RESOLUTION

of the Sejm of the Republic of Poland

of 10 October 2012

on declaring the proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC to be incompatible with the principle of subsidiarity

Pursuant to Article 148cc of the Standing Orders of the Sejm, the Sejm of the Republic of Poland declares that the proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (COM(2012) 369 final) is incompatible with the principle of subsidiarity referred to in Article 5(3) of the Treaty on European Union. The proposal infringes the principle of subsidiarity inasmuch as the proposed Regulation – as a legal act binding in its entirety and directly applicable in all Member States – does not guarantee that the objectives of the proposed action would be better achieved at the European Union level than as a result of actions taken at the national level. The reasoned opinion, stating the reasons why the Sejm considers that the proposal does not comply with the principle of subsidiarity, is annexed to this Resolution.

Annex to the Resolution of the Sejm
of the Republic of Poland of 10 October 2012

Reasoned opinion of the Sejm of the Republic of Poland stating the reasons why the Sejm considers that the proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC does not comply with the principle of subsidiarity

Having considered the proposal for a Regulation of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (COM(2012) 369 final), the Sejm of the Republic of Poland declares that the proposal does not comply with the principle of subsidiarity referred to in Article 5(3) of the Treaty on European Union (TEU). The proposal infringes the principle of subsidiarity inasmuch as the proposed Regulation – as a legal act binding in its entirety and directly applicable in all Member States – does not guarantee that the objectives of the proposed action would be better achieved at the European Union level than as a result of measures taken at the national level.

As declared by the European Commission, the objective of the proposed Regulation is, in particular, to allow for independent control of the protection of the safety and rights of clinical trial subjects (recitals 1 and 2 of the proposed Regulation). In the opinion of the Sejm, the proposal does not fulfil this objective "better" – within the meaning of Article 5(3) TEU and Article 5 of Protocol (No 2) on the Application of the Principles of Subsidiarity and Proportionality enclosed to TEU and the Treaty on the Functioning of the European Union (TFEU) – than the Member States currently acting in accordance with the binding Directive 2001/20/EC. On the contrary, the analysis of the proposal indicates a reduction in the minimum level of protection of clinical trial subjects as established in Directive 2001/20/EC, insofar as the proposal:

- allows experimental trials without the consent of the clinical trial subject;
- sets aside the sponsor's obligation to insure the clinical trial while imposing on the Member States the obligation to establish a national indemnification mechanism;

- sets aside the obligation to obtain a favourable opinion on the research project from an independent and interdisciplinary Ethics Committee and the obligation to obtain the Member State's consent, replacing them with a "uniform decision";

- sets up unrealistically short time periods for the Member States to assess applications for clinical trial authorisation, which, in conjunction with the Member State's obligation to consent to the trial should it fail to recognise the application in the given time period, may in practice prevent the effective protection of the rights of clinical trial subjects.

The proposed Regulation harmonises the rules for the conduct of clinical trials in the Union – both for cross-border clinical trials and for those with a strictly national character (the first paragraph of Article 1 of the proposal). Contrary to the obligation resulting from Article 5 of Protocol (No 2), the European Commission has not provided sufficient grounds for the harmonisation of the rules on the conduct of non-cross-border trials. The Sejm finds no grounds or justification for the claim that clinical trials of strictly national character have hitherto been conducted riskily or badly for the subjects and that following the entry into force of the new regulation they would be conducted better than before. It may not be assumed in advance that the Member States will not be able to independently improve their procedures, at least with respect to non-cross-border trials. The Sejm has reservations about the general concept of the proposal: binding the Member States with the regulation provisions in the assessment of matters of strictly national character and of ethical aspects of the clinical trial (in particular Articles 7, 8, 14 and 20 of the proposal).

To sum up, the Sejm believes that regulating non-cross-border trials in the Member States by way of regulation is in breach of the principle of subsidiarity.

To supplement the objection of the proposed Regulation's non-compliance with the principle of subsidiarity, the Sejm would like to express its reservations concerning the faulty legal basis of the proposed legal act.

According to Article 1 of the proposal, the Regulation shall apply to "clinical trials conducted in the Union". However, no provision of Title XIX of TFEU concerning research and technological development has been referred to in the proposal's legal basis. The faulty legal basis raises the question of the Union's competencies to adopt measures aimed at harmonising Member States' law in the area covered by the

regulation. According to Article 180 of TFEU, the Union's activities in the area of research and technological development may only complement the activities carried out in the Member States, and according to Article 4(3) of TFEU, the exercise of the Union's competence in that area shall not result in Member States being prevented from exercising theirs. Referral to the general Article 114 of TFEU as the legal basis for regulating research on humans by way of a regulation constitutes circumvention of the law, i.e. the specific provisions of Title XIX of TFEU concerning research, and a violation of Article 179(3) of TFEU, according to which all Union activities under the Treaties in the area of research shall be decided on and implemented in accordance with the provisions of Title XIX of TFEU. By defining the pattern for the division of competence between the Member States and the Union, this provision excludes the possibility of harmonisation in the area of trials on humans.

Furthermore, as stated by the Court of Justice of the European Union, a measure adopted on the general basis of Article 114 of TFEU must genuinely have as its object the improvement of the conditions for the establishment and functioning of the internal market, in particular, to remove obstacles to competition (Judgement of the Court of Justice of 5 October 2000, Case C-376/98 Federal Republic of Germany v European Parliament and Council of the European Union, paragraphs 77–79). The European Commission has not proved that it is justifiable to combine the matter of scientific research on humans and the protection of their basic rights with the problem of disruptions to the common market.

Moreover, the European Commission wrongly applies the provision of Article 168(4)(c) as the legal basis for regulating research on humans, consequently violating the provision in question. This provision does not provide any explicit or implicit justification for regulating research on humans.