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	National Coordination Centre-Pharmacovigilance Programme of India		
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	Division MAHs		SOP No. IPC/PvPI/MAHs/001
	Effective Date 02/01/2017	Revision No. 01	Review Date 01/01/2020

Title : Processing of ICSRs Reported by Pharmaceutical Industries

1.0 OBJECTIVE

To lay down the procedure for Processing of ICSRs Reported by Pharmaceutical Industries.

2.0 SCOPE

This SOP shall be applicable to NCC-PvPI.

3.0 RESPONSIBILITY

3.1 The personnel engaged in the Pharmaceuticals Industry ICSRs processing under PvPI shall be responsible for adhering to this SOP.

3.2 MAHs division Incharge shall ensure that this parent SOP has been reflected in the section.

3.3 Quality Manager/Technical Manager shall ensure overall implementation of this SOP.

4.0 ACCOUNTABILITY

Officer-in-charge-Pharmacovigilance Programme of India

5.0 PROCEDURE

5.1 NCC receives the ICSRs from Pharmaceutical Industries in the following manner.

5.1.1 Pharmaceutical Industries send ICSRs of their domestic marketed product either in CIOMS or E2B, XML format through PvPI official email id: pvpi@ipcindia.net, pvpi.ipc@gov.in.

	Name	Designation	Signature	Date
Prepared by	<i>G. Navaranchandru</i>	SY. PVA	<i>[Signature]</i>	20/12/2016
Reviewed by	<i>Dr. Prasad Mehta</i>	SA	<i>[Signature]</i>	21/12/2016
Approved by	<i>Dr. Vikalabehn</i>	PSO	<i>[Signature]</i>	22/12/2016

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5.1.2 ICSRs received through PvPI official email Id are downloaded and stored in individual folder created by concern division on monthly basis.

5.2 Processing of ICSRs after receiving from Pharmaceuticals Industries as follows.

5.2.1 Processing of ICSRs from CIOMS pdf format into VigiFlow

5.2.1.1 The ICSRs cases which are received in CIOMS pdf are to be entered manually in to the VigiFlow. Under report info division of the standard case/parent child case select type of sender as Pharmaceuticals Company as given in figure 01 and further enter the remaining data manually into VigiFlow to process the ICSRs as per the SOP No. IPC/PvPI/QA/014

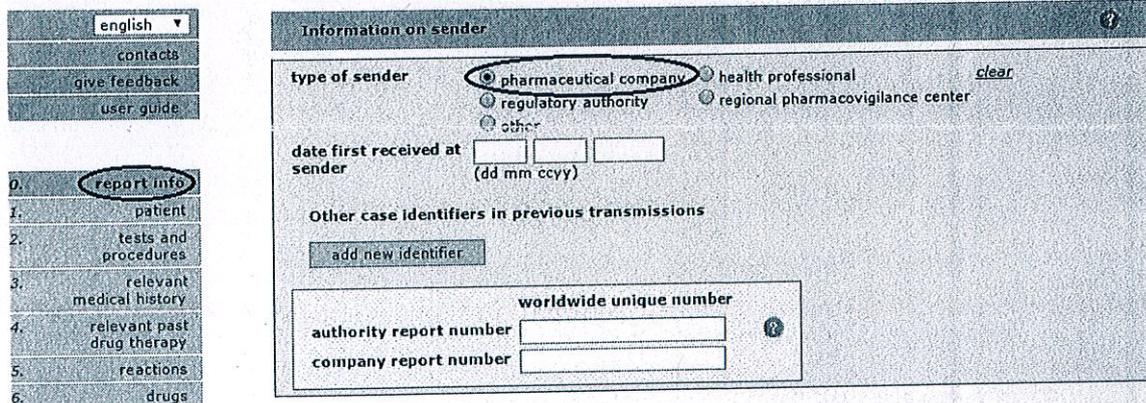


Fig. 01

5.2.2 Processing of ICSRs of E2B formatted, xml file into VigiFlow

	Name	Designation	Signature	Date
Prepared by	G. Naveen chandee	SV. PvA	<i>[Signature]</i>	20/12/2016
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Approved by	Dr. Kalaisehan	PdO	<i>[Signature]</i>	22/12/2016

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5.2.2.1 Login to VigiFlow and select tools → Select E2B handling → Select E2B import in the left hand menu to import an E2B XML file from the folder created for individual industry as shown in figure 02.

