SIDE EFFECT NOTIFICATION FORM

Date of declaration:

Reporter Information

Practitioner Name: Title: Sector: Private ☐ Public ☐ Health Institution:	Phone: E-mail: Service:	Stamp of the treating doctor

Patient Information

Name-surname : Medical File Reference: Phone:

Sex: F ☐ M ☐	Date of Birth / Age:	Size : cm	Weight: kg

Medical History/ Relevant Information/ Factors that may have contributed to Side effects

(Allergy, Alcohol use, smoking / liver and renal dysfunction ,etc …)

Suspected Product

Product Name	Batch Number	Manufacturing Date
International Denomination	**Bar code**	**Expiry Date**

Product Storage Conditions

Indication-schematic / Therapeutic protocol - Administered Doses and dates

Date of the 1st cure : **Actual cure N°:**

Administered Dose: **Duration of Infusion:**

Premedication : Yes ☐ Specify: No ☐

Associated Drugs

	Drug	way of Administration	Dosage	Beginning of use	Ending of use
1					
2					
3					
4					

Detailed description of suspected Side Effect due to the product

Specify the timing and evolution of clinical and biological disorders with dates. Indicate if such disorders have been noted

<table>
<tr><td colspan="4">Seriousness of Side Effect</td></tr>
<tr><td>Minor ☐</td><td>Major ☐</td><td colspan="2">Critical ☐</td></tr>
<tr><td>Side Effect (s)</td><td>Department Of Occurrence</td><td>Date of occurrence</td><td>Duration of Effect</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="4">Period since the last cure /beginning of the cure</td></tr>
<tr><td>Discontinuation of the concerned drug</td><td>Yes ☐</td><td colspan="2">No ☐</td></tr>
<tr><td>Treatment of Side Effect(s)</td><td>Medicinal Treatment (Specify)</td><td colspan="2">Non-Medicinal Treatment (Specify)</td></tr>
<tr><td colspan="2">Severity
☐ Hospitalization or Lengthened of hospital stay
☐ Disability
☐ Life threatening
☐ Death (Date)
☐ Birth Defect
☐ Other serious medical conditions
☐ Not serious</td><td colspan="2">Evolution
☐ Recovery ☐ In progress ☐ Without Sequelaes ☐ With Sequelaes
☐ Subject not recovered yet
☐ Death ☐ Due to the effect ☐ To which the effect may have contributed ☐ Unrelated to the effect
☐ unknown</td></tr>
<tr><td colspan="4">Claim submitted by:
☐ Fax ☐ E-mail ☐ Mail ☐ Phone ☐ Others ………………………………….</td></tr>
<tr><td colspan="4">CYTOPHARMA Preliminary Investigations</td></tr>
<tr><td colspan="4"></td></tr>
<tr><td colspan="4">Decision (s) taken by CYTOPHARMA</td></tr>
<tr><td>☐ Further Imminent Investigation</td><td>☐ Proposal of preventive actions</td><td colspan="2">☐ Others</td></tr>
<tr><td>Date and visa
Medical Officer</td><td>Date and visa
Quality management Responsible</td><td colspan="2">Date and visa
Qualified person</td></tr>
</table>

Attach a copy of available medical documents + Photos if possible (biological reports, hospitalization reports, etc.)

National Center of Pharmacovigilance Service of Collection and Analysis of side effect(s) Phone:+21671260669 +21671260689 +21671260697 +21671260636	**Cytopharma Laboratories** Phone : +216 72668444 Fax: +216 72668555