

A.L. 29 tal-2009

**ATT DWAR IL-MEDIĊINI
(KAP. 458)**

**Regolamenti ta' l-2009 dwar Drittijiet li jingabru mill-Kumitat
dwar l-Etika fl-Affarijiet tas-Saħħa**

BIS-SAĦĦA tas-setgħat mogħtija bl-artikolu 106(q) ta' l-Att dwar il-Mediċini, il-Ministru għall-Politika Soċjali, bi ftehim mal-Ministru tal-Finanzi, l-Ekonomija u l-Investment, għamel dawn ir-regolamenti li ġejjin:-

1. It-titolu ta' dawn ir-regoli hu Regolamenti ta' l-2009 dwar Drittijiet li jingabru mill-Kumitat dwar l-Etika fl-Affarijiet tas-Saħħa. Titolu.

2. (1) Għandhom jintalbu u jithallsu lill-Kumitat dwar l-Etika fl-Affarijiet tas-Saħħa dawn id-drittijiet li ġejjin għal kull prova klinika fuq: Drittijiet.

- (a) prodotti mediċinali investigattivi € 1,000
- (b) apparat mediku € 1,000
- (c) prodotti kombinattivi € 1,200
- (d) oħrajn € 1,000.

(2) (a) Id-dritt li għandu jintalab mill-imsemmi Kumitat għal studji non-intervenzjonisti għandu jkun ta' € 500.

(b) Id-dritt li għandu jintalab għal emendi li jsiru fi provi kliniċi u fi studji non-intervenzjonisti għandu jkun ta' € 100.

(c) Fil-każ ta' provi akkademiċi, id-dritt li għandu jintalab ikun ta' 25% tad-dritt li jintalab dwar dik il-prova jew dak l-istudju.

3. Mingħajr preġudizzju għad-drittijiet imsemmija f'dawn ir-regolamenti, il-Kumitat dwar l-Etika fl-Affarijiet tas-Saħħa jista' jiskonta kull dritt meta l-prodott mediċinali jkun jaqa' taħt il-kategorija ta' mediċinali orfni, jew inkella jkun qiegħed jiġi investigat bħala wieħed li jista' jiġi indikat għall-kura pedjatrika, jew fil-każ ta' studji li ma jkunux koperti minn xi sponsor kummerċjali. Skontijiet.

L.N. 29 of 2009

MEDICINES ACT
(CAP. 458)

Health Ethics Committee (Fees) Regulations, 2009

IN exercise of the powers conferred by article 106(q) of the Medicines Act, the Minister of Social Policy, with the concurrence of the Minister of Finance, the Economy and Investment, has made the following regulations:-

Title. **1.** The title of these regulations is the Health Ethics Committee (Fees) Regulations, 2009.

Fees. **2.** (1) There shall be charged and collected by the Health Ethics Committee the following fees for any clinical trial on:

(a) investigational medicinal products € 1,000

(b) medical devices € 1,000

(c) combination products € 1,200

(d) other € 1,000.

(2) (a) The fee to be charged by the said Committee for non-interventional studies shall be € 500.

(b) The fee to be charged for amendments to clinical trials and non-interventional studies shall be € 100.

(c) In the case of academic trials, the fee to be charged shall be 25% of the fee charged in respect of such trial or study.

Discounts. **3.** Without prejudice to the fees referred to in these regulations, the Health Ethics Committee may discount any fee when the medicinal product falls under the category of orphan drugs, or is being investigated for a paediatric indication, or in the case of studies which are not covered by any commercial sponsorship.

