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Official Gazette
no. 213 of 14.9.2009

MINISTRY OF LABOUR, HEALTH AND SOCIAL POLICIES

DECREE dated July 14, 2009

Minimum requirements for insurance policies which safeguard participants to clinical trials of medicinal products. (09A10578)

THE MINISTRY OF LABOUR, HEALTH AND SOCIAL POLICIES

in concert with

THE MINISTRY OF ECONOMIC DEVELOPMENT

Having regard to Legislative Decree no. 211 of June 24, 2003, duly published in the ordinary supplement no. 130/L to the Official Gazette no. 184 of August 9, 2003, which ordered the reconciliation of law, regulatory and administrative provisions enacted in the Member States and concerning the application of the rules of good clinical practice when performing clinical trials of drugs for human use;

Having regard to article 3, paragraph 3, of the above Legislative Decree, which requires that a specific decree of the Ministry of Labour, Health and Social Policies acting in concert with the Ministry of Economic Development establishes minimum requirements for insurance policies safeguarding participants to clinical trials of medicinal products;

Having regard to article 6, paragraph 2, letters h) and i) of said Legislative Decree, which require that the Ethics Committee gives its opinion on the trial concerned while particularly considering, inter alia, any provisions regarding compensation of damages or death which can be attributed to the clinical trial and any provisions on insurance policies to cover reimbursement of damages caused to participants by clinical trial activities, thus covering any civil liability of the investigator and the promotor of the clinical trial;

Having regard to Ministerial Decree of December 17, 2004 “General requirements and conditions concerning the performance of drugs clinical trials, particularly those targeted to the improvement of clinical practice as an integral part of healthcare”;

Having regard to Ministerial Decree of December 21, 2007 concerning “Forms and documents required to submit an application for authorization to the competent Authority, to notify substantial amendments and to declare that the clinical trial was completed and to apply for the Ethics Committee’s opinion”;

Considering the need to define minimum requirements to which the above mentioned insurance policies safeguarding participants to clinical trials of medicinal products must conform;

Having regard to Presidential Decree of May 21, 2009 (duly published in the Official Gazette – general series – no. 122 of May 28, 2009), which ordered the “Appointment of Prof. Ferruccio Fazio, State Sub-Secretary for Labour, Health and Social Policies, as Vice Minister, pursuant to article 10, paragraph 3 of Law no. 400 of August 23, 1988” and the attached ministerial decree dated May 20, 2008 concerning delegation of powers granted to Prof. Ferruccio Fazio;

Hereby enacts as follows:

Article 1

1. The promoter of the clinical trial shall submit to the Ethics Committee, pursuant to article 3, paragraph 3 of Legislative Decree no. 211 of June 24, 2003, an insurance certificate in Italian, duly executed by the insurance company under a valid insurance policy, as per the attached standard form which forms an integral part of this decree, which is to make explicit reference to the proposed interventional study and describe its essential aspects as provided by this decree. When giving its opinion in accordance with the form/format required by Italian Ministerial Decree of December 21, 2007 (Appendices 6 and 8), the Ethics Committee shall consider the insurance certificate submitted by the promoter of the clinical trial, as drafted in compliance with the requirements set forth in this decree.

2. The insurance policy is to grant specific cover in connection with the reimbursement of damages caused to the subjects by the clinical trial activities throughout the entire duration thereof, thus covering any civil liability of investigator and promoter of the clinical trial, without excluding any damage which may be unintentionally caused by accident e/o be attributed to negligence, imprudence or inexperience, provided that they showed themselves within the periods set forth in paragraph 3 below. If the term of validity of the certificate referred to in paragraph 1 above is shorter than the actual term of the trial, the promoter is to submit to the Ethics Committee the relevant renewal certificate upon and by the scheduled expiry date thereof. The submission of the renewal certificate to the Ethics Committee / Competent Authority is a non-substantial amendment.

3. Terms set forth in the insurance policy in connection with the outbreak of damages referred to in paragraph 6 below and with the submission of claims may not be respectively shorter than 24 and 36 months from completion of the clinical trial. Completion of the clinical trial shall mean the last medical-surgical, diagnostic and/or therapeutic service performed in accordance with the trial protocol applying to the last patient enrolled in Italy.

4. In case of trials which are potentially eligible to cause damages which may show after longer periods of time, the minimum period of tail coverage for the risk referred to in paragraph 3 above shall be extended accordingly. As regards clinical trials on children, such extension is to contemplate a coverage of at least 10 years, this being the minimum time required to ascertain their regular psychophysical development.

5. Clinical trials which involve gene therapy, cellular therapy and radio-pharmaceutical shall require a minimum extended tail coverage for the risk referred to in paragraph 3 above of at least 10 years.

