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Clinical research in emergency situations in incompetent persons: the situation in Italy

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Dear Editor,
We read with great interest the article by Kompanje et al. [1]. According to the table they present in their article, clinical research in incapacitated patients in Italy is seemingly regulated by ‘consent by a legal representative.’ The actual situation is quite more complex.

The implementation of Directive 2001/20/EC by means of Legislative Decree nr. 211/2003 [2] provides that only the legal guardian is competent to give valid consent on behalf of the incompetent patient. However, it fails to specify who the legal guardian should be (who—according to Italian law—has to be specifically appointed by the Court in the case of adult patients).

A possible interpretation is the one offered by Kompanje et al. [1], which has also been adopted by a number of local Ethics Committees for Research. However this interpretation makes it impossible to implement clinical research in an emergency situation on adult incompetent

patients, unless there is a previously appointed legal substitute (as in case of paediatric patients or patients with a previous mental impairment).

An alternative solution—adopted by a number of other local Ethics Committees for Research—is to consider that legal representation, as it has been developed in the Italian legal system, is not applicable to the emergency situation, in the absence of a previously appointed legal substitute. As a consequence, according to art. 4 of Legislative Decree nr. 200/2007 [3], point 4.8.15 of the Annex I to the Ministerial Decree 15.7.1997, which implemented GCP CPMP/ICH/135/1995 in Italy, must be considered applicable:

“When prior consent of the subject is not possible, and the subject’s legally acceptable representative is not available, enrolment of the subject should require measures described in the protocol and/or elsewhere, with documented approval/favourable opinion by the IRB/IEC, to protect the rights, safety and well-being of the subject and to ensure compliance with applicable regulatory requirements. The subject or the subject’s legally acceptable representative should be informed about the trial as soon as possible and consent to continue and other consent as appropriate (see 4.8.10) should be requested.”

As a consequence, at the present time in Italy the destiny of a protocol of research in incompetent patients depends on how local Ethics

Committees for Research understand and apply the law.

Conflicts of interest None.

References

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2. Gazzetta Ufficiale (2003) Attuazione della direttiva 2001/20/CE relativa all’applicazione della buona pratica clinica nell’esecuzione delle sperimentazioni cliniche di medicinali per uso clinico. Decreto legislativo 24/06/2003, no. 211, art. 3. Rome
3. Gazzetta Ufficiale (2007) Attuazione della direttiva 2005/28/CE recante principi e linee guida dettagliate per la buona pratica clinica relativa ai medicinali in fase di sperimentazione a uso umano, nonché requisiti per l’autorizzazione alla fabbricazione o importazione di tali medicinali. Decreto legislativo 6/11/2007 no. 200, art. 4. Rome

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