



## Work instructions

Title: Review of active substances in products under evaluation in the centralised procedure (from SIAMED listing)		
Applies to: Pharmacovigilance and Risk Management Sector		
Status: <b>PUBLIC</b>		Document no.: WIN/H/3284
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### 1. Changes since last revision

Updated to reflect the new organisational names in the Agency.

### 2. Records

The files are saved by date in DREAM: [Cabinets/13. Projects/EudraVigilance - NEW STRUCTURE/Pharmacovigilance/Data Analysis/SAS analysis/SIAMED Listing \(SDG\)/Listings.](#)

### 3. Instructions

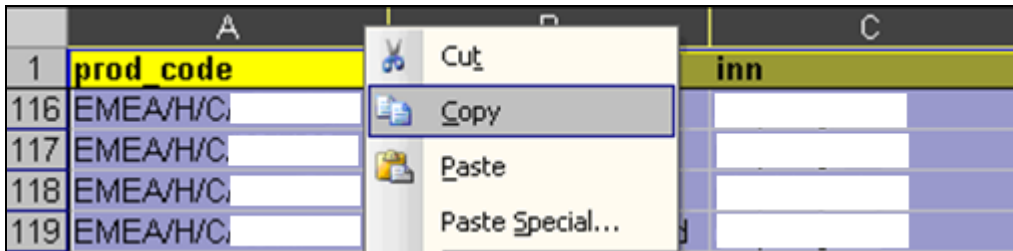
This WIN refers to the SOP/H/3275 - Population and maintenance of the scientific group table for active substances in Centrally Authorised Products or in products under evaluation in the centralised procedure.

The access to Dream is required to retrieve the SIAMED listings from the previous and current month (refer to WIN/H/3280 - Identification of active substances in products under evaluation in the centralised procedure (from SIAMED listing)).

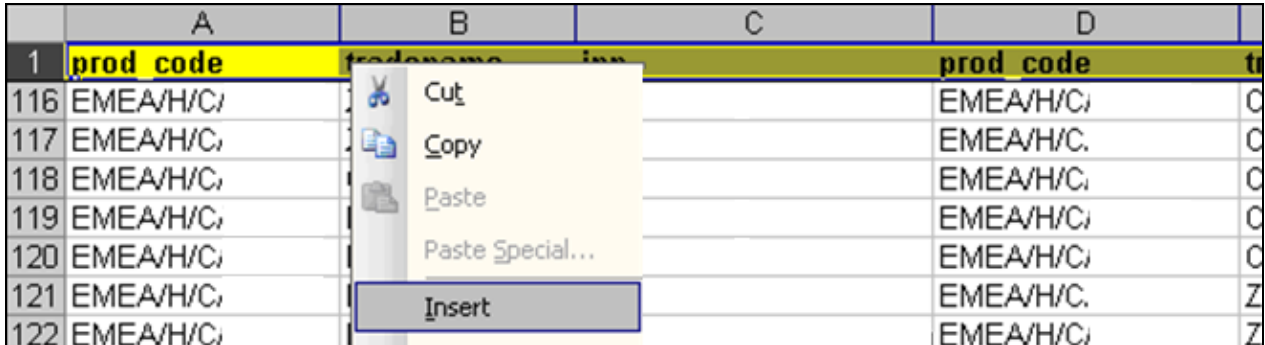
Note: "Tradename" is used in the WIN to maintain the same terminology as used in the tables and in other cross-referenced WINS. However, it has to be intended as synonyms of Invented Name.



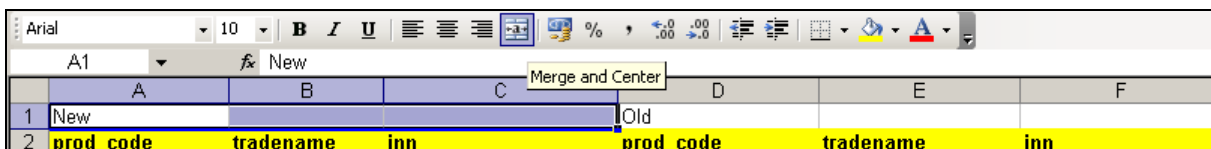
1. Identify the files 'pending\_MONYY' saved by the SGD Secretariat (the listing from Siamed for the previous month is called 'pending\_previous' and the listing from Siamed for the current month is called 'pending\_new' in this WIN).
2. Open the 'pending\_new' file, keep the columns A ('prod\_code'), B ('tradename') and D ('inn') and deleted all the other columns.
3. Open the 'pending\_ previous' file, keep the columns A ('prod\_code'), B ('tradename') and D ('inn') and deleted all the other columns.
4. In the 'pending\_previous' file, select the data in columns A, B and C, right-click on the headers and select 'Copy'.



