STANDARD OPERATING PROCEDURE	
Department: Pharmacovigilance	**URS No.:**
Title: Safety Data Exchange Agreements	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure on Safety Data Exchange Agreements (SDEA's) and its execution for …….. approved products (based on active pharmaceutical ingredients).

2.0 SCOPE:

This procedure is applicable to the arrangements in between ……. and its licensing partners involved in manufacturing, import, export, marketing and sales of pharmaceutical products.

3.0 RESPONSIBILITY:

3.1 Pharmacovigilance Department:

Responsible to prepare, execute and maintain the SDEA.
Preparation, distribution, retrieval and destruction of this SOP.

3.2 Pharmacovigilance Officer In-charge (PvOI):

Review and Approval of SDEA of ……. ,Review, training and effective implementation of this SOP.

3.3 Regulatory Affairs Department:

To inform Pharmacovigilance department of any new SDEA or PV agreement or PV clause that ……is entering into with any third party/marketing clients, which make …….. responsible to perform Pharmacovigilance activities/exchange Pharmacovigilance data with them for their products.

4.0 ACCOUNTABILITY:

General Management, PvOI

5.0 PROCEDURES:

5.1 SDEA PREPARATION:

5.1.1 ……./subsidiary will enter into SDEA with the third party or clients (marketing company) or Pharmacovigilance clause will be mentioned in main business agreement instead of signing SDEA separately (if required)

5.1.2 Whenever ……../subsidiary enters into any business relationship with any third party or clients (marketing company) which involves performance of Pharmacovigilance activities, a SDEA shall be executed. It shall be executed in accordance with applicable legislation and guidelines and in order to ensure that all Parties understand and formally agree to the roles and responsibilities that were outlined in the agreement.

5.1.3 PV (officer/executive)/designee will prepare SDEA as per SDEA Template (Annexure I) or ……..will use the SDEA template which will be provided by third party or clients (marketing company) (if required). The SDEA will be reviewed and finalized by PvOI/ operating manager.

5.1.4 Element of Safety Data Exchange Agreement:

The following elements shall be considered when executing a SDEA but not limited to:

- Scope
- Definitions and abbreviations
- Safety reference documents
- Pharmacovigilance data exchange
- Spontaneous and regulatory authority reports
- PSUR's
- Submission to regulatory authorities
- Regulatory authority requests for additional information
- Additional information on a specific ICSR
- Additional information of a more general nature
- RMP
- Qualified personnel and training
- Signal detection
- Archiving
- Audits and regulatory inspections
- Maintenance of this agreement
- Confidentiality
- Contact details
- Governing law and dispute resolution

5.1.5. Final draft shall be shared with the respective stakeholder for review.

5.1.6. Once all parties agree upon mutual responsibilities, terms and conditions, two copies of the final SDEA shall be printed and signed by the authorised signatories of the parties. Each party shall maintain assigned copy of the SDEA.

5.1.7. Original SDEA (…… copy) shall be maintained at the legal/RA department of ……. and a copy of the same shall be maintained at PV department.

5.2 SDEA REVISION/AMENDMENT/TERMINATION:

5.2.1 SDEA shall be Revised/Amended:

- If there is a major revision to the current legislation and guidance
- If mutually agreed Pharmacovigilance responsibilities revised
- If change in the key contact person and their details

5.2.2 SDEA shall be terminated if parent contract/agreement terminated. All the parties reserve the right to terminate the SDEA.

5.3. SDEA COMPLIANCE:

5.3.1. PV shall ensure the SDEA compliance on regular basis.

Any deviation to the same shall be documented, shared with the concerned parties and necessary action shall be initiated as per the current version of SOP "Management Review".

6.0 DISTRIBUTIONS:

Master copy: Remains with Pharmacovigilance Department

7.0 REFERENCES:

Pharmacovigilance Guidance Documents.

8.0 ANNEXURES:

S.No.	Title	Annexure No.	Format No.
1.	Safety data exchange agreement template	I	

9.0 ABBREVIATIONS:

ACO	Addendum to Clinical Overview
ICSR	Individual Case Safety Report
MAH	Marketing Authorization Holders
NA	Not Applicable
PSUR	Periodic Safety Update Report
PV	Pharmacovigilance
PvOI	Pharmacovigilance Officer In-charge
RA	Regulatory Affairs
RMP	Risk Management Plan
RSI	Reference Safety Information
SDEA	Safety Data Exchange Agreement

10.0 RECORDS OF HISTORY:

Revision No.	Effective Date	Reason for change	CC No.
00		New SOP	Nil

ANNEXURE I

SAFETY DATA EXCHANGE AGREEMENTS TEMPLATE

Table of content

1. SCOPE

This Safety Data Exchange Agreement (SDEA) describes the procedures and defines the

responsibilities regarding Pharmacovigilance for the products defined in Appendix A, which …….. and marketing company or client (Company X) will employ to ensure adequate
Safety data exchange and compliance with the regulatory requirement.
This Agreement covers Individual Case Safety Reports (ICSR's) from health care professionals, consumers, scientific and medical literature, regulatory authorities, digital media (including newspaper) or social media etc., collected either by Company X or by …….. in relation to the product(s) listed in Appendix A. This Agreement does not cover technical and product complaints unless they are associated with an Adverse Event (AE)/ Adverse Drug Reaction (ADR).Appendix A provides an overview of product(s) and formulation(s) in its respective territory(ies)and their regulatory status for which ……. and Company X need to have a contractual agreement in place.
Appendix B provides the contact details of the relevant Pharmacovigilance personnel of each Party.
Appendix C provides the summary of Pharmacovigilance obligations of each Party.

