Opinion No. 21

of the European Union Affairs Committee of the Sejm of the Republic of Poland

on 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)"

adopted at its 67th meeting on 29th August 2012

The European Affairs Committee of the Sejm of the Republic of Poland:

1. Finds 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)" incompatible with the principle of subsidiarity.

Chairman of the Committee

/-/ Agnieszka Pomaska