5. In the 'pending\_new' file, select the cell D1, right-click and select 'Paste'.
6. Close the 'pending\_previous' file.
7. Select the first row (move the mouse to the number '1' on the first row), right-click and select 'Insert'.



8. In cell A1, enter 'New', in cell D1 enter 'Old'.
9. Select the cells A1-C1, and click on the 'Merge and Center' icon. Repeat the same operation for cells D1-F1



10. In cell G2 enter 'Compare Code', in cell H2 enter 'Compare Tradename' and in cell I2 enter 'Compare Inn'.

11. Select the cells A2 to I2 and in the 'Data' menu, select 'Filter' -> 'AutoFilter'.
12. Select cell G3, go to the Edit field and enter: '=EXACT(A3,D3)' and press 'Enter'.

G3		fx =EXACT(A3,D3)			
	F	G	H	I	
1					
2	inn	Compare Code	Compare Tradename	Compare Inn	
3		TRUE			

13. Select the cell G3, left-click on the bottom right-hand corner of the cell (a little black cross appears) and drag down to the last row with text.
14. When looking at the data on the same row:

- if the Authorisation codes (column A and D 'prod\_code') are matching, the value in 'Compare Code' (column G) is 'TRUE'
- if the Authorisation codes (column A and D 'prod\_code') are not matching, the value in 'Compare Code' (column G) is 'FALSE'

When the value in 'Compare Code' (column G) is 'FALSE', the columns (A, B, C) or (D, E, F) should be moved as a block so the value in column A ('prod\_code') equals the value in column D ('prod\_code').

For a selected row, when the value in column A can not be found in column D, the cells in columns D, E and F should remain empty and the 'Compare Code' (column G) returns 'FALSE'.

	A	B	C	D	E	F	G
1	New			Old			
2	prod_code	tradename	inn	prod_code	tradename	inn	Compare Code
3	EMEA/H/C/001	C	c				FALSE

Reciprocally, for a selected row, when the value in column D can not be found in column A, the cells in columns A, B and C should remain empty and the 'Compare Code' (column G) returns 'FALSE'.

	A	B	C	D	E	F	G
1	New			Old			
2	prod_code	tradename	inn	prod_code	tradename	inn	Compare Code
10				EMEA/H/C/008	K	c	FALSE

**Example:**

	A	B	C	D	E	F	G	H	I
1	New			Old					
2	prod_code	tradename	inn	prod_code	tradename	inn	Compare Code	Compare Tradename	Compare Inn
3	EMEA/H/C/001	C	c	EMEA/H/C/002	V	t	FALSE		
4	EMEA/H/C/002	V	t	EMEA/H/C/003	O	c	FALSE		
5	EMEA/H/C/003	O	c	EMEA/H/C/004	B	m	FALSE		
6	EMEA/H/C/004	B	m	EMEA/H/C/005	R	a	FALSE		
7	EMEA/H/C/005	R	a	EMEA/H/C/007	N	m	FALSE		
8	EMEA/H/C/006	S	p	EMEA/H/C/008	K	c	FALSE		
9	EMEA/H/C/007	N	m				FALSE		

1) The value 'EMEA/H/C/001' in column A ('prod\_code') does not match the value in column D ('prod\_code') and the 'Compare Code' (column G) returns 'FALSE' and it cannot be found in any column in D.

2) Select the data in columns (D, E and F).

	A	B	C	D	E	F	G	H	I
1	New			Old					
2	prod_code	tradename	inn	prod_code	tradename	inn	Compare Code	Compare Tradename	Compare Inn
3	EMEA/H/C/001	C	c	EMEA/H/C/002	V	t	FALSE		
4	EMEA/H/C/002	V	t	EMEA/H/C/003	O	c	FALSE		
5	EMEA/H/C/003	O	c	EMEA/H/C/004	B	m	FALSE		
6	EMEA/H/C/004	B	m	EMEA/H/C/005	R	a	FALSE		
7	EMEA/H/C/005	R	a	EMEA/H/C/007	N	m	FALSE		
8	EMEA/H/C/006	S	p	EMEA/H/C/008	K	c	FALSE		
9	EMEA/H/C/007	N	m				FALSE		

3) Cut ('Ctrl+X'), click in cell D4 and paste ('Ctrl+V').

