

CERTIFICATE OF COMPLEMENTARY PROTECTION (CCP) FOR DRUGS

In Italy this certificate is connected to patents concerning a medicine, a product which is an ingredient of the medicine in question, the use of a product as a medicine or a procedure for its production. Certain fields such as pharmaceuticals regulate and delay the introduction of new products on the market through experimentation and checks before authorisation is granted for the product to be put on sale.

The following regulations are applicable to the issue:

- for Italy: Law n. 349 dated 19 October 1991;
- for the European Community : Regulation n. 1768/92/CE dated 18 June 1992;
- for Italy: Law n. 112 dated 15 June 2002.

EC regulations override Italian legislation, which remains in force for CCPs issued prior to the entry in force of the said EC regulation.

PROCEDURE

Applications for the CCP must be submitted within six months of the first authorisation for sale of the drug if the first authorisation is dated after the patent has been granted, or within six months of the patent being granted if the date of the first authorisation for sale of the drug is prior to the said grant date.

Since joining the European Patent Convention the majority of patents granted in Italy have been biotechnology inventions, 28.4%, Pharmaceuticals, 19.5%, Chemicals, 12.2% and Organic Chemicals 12.1%.