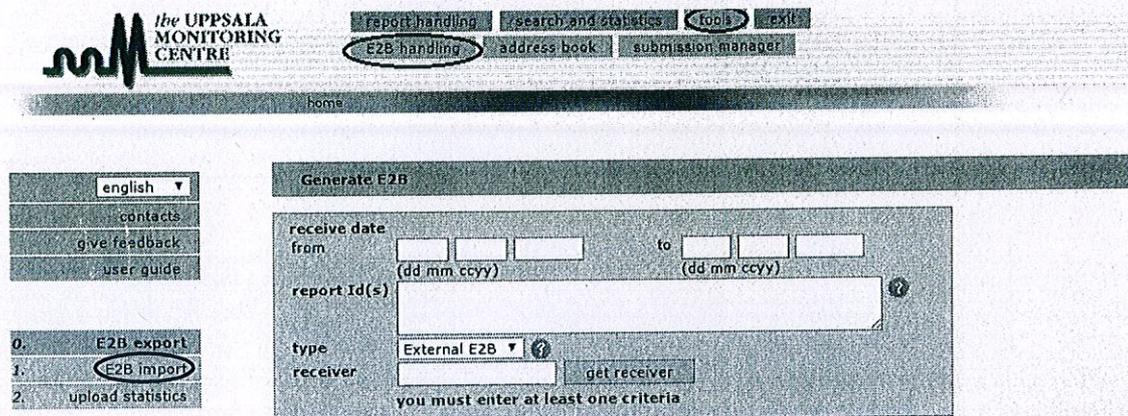


Fig. 02

5.2.2.2 Only correct E2B formatted xml file can be imported. If the file is incorrect an error message will appear. Write the location and file name in the field file, or click the browse button to find the file to upload.

5.2.2.2.1 Select “Standard E2B” under type of import as shown in figure 03. If “Incomplete E2B” is chosen a number of exceptions from the normal E2B import process are made.

5.2.2.2.2 After choosing the E2B XML file from the folder, click option “generate report id” during import. Click on the upload button when the correct file is identified as shown in figure 03.

	Name	Designation	Signature	Date
Prepared by	<i>G. Naveen Chandan</i>	SY.PVA	<i>[Signature]</i>	20/12/2016
Reviewed by	<i>Dr. Prasad Sharma</i>	SA	<i>[Signature]</i>	21/12/2016
Approved by	<i>Dr. Kalal Jehan</i>	PSO	<i>[Signature]</i>	22/12/2016

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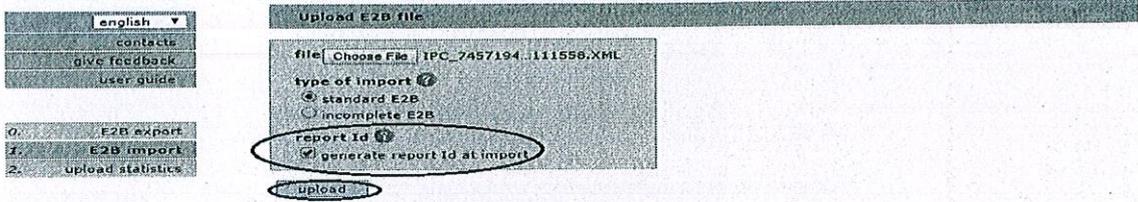


Fig. 03

5.2.2.2.3 After uploading of correct file, a message shall appear as shown in figure 04.

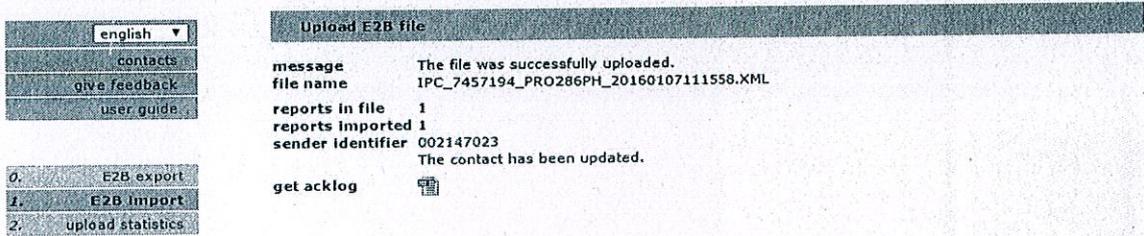


Fig. 04

5.2.2.2.4 After successful uploading, click on the upload statistics to check the report id generated after uploading of file as shown in figure 05.