	A	B	C	D	E	F	G	H	I
1	New			Old					
2	prod_code	tradename	inn	prod_code	tradename	inn	Compare Code	Compare Tradename	Compare Inn
3	EMEA/H/C/001	C	c				FALSE		
4	EMEA/H/C/002	V	t	EMEA/H/C/002	V	t	FALSE		
5	EMEA/H/C/003	O	c	EMEA/H/C/003	O	c	FALSE		
6	EMEA/H/C/004	B	m	EMEA/H/C/004	B	m	FALSE		
7	EMEA/H/C/005	R	a	EMEA/H/C/005	R	a	FALSE		
8	EMEA/H/C/006	S	p	EMEA/H/C/007	N	m	FALSE		
9	EMEA/H/C/007	N	m	EMEA/H/C/008	K	c	#REF!		

4) Select the cell G3, double-click on the bottom right-hand corner of the cell (a little black cross appears) to update the calculation for the column G.

	A	B	C	D	E	F	G	H	I
1	New			Old					
2	prod_code	tradename	inn	prod_code	tradename	inn	Compare Code	Compare Tradename	Compare Inn
3	EMEA/H/C/001	C	c				FALSE		
4	EMEA/H/C/002	V	t	EMEA/H/C/002	V	t	TRUE		
5	EMEA/H/C/003	O	c	EMEA/H/C/003	O	c	TRUE		
6	EMEA/H/C/004	B	m	EMEA/H/C/004	B	m	TRUE		
7	EMEA/H/C/005	R	a	EMEA/H/C/005	R	a	TRUE		
8	EMEA/H/C/006	S	p	EMEA/H/C/007	N	m	FALSE		
9	EMEA/H/C/007	N	m	EMEA/H/C/008	K	c	FALSE		
10									

5) Repeat the example steps 1 to 4 until the column 'Compare Code' (column G) returns:

- 'TRUE'

Or

- 'FALSE' with blank values in (A, B, C) or (D, E, F).

6) The final result should look as follow

	A	B	C	D	E	F	G	H	I
1		New			Old				
2	prod_code	tradenname	inn	prod_code	tradenname	inn	Compare Code	Compare Tradename	Compare Inn
3	EMEA/H/C/001	C	c				FALSE		
4	EMEA/H/C/002	V	t	EMEA/H/C/002	V	t	TRUE		
5	EMEA/H/C/003	O	c	EMEA/H/C/003	O	c	TRUE		
6	EMEA/H/C/004	B	m	EMEA/H/C/004	B	m	TRUE		
7	EMEA/H/C/005	R	a	EMEA/H/C/005	R	a	TRUE		
8	EMEA/H/C/006	S	p				FALSE		
9	EMEA/H/C/007	N	m	EMEA/H/C/007	N	m	TRUE		
10				EMEA/H/C/008	K	c	FALSE		

15. Select the cell G3, left-click on the bottom right-hand corner of the cell (a little black cross appears) and drag horizontally to the right to cells H3 and I3.

	F	G	H	I
1				
2	inn	Compare Code	Compare Tradename	Compare Inn
3		TRUE		

16. Select the cells H3, left-click on the bottom right-hand corner of the cell (a little black cross appears) and drag down to the last row with text.
17. Select the cells I3, left-click on the bottom right-hand corner of the cell (a little black cross appears) and drag down to the last row with text.
18. Using the filters, select 'TRUE' for each column ('Compare Code', 'Compare Tradename' and 'Compare Code').

	G	H	I
1			
2	Compare Code	Compare Tradename	Compare Inn
3	TRUE	TRUE	Sort Ascending
4	TRUE	TRUE	Sort Descending
5	TRUE	TRUE	(All)
6	TRUE	TRUE	(Top 10...)
7	TRUE	TRUE	(Custom...)
8	TRUE	TRUE	FALSE
9	TRUE	TRUE	TRUE

19. Select all the rows identified by the filtering, right-click and select 'Delete'.
20. Using the filters, select '(All)' for each column ('Compare Code', 'Compare Tradename' and 'Compare Code').
21. Using the filters, **define the different status of the Substance in products under evaluation** as follows:

**MAINTENANCE OF THE SCIENTIFIC GROUP TABLE**

- **Change of INN** (Code and Tradename are the same, INN is different)
  - Select 'TRUE' for the column 'Compare Code'
  - Select 'TRUE' for the column 'Compare Tradename'

