment via the usual download steps.
 - The downloaded file is in zip format and can be extracted using any standard zip utility for subsequent processing as required and contains one or more .xml files each containing a maximum of 100 product sections.
 - If more than one xml file is contained within the zip file each is named using the convention:
Username_export title_date_time.exportformat.filecounter.xml
 - If the file export requested Excel format files then the zip file also contains a macro enabled Excel template for visualising the data. See section 8. for the use of this template.
 - If the file export requested both Excel and xEVMPD format exports then the zip file will contain;
 - A series of xml files in Excel format identified by the following naming convention:
Username_title_date_time.excel. filecounter.xml

The Excel Export Visualisation Template.

A series of xml files in xEVMPD format identified by the following naming convention:

Username_title_date_time.xEVMPD.filecounter.xml

- If both formats were requested and more than one xml file per format is required to hold all of the exported products then each product will appear in the same position in both file series e.g. if a product appears in Excel.0012.xml in file position three then it will be the third product element of_xEVMPD.0012.xml
- **Archive Button:** For users that perform many exports the archive button is provided to remove exports that are no longer of any interest i.e. they failed or have been successfully downloaded and processed locally by the user. Once archived exports cannot be retrieved except by request from the EMA.

8. The use of Excel format exports

This section describes the steps required to use the Excel Template to provide a view of the Excel format data in both flat table and pivot table forms. The process requires the use of Excel 2007 or later and access to a zip file extraction tool (the freely downloadable application 7-Zip is suitable for this purpose and can be obtained at: <http://www.7-zip.org/>).

1. Download the export as described in section 7.
2. Follow the user instructions for your zip utility to extract the files in the downloaded extract the desired location. It is advisable to keep each the extracted download for each export in a separate folder.
3. Navigate to the location containing the extracted files from step 2.
4. Open the file called Excel Product Export Template.xlsm using Excel, ensure that macros are enabled.
5. Activate the xml Import Page sheet this is a sheet with the following layout:

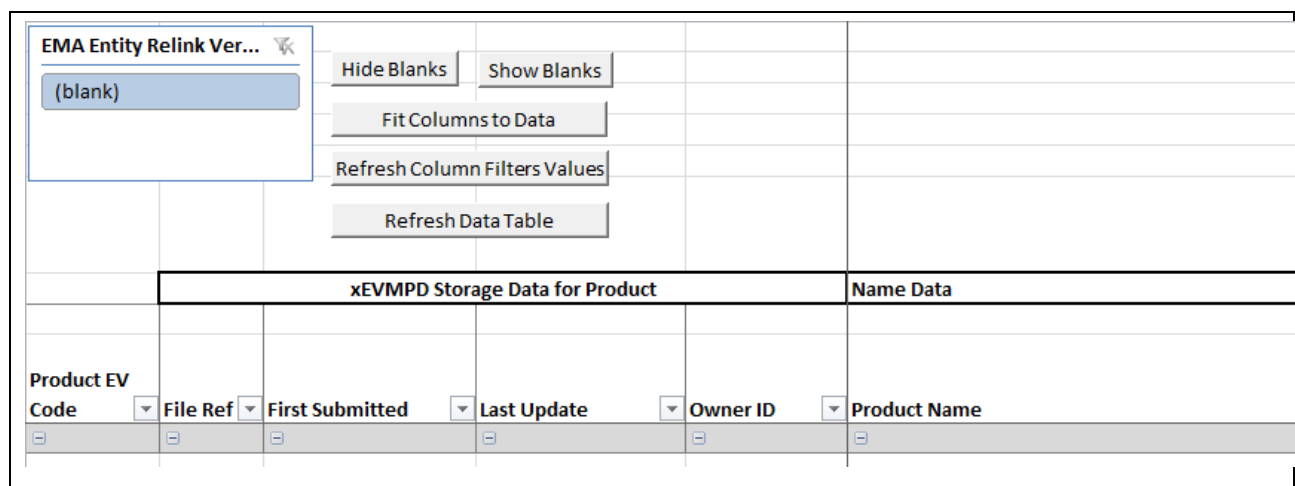
Figure 17: The xml Import Page sheet

	A	B	C	D	E	F	G	H	I	J	K
1	Replace Data										
2	Add Data										
3	Fit Columns to Data										
4											
5						Dev Product Sponsor		Dev Prod Name Data		Authorised Product MAH	
6	Product EV Code	File Ref	Product Type	Sender Local Code	Product Name	Sponsor Code	Sponsor Name	Dev Product Code	Dev Product Other Name	MAH Code	MAH Name
7											
8											
9											
10											
11											
12											
13											
14											