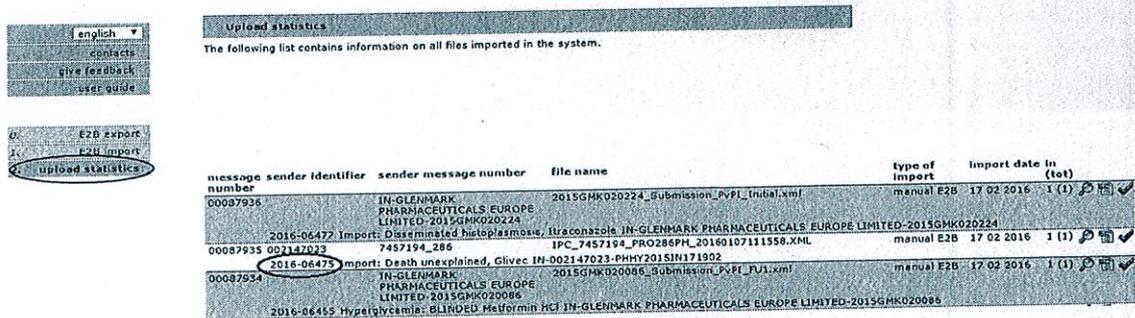
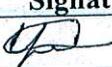
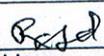


Fig. 05

	Name	Designation	Signature	Date
Prepared by	Dr. Naveenchandru	S.Y. PVA		20/12/2016
Reviewed by	Dr. Rajesh Prasad	SA		21/12/2016
Approved by	Dr. Kalai Selvan	PSO		22/12/2016

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5.2.2.2.5 The imported reports can be found in the List of Reports (Under Report handling → list report) by using report id generated in Figure 05. All imported reports get the title “Import: [First reaction], [First drug]” as shown in figure 06.

Updates of previously received cases					
Report title	Report status	Receive date	Receipt date	Checked out by	
2016-06188 Cough:Avastin	committed	16 02 2016	16 02 2016	kumari	
2015-11821 Acute interstitial nephritis: Rosuvastatin	committed	07 04 2015	29 12 2015		

Reports under central assessment					
Report title	Receive date	Change date	Creator		
2016-06480 Import: DRESS syndrome	17 02 2016	17 02 2016	import		
2016-06130 Drug-induced safety lesions on whole body: Biphasic Isophane Insulin	17 02 2016	17 02 2016	rajesh		
2016-06414 Redness and Itching: Azithromycin	17 02 2016	17 02 2016	chelda		
2016-06474 CONSTIPATION : METFORMIN	17 02 2016	17 02 2016	guptk		
2016-06475 Import: Death unexplained, Glivec	17 02 2016	17 02 2016	import		
2016-06466 HYPOGLYCEMIA : METFORMIN	17 02 2016	17 02 2016	guptk		

Fig. 06

5.2.2.2.6 Each imported report need to be committed as per the reference SOP No. IPC/PvPI/QA/014

5.3 Documentation grading of each ICSR received from pharmaceutical industries as per SOP No. IPC/PvPI/QA/015.

6.0 SAFETY AND PRECAUTION

6.1 Do not use any SOP if it is not signed and issued by QA Personnel or the authorized signatories.

6.2 Do not use adhesive tape or whitener on SOP.

6.3 Do not share the SOP information outside the organization.

	Name	Designation	Signature	Date
Prepared by	<i>Gr. Naveen chandru</i>	SR.PVA	<i>[Signature]</i>	20/12/2016
Reviewed by	<i>Dr. Prasad</i>	SA	<i>[Signature]</i>	21/12/2016
Approved by	<i>Dr. Kalaitwan</i>	PSO	<i>[Signature]</i>	22/12/2016

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7.0 REFERENCES

VigiFlow user guide (<https://adr.who-umc.org/userguide.pdf>).

8.0 ABBREVIATION

ICSRs	:	Individual Case Safety Reports
CIOMS	:	Council for International Organization of Medical Sciences
E2B	:	Electronic Transmission of Individual Case Safety Reports in
XML	:	Extensible Mark-up Language
NCC	:	National Coordination Centre
PvPI	:	Pharmacovigilance Programme of India

9.0 ANNEXURE :

Annexure I: Log book for ICSRs Received from MAHs
(Format No: IPC/PvPI/MAHs/001-F01)

	Name	Designation	Signature	Date
Prepared by	<i>G. Naveen Chandra</i>	SV. PVA	<i>[Signature]</i>	20/12/2016
Reviewed by	<i>Dr. Rakesh Thota</i>	SA	<i>[Signature]</i>	21/12/2016
Approved by	<i>Dr. Kalisharan</i>	AS	<i>[Signature]</i>	22/12/2016

