

L.N. 248 of 2007

**MEDICINES ACT
(CAP. 458)**

Clinical Trials (Amendment) Regulations, 2007

IN exercise of the powers conferred by article 106 of the Medicines Act, the Minister of Health, the Elderly and Community Care has made the following regulations:–

Citation.

L.N. 490 of 2004.

Amends regulation
11 of
the principal
regulations.

1. The title of these regulations is the Clinical Trials (Amendment) Regulations, 2007 and they shall be read and construed as one with the Clinical Trials Regulations, 2004, hereinafter referred to as “the principal regulations”.

2. Immediately after sub-regulation (2) of regulation 11 of the principal regulations there shall be inserted the following new sub-regulation:–

“(3) By way of derogation from sub-regulation (1), the Agency shall make public part of the information on paediatric clinical trials entered in the European database in accordance with the provisions of Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of the 12th December, 2006 on medicinal products for paediatric use.”.