Title: Creating the SAFE Print		
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Name: Nick Halsey	Name: Panos Tsintis	Review Date: 07-JUN-10
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1. Purpose

A line listing of adverse drug reactions for Central Approved medicinal products are produced each month covering the period of time since the last line listing was produced. This list is then distributed to the PASE signal detection team so that they can hold their pharmacovigilance meetings. The adverse drug reaction reports are received by the EMEA either electronically via EudraVigilance or on paper CIOMS forms. The data for the line listings are stored in the Interim Pharmacovigilance database.

2. Scope

This SOP applies to EudraVigilance Team in the Pharmacovigilance and Post-Authorisation Safety & Efficacy Sector of the Post-Authorisation Evaluation of Medicines for Human Use Unit.

3. Responsibilities

It is the responsibility of the Head of Sector to ensure that this procedure is adhered to within their Sector. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of **9. Procedure**.

4. Changes since last revision

References to related documents and files updated to reflect new locations. Process flow changed to take into account new requirements made by the Signal detection group.

5. Documents needed for this SOP

The computer program “DAP.exe” produces a word document for distribution to the therapeutic teams in the Pharmacovigilance and Post-Authorisation Safety & Efficacy Sector and is located in the following directory:

G:\SharedAreas\EV Simple DB\ADR Database

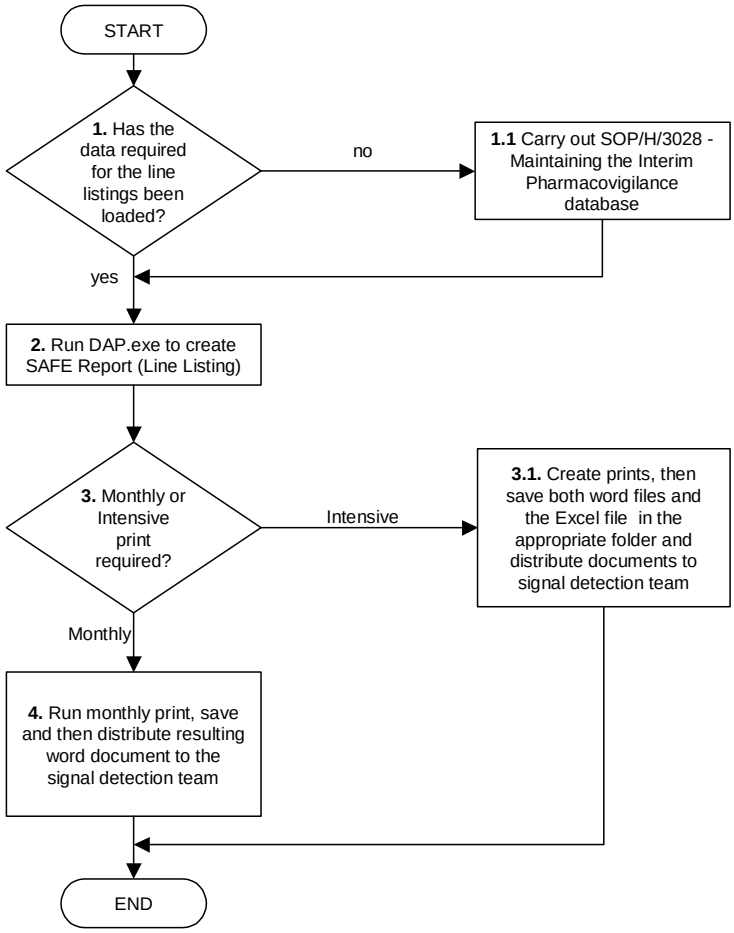
6. Related documents

- SOP/H/3028 - Maintaining of the Interim pharmacovigilance database
- SOP/H3065 - Signal Detection
- SOP/H/3032 - Manual coding of data in the interim database
- Conduct of pharmacovigilance for Centrally Authorised Products (Doc Ref: CPMP/183/97) http://www.emea.europa.eu/pdfs/human/phv/018397en.pdf
- Regulation (EC) No 726/2004 Of The European Parliament And Of The Council http://europa.eu/eur-lex/pri/en/oj/dat/2004/l_136/l_13620040430en00010033.pdf

7. Definitions

Term	Definition
EudraVigilance	The European data-processing network and management system.
EudraVigilance Team member (EVTM)	EMEA staff working on the EudraVigilance project.

8. Process Map(s)/ Flow Chart(s)



9. Procedure

Step	Action	Responsibility
1.	**Has the data required for the line listings been loaded?** Before creating the line listings, the data for the period to be extracted must be available in the Interim Pharmacovigilance database. The procedures for doing this are described in the SOP/H/3028 - Maintaining the Interim Pharmacovigilance database. If this has been done continue with Step 2. If not continue with Step 1.1	EVTM
1.1	**Carry out SOP/H/3028 - Maintaining the Interim Pharmacovigilance database** and continue with Step 2.	EVTM
2.	**Run DAP.exe to create SAFE Report (Line Listing)** To create the line listings go to the following directory and run the program "DAP.exe" located in the following folder: G:\SharedAreas\EV Simple DB\ADR Database ▪ From the options press the button marked " New SAFE print" Continue to step 3	EVTM
3.	**Monthly or Intensive print required?** If a bi-weekly intensive pharmacovigilance print is being prepared go to step 3.1. If a monthly pharmcovigilance print is being prepared go to step 4	
3.1.	▪ Select the report type as "Intensive" in the DAP program ▪ Next fill in the dates to perform the extraction of the data, the dates should be from the last print up to yesterdays date The program will then create two Word file. This process will take around 1-2 hours to complete and it is advised that you run it over night. Save the first Word document with the Name "SAFE Print <date from> - <date to>": Save the second word document with the Name "Paediatric SAFE print <date from> - <date to>": Both files should be saved in the following directory \projects\EudraVigilance\EudraVigilance Human\ADR database\Safe Prints Next choose "New Safe Print Line List" from the DAP main menu and enter the same dates as previously used . Press the "Run" button, the program will then generate an Excel spreadsheet. Save this file in the same location as the two word documents with the file name "Name "SAFE Print <date from> - <date to>"" Distribute the three files to the signal detection team via the group e-mail "**H-SD**"	
4.	▪ Select the report type as "Monthly" in the DAP program ▪ Next fill in the dates to perform the extraction of the data, the dates should be from the last print up to yesterdays date or the 15th of the Month, choose the lowest date value.	EVTM

Step	Action	Responsibility
	The program will then create a Word file. This process will take around 2-3 hours to complete and it is advised that you run it over night. Save the Word document in the following directory path with the Name “Monthly SAFE Print <Month>”: \projects\EudraVigilance\EudraVigilance Human\ADR database\Safe Prints These will be page separators within the print: ▪ AI - Anti-infective ▪ CNS - Central Nervous System ▪ ONC - Oncology ▪ WD – Unassigned medicinal products and medicinal products withdrawn from the market Distribute the print to the signal detection team via the group e-mail “**H-SD**”	

10. Records

Electronic copies are saved in the appropriately labelled folder in EDMS according to information given in Steps 4 and 5