6. Click the Replace Data button to obtain a list of Excel format files which are contained in the same location as the template, having selected your file(s) click the "Open" button on the file dialog box – this will cause the template to load the selected xml data which may take some time
 - a. You may navigate to other locations as required;
 - b. You may select one or more files.
7. Once the files in 6 have loaded you may either replace the data completely using the replace data button or append more data to the bottom of it using the "Add Data" button.
8. Once all export data required is you may click the "Fit Columns to Data" button which sizes all columns in the export to show all of the data, you may need to do this several times depending on the data imported.
9. You may now use the auto filter buttons on each column heading to examine the data.

10. To see a pivot table view of the data activate either the Authorised or Development products sheet;

Figure 18: One of the product pivot sheets



11. Use the buttons and report filters at the top of the page to build a pivot view of the data as follows;
 - a. Refresh Data Table – clicking this button populates the pivot table with the data from the xml import sheet;
 - b. Refresh Column Filters Values – from time to time Excel pivot tables “remember” values from previous data – before using the column filters to hide or show rows of data it is best to click this button to ensure that the correct values are contained in the lists presented;
 - c. Fit columns to data – adjusts the column widths of all columns to the display the widest value;
 - d. Hide/Show blanks – by default Excel displays empty cells in a pivot table with the value “(blank)” this can make the table difficult to read, the hide button and show button dictate whether or not the “(blank)” values are visible. Note that when expanding sections with hide blanks activated it may be necessary to click the button again to hide blank values that become visible as the work area is expanded;
 - e. EMA Entity Relinked filter – there is a sheet level filter in the top left hand corner of the page that can be used to show relinked data, un-relinked data or both by selecting value accordingly. In Excel versions pre 2010 this will show the following text and is not available so all data will be displayed;

- i. “This shape represents a slicer. Slicers can be used in at least Excel 2010.

If the shape was modified in an earlier version of Excel, or if the workbook was saved in Excel 2003 or earlier, the slicer cannot be used.”

12. Continue adding more data and refreshing the pivot tables as required.

9. Quick reference guide

9.1. Quick Guide

The steps required to prepare an export are as follows:

1. Log on to <https://eudravigilance.ema.europa.eu/evmpdex/>;
2. Using the fields in the filter section prepare an export which targets the products required in the export. Most controls behave very similarly to those in EV WEB. See section 4;
3. Set the export format and give the export a title. See section 5;
4. Request the export. See section 5.1.4;
5. Monitor the export queue until the export is completed. See section 6;
6. Download the export to your local environment for further use. See section 7.

9.2. FAQs

9.2.1. User Access

1. Where is the export tool located?
 - a. <https://eudravigilance.ema.europa.eu/evmpdex/>
 - b.
2. Can I bookmark that location?
 - a. Yes
3. Why am I refused access?
 - a. This may be because you don't have sufficient user privileges or your organisation does not have the correct profile; the message you receive should give you more information. Refer to Section 2. Accessing the export tool.
4. Which user name/password should I use?
 - a. The one that was issued to you when you registered for a EudraVigilance account. If you have changed your password use the latest value.
5. I have forgotten my user name/password what should I do
 - a. Apply for a reminder from the registration team by email to EudraVigilanceRegistration@ema.europa.eu quoting salient details e.g. name, organisation etc.
6. Why didn't the system ask me for a password?
 - a. You are already logged on in an EV WEB session
7. Why won't the system work on my computer?
 - a. It is likely that your system does not meet the stated system requirements, refer to Section 2.2. System Requirements for further details.

9.2.2. Filters

1. What happens if I don't set any filters?
 - a. All of your products and those of your HQ and all other affiliates will be exported subject to certain date restrictions for authorised products.
2. Why do I have to hit refresh before a filter is populated?
 - a. This is to enhance the performance of the system; some of the filters have to check in big lists for values used in many thousands of products. Loading all of this data when it might not be needed to prepare the export would slow the application down.
3. Why are some labels blue?
 - a. These indicate filters where a selection has been made.
4. I used a filter and its label is not blue – why not?

- a. Although you visited a filter you have not selected any of the presented values – therefore the filter is not used.
- 5. My filter is blue but it doesn't make any difference to the results count or preview, why not?
 - a. It is possible that the filter is inactivated – check that the filter label is not in ~~strike through~~ text in the Active Filters area.
 - b. It is possible that other filters prevent a particular filter from making the expected difference - try making some filters inactive in the Active Filters area to see the effect on the export count.
- 6. I have set the filters that I think I need but the product count is zero or not what I expected, what could cause this?
 - a. You may have set filters which mean that no product can fulfil all of the filter fields, try making some inactive in the Active Filters area to see the effect on the export count.

