1. Reporter Details		☐ Initial ☐ Follow-up
Reporter Name:		E-mail:
Contact address:		Telephone number:
		Fax number:
Type:	☐ Physician (Specialty): _____	☐ Nurse
	☐ Pharmacist	☐ Other Healthcare professional (Please specify) _____
If reporter is a consumer, have they informed their physician of the exposure?		☐ Yes ☐ No
Has the consumer provided permission to contact their healthcare professional?		☐ Yes ☐ No
If yes, please provide healthcare professional contact details:		
Name:	Type:	Telephone:
Address:		Email:

2. Patient Details			
Date of birth (Day/Month/Year)	Age Yrs/mo.	Height (cm)	Weight (kg)

3. Suspect Product Details									
	Name	**Strength**	**Dose**	**Route**	**Indication**	**Treatment Start date** (day/month/year)	**Treatment end date** (day/month/year)	**Lot**	**Exp. date**
1.									
2.									
3.									

4. Pancreatic Disorder Details	
Symptoms:	
☐ Abdominal pain	☐ Malaise
☐ Nausea	☐ Vomiting
☐ Jaundice	☐ Fever
☐ Weight loss	☐ Abdominal bleeding
☐ Diarrhoea	☐ Change in colour or consistency of stools
☐ Itching	☐ Bloating
Other relevant symptoms:	
Please provide, the diagnosis of the patient:	
Does the patient have acute pancreatitis? ☐ Yes ☐ No	

If yes, please specify the severity.

☐ Mild ☐ Moderate ☐ Severe.

Is the pancreatitis associated with any of the following?

☐ Interstitial edema ☐ Necrosis of pancreatic or peripancreatic tissue

Is the pancreatitis associated with any of the following organ failures?

☐ respiratory failure ☐ cardiovascular failure ☐ renal failure

Is the pancreatitis associated with any of these local complications?

☐ Peripancreatic fluid collections ☐ Pancreatic pseudocysts
☐ Acute necrotic collections ☐ Walled-off pancreatic necrosis

Other relevant details:

5. Laboratory tests

	Date (day/month/year)	**Results**	**Normal Range**
Amylase			
Lipase			
Ultrasonogram			
Endoscopic Ultrasound			
Abdominal X-Ray			
CT scan			
Magnetic Resonance Cholangiopancreatography			
Endoscopic Retrograde Cholangiopancreatography			
Liver function tests			
Other relevant test details:			

6. Medical History

Patient's concomitant conditions, relevant medical history, known risk factors, relevant tests, laboratory data.

☐ Trauma	☐ Diabetes
☐Cholecystitis	☐ Cholelithiasis

☐ Autoimmune disease	☐ Cystic fibrosis
☐ Pancreatitis	☐ Hepatitis
☐ Drug abuse	☐ Colitis
☐ Infections	☐ Toxic exposure
☐ Drug abuse	☐ Alcohol use: Glass/day
Other relevant medical history:	

7. Treatment for Pancreatic Disorders

8. Details of Other Adverse Events

Adverse Event	Start Date (day/month/year)	Stop Date (day/month/year)	Hospitalization	Outcome	Event Causality
			☐ Yes ☐ No If yes, provide dates of hospitalization.	☐ Recovered / Resolved ☐ Recovered / Resolved with Sequelae ☐ Recovering /Resolving ☐ Not Recovered /Not Resolved ☐ Fatal ☐ Unknown	☐ Related ☐ Not Related ☐ Unknown
			☐ Yes ☐ No If yes, provide dates of hospitalization.	☐ Recovered / Resolved ☐ Recovered / Resolved with Sequelae ☐ Recovering /Resolving ☐ Not Recovered /Not Resolved ☐ Fatal ☐ Unknown	☐ Related ☐ Not Related ☐ Unknown
			☐ Yes ☐ No If yes, provide dates of hospitalization.	☐ Recovered / Resolved ☐ Recovered / Resolved with Sequelae ☐ Recovering /Resolving ☐ Not Recovered /Not Resolved	☐ Related ☐ Not Related ☐ Unknown

8. Details of Other Adverse Events					
Adverse Event	Start Date (day/month/year)	Stop Date (day/month/year)	Hospitalization	Outcome	Event Causality
				☐ Fatal ☐ Unknown	

9. Concomitant Drugs & Therapies

10. Completed By		
Name:	Signature:	Date (day/month/year):