

A.L. 248 ta' l-2007

**ATT DWAR IL-MEDIĊINI
(KAP. 458)**

**Regolamenti ta' l-2007 li jemendaw ir-Regolamenti dwar
Provi Kliniċi**

BIS-SAHHA tas-setghat moghtija bl-artikolu 106 ta' l-Att ta' l-2003 dwar il-Mediċini, il-Ministru tas-Sahha, l-Anzjani u Kura fil-Komunità ghamel dawn ir-regolamenti li ġejjin:-

1. It-titolu ta' dawn ir-regolamenti huwa Regolamenti ta' l-2007 Titolu.
li jemendaw ir-Regolamenti dwar Provi Kliniċi, u għandhom jinqraw u A.L. 490 ta' l-2004.
jiftiehm u haġa wahda mar-Regolamenti ta' l-2004 dwar Provi Kliniċi,
hawnhekk iżjed 'il quddiem imsejhin "ir-regolamenti prinċipali".

2. Minnufih wara s-subregolament (2) tar-regolament 11 tar- Jemenda
r-regolament 11
tar-regolamenti
prinċipali.
regolamenti prinċipali, għandu jidhol dan is-subregolament ġdid li ġej:-

“(3) B’deroga mis-subregolament (1), l-Aġenzija għandha tagħmel pubblika parti mill-informazzjoni dwar provi pedjatriċi kliniċi mdaħhla fid-*database* Ewropea skond id-disposizzjonijiet tar-Regolament (KE) Nru. 1901/2006 tal-Parlament Ewropew u tal-Kunsill, tat-12 ta’ Diċembru, 2006 dwar prodotti mediċinali għall-użu pedjatriku.”.

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.”.