2. DEFINITIONS AND ABBREVIATIONS:

The definitions used in this Agreement are those from Guideline on Good Pharmacovigilance Practices (GVP) - Annex 1 and PV Guidance Document for MAH's of Pharmaceutical Products in India. Definitions not covered by GVP-Annex 1 are defined below.
Product: Product(s), listed in appendix A, is (are) the medicinal product(s) for which ……
and Company X have executed this Pharmacovigilance Agreement.

Date received by company

The date received by ……/subsidiary (day 0) is the date when the clock starts for expedited reporting and is always the date of first notification of an adverse drug reaction to the Marketing company (client) or ……

.

ACO	Addendum to Clinical Overview
ADR	Adverse drug reaction
AE	Adverse event
GVP	Guidelines for Good Pharmacovigilance Practice
HCP	Health-Care Professional

ICSR	Individual Case Safety Report
MA	Marketing Authorization
MAH	Marketing Authorization Holder
MedDRA	Medical Dictionary for Regulatory Activities
NCC	National Coordination Centre
PI	Package Insert
PSUR	Periodic Safety Update Report
PvOI	Pharmacovigilance Officer In-charge
PvPI	Pharmacovigilance Programme of India
QPPV	Qualified Person responsible for Pharmacovigilance Activities
RMP	Risk Management Plan
SOP	Standard Operating Procedure
SPC/SmPC	Summary of Product Characteristic

3. SAFETY REFERENCE DOCUMENTS:

……. will maintain an updated PI or reference document. Each Party will be responsible for maintaining and updating any local safety reference documents in its territories.

4. PHARMACOVIGILANCE DATA EXCHANGE:

Both Parties will collect and report to each other safety data related to the product(s) listed in Appendix A. In this manner, each Party shall assist the other as necessary to ensure that both networks have complete and accurate information in their respective databases. The language of all exchange will be English.

5. SAFETY INFORMATION TO BE COMMUNICATED:

Spontaneous reports of AE's from HCP's and non–HCP's or social media or regulatory authority or AE/ADR reports from non-interventional (observational) studies, patient support programs, market research programs, compassionate use programs including special situation cases mentioned below coming to the knowledge of any personnel of COMPANY X from the Territory should be communicated to …….., as soon as possible, but in no event later than the timelines specified below in Section 8. (Timelines for Communication).

The following special situation cases, with or without an AE, shall be communicated:

- Overdose
- Abuse or misuse, i.e. use for non-clinical reasons

- Medication errors, i.e. any event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer
- Unexpected therapeutic or clinical benefit from use of the Product
- Suspected transmission of any infectious agent(s)
- Trans-mammary exposure (transmission via breast milk)
- Off-label use
- Occupational exposure
- Lack of Efficacy
- Pregnancy or parental exposure

Medical information requests and/or product quality complaints which are associated with reports of AE or special situation cases shall also be communicated in a similar manner as describe above.
Safety related queries from regulatory authorities coming to the knowledge of any personnel of either of the Parties from the Territory should be communicated to other Party, as soon as possible.

6. DATABASE RECONCILIATION:

Company X will be responsible for maintaining a worldwide database of ICSR's concerning applicable products. Both Parties will exchange information on duplicate database entries (if applicable). Reconciliation of ICSRs will be done by ……..

7. PSURS:

Company X will be responsible for the preparation of PSUR's in line with its submission plans for all the applicable products.
It is understood by both Partiers that regulatory authorities might require additional safety reports for which other timeframes might apply.
The format of the PSUR will be in accordance with the format and content as stated in the GVP. All PSUR's will be written in English.

8. SUBMISSION TO REGULATORY AUTHORITIES:

……. will be responsible to submit the appropriate reports in Pharmacovigilance, expedited or periodic, to the regulatory authority in its territories, and within the time frames required by the current regulations in each country. Appendix A provides an overview of countries for which ……. have reporting obligations for product(s) that are subject to this Agreement. Furthermore, …… will be responsible for submitting all reports, and other safety information to regulatory authority, as required by current regulation.

STANDARD OPERATING PROCEDURE	
Department: Pharmacovigilance	**URS No.:**
Title: Safety Data Exchange Agreements	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

9. REGULATORY AUTHORITY REQUESTS FOR ADDITIONAL INFORMATION:

9.1 Additional information on a specific ICSR

If regulatory authorities request additional information regarding a particular ICSR, the ……. will be responsible for the submission of this particular ICSR and obtain the requested information and submit to the authority.