9.2.3. Requesting an Export

1. Why won't the system accept my request?
 - a. The combination of filters that you have made excludes all of your products.
2. What is the difference between xEVMPD format and Excel format and why would I want it decoded?
 - a. xEVMPD is a valid format that can be resubmitted after editing whilst Excel format cannot be used for submitting messages.
 - b. Decoding makes the data easier to understand for a human because it contains the value of codes for referenced data.
3. Why should I bother to give my export a title?
 - a. Giving a title we make it easier to identify particular exports if you, or your organisation, make many requests.
4. Should I include the date or format in my export title?
 - a. This is not advised because the system will add this information to the title.

9.2.4. Monitoring an Export

1. Why does the monitoring area say that my export of few products is likely to take a long time?
 - a. Export requests are added to the queue in the order in which they arrive – although you cannot see them there a many requests in the queue in front of yours.
2. I don't need my export anymore and it is still in the queue – what should I do?
 - a. Please cancel the request to free up processing time for other users.
3. The system says that my export is in the queue and the count of progress is not changing or its time to completion is not changing why not?
 - a. In order to update the time to completion you need to click the "Refresh Lists" button

9.2.5. Downloading an Export

4. My export has failed – what should I do?
 - a. Unfortunately there is no option but to repeat the request and delete the failed export. If the problem persists please contact the Article 57 help desk
5. I don't need my export anymore and it is still in download area – what should I do?
 - a. Please archive the request to free up screen space.
6. I requested both Excel and xEVMPD files in the same export how can I tell them apart?
 - a. Excel files contain the text ".Excel.filename.xml" whilst xEVMPD files contain ".xEVMPD.filename.xml"
7. I have extracted an export and there are many xml files – why?
 - a. The limit of the number of products within any one xml file is 100 since you requested more products than this you have many files each containing a maximum of 100 files in your zip file.

10. Annex 1: Search logic applied

The logical search that is performed in order to prepare the export follows the following pattern; the portion of the query that is always performed is shown in *italics* and the use of the portion shown in normal type depends on the presence of selected values in the available filters (red text). NB all complex field searches take the form of the ingredients but have been simplified as per the following complex elements to make the text clearer.

```
SELECT all_products
FROM the_xEVMPD
WHERE
Product_owner_HQ = logged on user's organisationHQ
(AND product last information date >= selected Start Date)
(AND product last information date <= selected End Date)
(AND product data cleaning update status in (selected values in Relinked by EMA))
(AND authorised or development product in (selected values in Authorised/Development))
(AND //Complex
  (any ingredient in (selected values in ingredients 1)
  OR ..... OR any ingredient in (selected values in ingredients n)
  )
)
(AND //Complex (any pharmaceutical form in (selected values in pharmaceutical form 1) OR (.n)))
(AND //Complex (any ATC Code in (selected values in ATC Code 1) OR (.n)))
(AND //Complex (any Indication Code in (selected values in Indication MedDRA Code 1) OR (.n)))
(AND //Complex (any MAH/Sponsor in (selected values in MAH/Sponsor 1) OR (.n)))
(AND QPPV in (selected values in QPPV))
(AND Master File Location in (selected values in QPPV))
(AND Submitting Organisation in (selected values in Owner Organisation))
(AND Authorisation Country in (selected values in Authorisation Country))
(AND Authorisation Procedure in (selected values in Authorisation Procedure))
(AND Authorisation Status (selected values in Authorisation Status))
(AND //Complex (any product name field in (selected values in Any Name 1) OR (.n)))
(AND //Complex (any product name in (selected values in Full Name 1) OR (.n)))
(AND //Complex (any short name in (selected values in Short Name 1) OR (.n)))
(AND //Complex (any generic name in (selected values in Generic Name 1) OR (.n)))
(AND //Complex (any company name in (selected values in Company Name 1) OR (.n)))
(AND //Complex (any Product EV Code in (selected values in Company Name 1) OR (.n)))
(AND //Complex (any Product EV Code in (selected values in Preview 1) OR (.n)))
UNION MINUS --(excluding authorised products last updated before Article 57 go live)
SELECT all_products
FROM the_xEVMPD
WHERE
Product_owner_HQ = logged on user's organisationHQ
AND Product last information date < 05-MAR-2012
```