6. In any case, the investigator is always required to inform the participants to the trial protocol, even through the informed consent, that the insurance policy covering damages caused by civil liability (as third part liability) in the trial will not cover any amount exceeding its limit of liability and that such policy exclusively applies to damages for which a claim was submitted within and not later than the period provided in the policy and defined in accordance with the criteria hereunder. This restriction shall not in any event impair the right of the damaged party to seek reimbursement of damages from the person liable therefor.

Article 2

1. Insurance shall cover death, all permanent and/or temporary impairment of health conditions, relevant financial consequential losses which are the direct consequence of the trial and which can be traced to the liability of all persons operating for the performance of the trial.

2. Insurance shall provide for an insured limit for the reimbursement of damages not lower than Euro 1 million per participant, although the following minimum limits for each individual protocol are required, not less than:

- a) Euro 5 million if trial participants are less than or equal to 50;

- b) Euro 7 million five hundred thousand if the trial participants are more than 50 but less than 200;
- c) Euro 10 million if the trial participants are more than 200.

Trial participants shall mean the number of patients which take part in the trial in Italy.

3. No deductible enforceable against third parties who claim damages may be provided; if the insurance company wishes to terminate the contract, it shall in any case grant the cover to participants who have already been enrolled in the clinical trial even for the residual part of the trial. As regards participants who will be enrolled in the clinical trial after termination by the insurance company, the promotor shall execute a new insurance policy with another insurance company before enrolling them.

4. The amounts of the limits of liability referred to in paragraph 2 above are subject to review every three years.

Article 3

1. Promoters of clinical trials referred to in Ministerial Decree of December 17, 2004 referred to in the recitals hereof which intend to promote the trials mentioned in the above decree shall be under an obligation to extend their own insurance cover as executed in connection with the healthcare activities performed in their organization or execute an additional policy granting specific cover for the civil liability arising from clinical trial activities, in accordance with the minimum requirements provided in this decree.

2. In case of multicentre trials as contemplated in Italian Ministerial Decree of December 17, 2004, each centre involved may refer to its own insurance policy in accordance with paragraph 1 to cover participants from its centre; this being the case, the competent Ethics Committee of each centre shall assess that an appropriate insurance cover is in place for its centre.

Article 4

1. Obligations set forth in this decree shall not apply to non-interventional trials (or observational studies).

Article 5

1. Results of trials which do not satisfy the minimum requirements set forth in this decree will not be taken into account for the purpose of evaluating the marketing authorization application.

2. Any favourable opinions by the Ethics Committees referred to in articles 6 and 7 of Legislative Decree no. 211 of June 24, 2003 shall be null and void, together with the relevant authorizations, including those which stem from the lack of objection by the competent authority referred to in article 9 of said Legislative Decree, concerning clinical trials which do not satisfy the minimum requirements set forth in this decree.

Article 6

1. This decree shall come into force on the one hundred and eightieth day following its publication in the Official Journal and shall apply to clinical trials whose application for the sole opinion of the Ethics Committee will be submitted after this decree has come into force.

Rome, July 14, 2009

Ministry of Labour, Health and

Social Policies
By: Fazio
Vice Minister

Ministry
of Economic Development
By: Saglia

Exhibit

--- See exhibit at page 7 ---

Exhibit 1 – Standard form of insurance certificate

The insurance certificate to be attached to the documents of the interventional clinical trial shall at least contain the information referred to in the following scheme:

1. INFORMATION CONCERNING THE POLICY

1.1 Insurance company

1.2 Policy number

1.3 Initial Date

1.4 Expiry Date

1.5 Insured (Policy Holder)

1.6 Description of activity (purpose of the policy):

2. COVERS APPLYING TO THE PROTOCOL SUBMITTED TO THE COMPETENT AUTHORITY AND/OR THE ETHICS COMMITTEE

2.1 Title of insured protocol:

2.2 No. of trial centres

2.3 Protocol number (if available):

2.4 Number of participants (planned number of patients who will take part in the clinical trial in Italy):

2.5 Tail coverage as discovery period (in months):

2.6 Insureds (list all categories of insured participants)

2.7 Limits of indemnity¹ (this cover shall apply up to the following amounts)

Limit of Liability per Protocol	Euro _____
Limit of Liability per Person	Euro _____

If the amount of individual indemnities exceeds the above limits of liability for each period of insurance, insurance indemnities recognized to participants shall be reduced pro-rata.

Claims for reimbursement exceeding the above limit of liability shall be borne by the Policy Holder (sponsor).

2.8 Deductible

Not provided [___] Not enforceable against third parties who claim damages [___]

2.9 Exclusions (if provided for that specific protocol, please list all exclusions)

Stamp and signature of insurance company

¹ The limit of indemnity may vary according to the number of participants or to the risks (see article 2): a limit of at least Euro 1 million in case of damages to every participant shall be provided.