9.2 Additional information of a more general nature

Both Parties will handle requests of a more general nature from competent authorities such as changes to the SPC/package insert or requests for data from the (worldwide) safety database.

10. RMP

…… shall be primarily responsible for the initiation and maintenance of the RMP and is responsible for the submission of the RMP in its territories.

11. QUALIFIED PERSONNEL AND TRAINING:

Since Each Party is responsible for having adequately trained and qualified staff in their respective Pharmacovigilance units, for the training and instruction of their staff and for having access to a medically qualified person.

Both Parties will have appropriate SOP's in place to ensure that they consistently comply with this Agreement.

12. SIGNAL DETECTION:

…….will be responsible for the signal detection of new risks or increased frequencies of ADR and/or AE of the product(s) concerned (see Appendix A) and will inform Company X as soon as possible after confirmation.

…… and Company X are responsible for the communication of any identified change in the benefit/risk balance of the product(s) to third parties including competent authorities.

13. ARCHIVING:

…….. will archive the data derived from its territories, including the verbatim term, for the Lifetime of the product.

14. AUDITS AND REGULATORY INSPECTIONS:

Company X will be entitled to audit the Pharmacovigilance facilities of …….. or vendor, with a written notice of at least__days prior to a mutually-agreed audit date.

Each party shall conduct periodic internal audits related with Pharmacovigilance processes and procedures in order to assess the fulfillment of its obligations under this Agreement and the need for any change or improvement to its processes and procedures. In case of a regulatory inspection, each party shall inform the other in writing within__working days of inspection findings that may impact the compliance of this Agreement, and must keep the other party informed on the completion and effectiveness of corrective and preventive or actions taken after inspection.

STANDARD OPERATING PROCEDURE	
Department: Pharmacovigilance	**URS No.:**
Title: Safety Data Exchange Agreements	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

15. MAINTENANCE OF THIS AGREEMENT:

This Agreement shall come into force on the date of the last signature below and shall remain in full force and effect for so long as this Agreement is not terminated upon written request of either party.

At the written request of either Party, the parties shall meet to re-negotiate in good faith all or some of the terms of this Agreement.

16. CONFIDENTIALITY:

Both Parties agree that any information exchanged through this Agreement will be strictly confidential, and it shall be used only by both Parties for its intended purposes.

Any unauthorized use or dissemination of it in whole or in part is strictly prohibited. Each Party may only provide information to their local regulatory authority or other licensees, as known to the other party, as necessary to comply with regulatory reporting obligations.

17. CONTACT DETAILS:

See Appendix B for respective contact person from both Parties. Each Party has the obligation to inform the other Party in advance and if possible within_____hours, of changes in the ADR reporting address.

18. GOVERNING LAW AND DISPUTE RESOLUTION:

Any controversy or dispute or claim arising between the Parties in connection with or arising out of this Agreement or any Agreement in furtherance of it including any dispute or claim with respect to the validity of the Agreement, which cannot be settled amicably, shall be finally and exclusively settled by the competent court as indicated in the SDEA.

Parties have executed this Pharmacovigilance Service Agreement, the date the last signatory has signed as its effective date,

Company X……..

<Name><Name>

<Designation><Designation>

STANDARD OPERATING PROCEDURE	
Department: Pharmacovigilance	**URS No.:**
Title: Safety Data Exchange Agreements	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Appendix A

Overview of products, formulations and market.

Brand Name	Generic Name (with formulation and Strength)	Market(s)	Product Registration Holder

STANDARD OPERATING PROCEDURE	
Department: Pharmacovigilance	**URS No.:**
Title: Safety Data Exchange Agreements	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Appendix B

Contact Details:

1.COMPANY X
<Address>

Contact person:

Contact details:
……

Contact person:

Contact details:

STANDARD OPERATING PROCEDURE	
Department: Pharmacovigilance	**URS No.:**
Title: Safety Data Exchange Agreements	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Appendix C

Summary of Pharmacovigilance obligations:

Obligations	……	Company X
MAH in territory		
Local QPPV/PvOI for the product(s) in it's the territory(ies)		
Maintenance/Update of the Reference Safety Information		
Changes to the product Reference Safety Information in the local territories		
Maintenance/Update of local SOPs to comply with this agreement		
Owner of global safety database		
Expedited reporting responsibility in its territory(ies)		
Responsible for preparing CIOMS I Forms/XML file for ADR's/AE's reported in its territory(ies)		
Exchange ADR's/AE's between ……. & Company X		
Worldwide medical/scientific literature search /local literature search		
Obtaining additional information (follow-up) for ICSR		
Responsible for using Med DRA		
Assessment of ADR's/AEs in ICSR's		
Preparation of PSUR's for the product(s) under national registration		
Submission of PSUR's to the regulatory authority(ies) in local territory(ies)		
Submission of appropriate reports to regulatory authority(ies) of the countries in its territory(ies)		
Submission of additional information regarding specific ICSR's if requested by competent authorities		
Qualified personnel and training		
Archiving		
Audits		
Pharmacovigilance training in the local territory(ies)		
Pharmacovigilance Agreement maintenance including updates in contact details		
Confidentiality/Data Privacy		