THE MINISTER OF PUBLIC HEALTH

ORDER
on approval of the Suspect Adverse Reaction Report Form

Taking into account provisions of Law No. 95/2006 on healthcare reform, Title XVII, The medicinal product, and of Government Ordinance No. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved with changes and completions through Law No. 594/2002, with further changes and completions,

based on Government Decision No. 862/2006 on organisation and functioning of the Ministry of Public Health,

on seeing Approval Report of the General Pharmaceutical and Medical Devices Directorate No. E.N. 2.270 din 20 July 2006,

the minister of public health hereby issues the following order:

Article 1. - Approval of Suspect Adverse Reaction Report Form according to the Annex which is integral part of this order.

Article 2. - The present order shall come into force 28 July 2006, at which date all contrary provisions shall be repealed.

Article 3. - The present order is to be published in the Official Gazette of Romania, Part I.

The minister of public health,
Gheorghe Eugen Nicolăescu

Bucharest, 20 July 2006.
No. 891.

ANNEX

National Medicines Agency
Tel.: 3171101
Fax: 3163497

This is not just a piece of paper.
It can save lives.
Please fill in with as complete information as possible

SUSPECT ADVERSE REACTION REPORT

Confidential

Patient initials **Please check the appropriate to adverse reaction**
No. F.O./Reg. cons.: Sex: Age: Date of birth: Reaction onset: Duration: if applicable:

						Outcome of adverse reaction:
Describe suspect adverse reaction (s):						**□ Patient died** **□ Life threatening** **□ Involved in hospitalisation/prolonged inpatient hospitalisation** **□ Involved in persistence or significant disability or incapacity** **□ Involved in congenital anomaly/malformation**

Suspect drug(s) information (including vaccines) (name, manufacturer):

	Daily dose(s):	**Route(s) of administration:**
	Lot (for vaccines): **Batch** (for medicinal products):	
	Date of administration onset:	**Date of administration ending:**

Indications for use of the medicinal product/suspected medicinal product:

Concomitant medication (and self-medication): **Daily dose(s): Route(s) of administration: From/To: Indications for use:**

Treatment of adverse reaction:

Recovery after adverse reaction? Full:

Yes	*No*

Yes	No

Please comment:

Sechele:

Yes	*No*

Please comment:

Has administration of suspected medicinal product been stopped? What was the development of the suspected adverse reaction ?

Yes	*No*

Has the dose been reduced?

Please comment:

Has the suspected medicinal product been reintroduced?:

Yes	*No*

Please comment:

Other comments (relevant background, allergies, previous use of the suspected medicinal product):

Filled in by: …… Address of the health unit: .....

Speciality: ……..……

.....

Telephone: ……..……..….

.....

Date: ……..……...

..... Signature and stamp: …….….