Highlight the cells in Lavender and insert reference at the bottom of the table: **Change of INN**

- **Change of Tradename** (Code and INN are the same, Tradename is different)
  - Select 'TRUE' for the column 'Compare Code'
  - Select 'FALSE' for the column 'Compare Tradename'

Highlight the cells in Turquoise and insert reference at the bottom of the table: **Change of Tradename**

- **Entry missing in the New listing** (Tradenames/INN) (AU, PO, WD)
  - Select 'FALSE' for the column 'Compare Code'
  - Select 'BLANKS' for the column 'prod\_code' under the 'New' header

Highlight the cells in Gray 25% and insert reference at the bottom of the table: **Old Products missing in NEW**

**POPULATION OF THE SCIENTIFIC GROUP TABLE**

- **New entry** (Tradename/INN) (EV)
  - Select 'FALSE' for the column 'Compare Code'
  - Select 'BLANKS' for the column 'prod\_code' under the 'Old' header

Highlight the cells in Yellow and insert reference at the bottom of the table **NEW Products**

	New			Old					
1	prod_code	tradename	inn	prod_code	tradename	inn	Compare Code	Compare Tradename	Compare Inn
2	EMEA/H/C/	xxxxxxx		EMEA/H/C/	xxxxxxx		FALSE	FALSE	FALSE
3	EMEA/H/C/	xxxxxxx		EMEA/H/C/	xxxxxxx		TRUE	TRUE	FALSE
4	EMEA/H/C/	xxxxxxx		EMEA/H/C/	xxxxxxx		FALSE	FALSE	FALSE
5	EMEA/H/C/	xxxxxxx		EMEA/H/C/	xxxxxxx		FALSE	FALSE	FALSE
6	EMEA/H/C/	xxxxxxx		EMEA/H/C/	xxxxxxx		FALSE	FALSE	FALSE
7	EMEA/H/C/	xxxxxxx		EMEA/H/C/	xxxxxxx		FALSE	FALSE	FALSE
8	EMEA/H/C/	xxxxxxx		EMEA/H/C/	xxxxxxx		TRUE	TRUE	TRUE
9	EMEA/H/C/	xxxxxxx		EMEA/H/C/	xxxxxxx		FALSE	FALSE	FALSE
10	EMEA/H/C/	xxxxxxx		EMEA/H/C/	xxxxxxx		TRUE	TRUE	FALSE
11	EMEA/H/C/	xxxxxxx		EMEA/H/C/	xxxxxxx		TRUE	TRUE	FALSE
12	EMEA/H/C/	xxxxxxx		EMEA/H/C/	xxxxxxx		TRUE	TRUE	FALSE
13	EMEA/H/C/	xxxxxxx		EMEA/H/C/	xxxxxxx		TRUE	TRUE	FALSE
14	EMEA/H/C/	xxxxxxx		EMEA/H/C/	xxxxxxx		TRUE	TRUE	FALSE
15	EMEA/H/C/	xxxxxxx		EMEA/H/C/	xxxxxxx		TRUE	TRUE	TRUE
16	EMEA/H/C/	xxxxxxx		EMEA/H/C/	xxxxxxx		TRUE	TRUE	FALSE
17	EMEA/H/C/	xxxxxxx		EMEA/H/C/	xxxxxxx		TRUE	TRUE	FALSE
18	EMEA/H/C/	xxxxxxx					FALSE	FALSE	FALSE
19	EMEA/H/C/	xxxxxxx					FALSE	FALSE	FALSE
20	EMEA/H/C/	xxxxxxx					FALSE	FALSE	FALSE
21	EMEA/H/C/	xxxxxxx					FALSE	FALSE	FALSE
22	EMEA/H/C/	xxxxxxx					FALSE	FALSE	TRUE
23	EMEA/H/C/	xxxxxxx					FALSE	FALSE	TRUE
24	EMEA/H/C/	xxxxxxx					FALSE	FALSE	TRUE
25	EMEA/H/C/	xxxxxxx					FALSE	FALSE	TRUE
26									
27	New Products								
28	Change of INN								
29	Change of Tradename								
30	Old Product missing								

22. Save the file as 'pending\_mapping\_MonYY' (where 'Mon' is the current month and 'YY' the current year) in DREAM ([Cabinets/13. Projects/EudraVigilance - NEW STRUCTURE/Pharmacovigilance/Data Analysis/SAS analysis/SIAMED Listing \(SDG\)/Pending Mapping + NO](#)).