ANNEX VI

SPONSOR'S DECLARATION OF LIABILITY AND COMMITMENT FORM
EXPANDED ACCESS, COMPASSIONATE USE OR MEDICATION SUPPLY PROGRAMS
POST-STUDY

National Health Surveillance Agency
Coordination of Clinical Research in Medicines and Biological Products
Sponsor Liability and Commitment Statement Form

1	Sponsor Name:		
2	Address:	3	Fax:
4	Name of the medicine:		
5	Indications:		
6	Title of Expanded Access, Compassionate Use or Post-Study Drug Supply (if applicable)		

Responsibilities:

The SPONSOR, through its undersigned legal representative, declares that it is responsible in Brazil for conducting the expanded access, compassionate use or post-study drug supply programs entitled: **(insert the title of the protocol, if applicable)**

We assume the following responsibilities before the National Health Surveillance Agency – Anvisa, through this declaration:

• Provide complete and free treatment to the patient and, in the case of those with chronic diseases, guarantee treatment for the previously defined period, while the patient is benefiting;
• Be a faithful custodian of the product to be imported for expanded access, compassionate use or post-study drug supply programs, keeping it adequately stored;
• Do not market the product of expanded access, compassionate use or post-study drug supply programs;

• Maintain monitoring and records of products delivered to requesting physicians and of the physical stock remaining in storage, for possible inspection by Anvisa;
• Notify Anvisa of serious adverse events, using the form available on Anvisa's website, within a maximum period of 15 (fifteen) calendar days from becoming aware of the fact, except in cases involving the death of the patient, in which case notification must occur within a maximum of 7 (seven) calendar days.
• Whenever the brochure, safety data and procedures are updated, forward them to the responsible doctors;
• Provide comprehensive and free assistance to patients regarding the occurrence of adverse events resulting from the use of medications used in accordance with the approved program, except in the case of compassionate use;
• At the end of the program, account for the imported medication not used during the course, disposing of it properly, whether it be its destruction within the national territory or its return abroad, keeping a proper record of the procedures adopted;

• To ensure that the medicine in use is produced in accordance with Good Manufacturing Practices.

	Signature of Sponsor or Authorized Representative _____		Data: _____/_____/_____