



To: **Pharmacovigilance Reporting** Reported date: _____/_____/20____

Cc: PM _____ Accepted date (fill out by MRE): _____/_____/20____

SM _____

☐ Adverse Drug Reactions

☐ Lack of Efficacy

☐ Product Technical Complaint

Patient's name (initials):	Physician's name	Product Name:
Age & Sex: Male/Female*	Hospital/clinic address	Batch number :
Diagnosis:	Phone/mobile phone	Manufactured Date:
Duration of treatment: _____ to _____ (date/month/year)	Signature:	Expired Date:
Relevant patient history (e.g. allergies, pre-existing medical conditions, smoking & alcohol use, gestational age, etc.)		Indication(s) for use:
Describe the adverse reaction(s) / lack of efficacy chronologically:		Daily dose:
		Route of administration :
		Duration of therapy : _____ to _____ (date/month/year)

Adverse Drug Reaction that Occur (for adverse drug reaction(s))**	The Final Result (for adverse drug reaction(s))**	SPECIAL CONDITION**
☐ Death _____(date/month/year) ☐ Life-threatening ☐ Persistent/significant disability/incapacity ☐ Intervention to prevent damage / permanent disturbance ☐ Congenital anomaly/birth defect ☐ Hospitalization - initial/prolonged ☐ Other medically significant. ☐ Nonserious	☐ Recovered _____(date/month/year) ☐ Recovered with sequelae : (please specify) ☐ Permanently disabled ☐ Death _____(date/month/year) ☐ Deteriorated conditions ☐ Not yet recovered ☐ Unknown	☐ Overdose ☐ Off-label use ☐ Abuse, misuse, dependency or medication error; ☐ Unknown/unexpected therapeutic effect; ☐ Occupational exposure ☐ Drug exposure via the mother / father (during conception, pregnancy, childbirth, or breastfeeding); ☐ The use in children or the elderly ☐ Suspected ADRs related to quality defect or falsified product (counterfeit); ☐ The use of the product out of registered storage conditions.

CONCOMITANT MEDICINAL PRODUCT (not including those used to treat the adverse drug reaction) or PRODUCT COMPETITORS (for lack of efficacy report)						
Product(s) (brand name)/dosage form	Batch Number and ED	Daily dose	Route of administration (IV, IM, SC, oral, suppo, EXT)	Date of administration (start-stop)	Indication(s) for use	Competitors Company Name

Product Name:	Reporter name:	(full name and title)
Batch number :	Job title:	
Manufactured Date:	Institution name:	
Expired Date:	Address:	
Preparation:	Phone/mobile phone:	
Quantity:		

Describe the product technical complaint chronologically:

MR		PIMDA		DM		Note:	
Date							
Area/country							
Name							
Phone/mobile phone							
Signature							

* scratch the unnecessary ones ** Tick $\checkmark$ on selected columns