Regulatory Affairs by ELC

Update of the SmPC and PIL for 5-fluorouracil and fluorouracil-related substances

5-fluorouracil (5-FU) inhibits the synthesis of DNA and RNA especially in rapidly growing cells, making 5-FU and related products suitable for cancer treatments.

The role of the DPT

The dihydropyrimidine dehydrogenase (DPD) plays a critical role in 5-fluorouracil (and related substances) elimination patterns. The treatment of patients with DPD deficiency with 5-fluorouracil or 5-fluorouracil-related substances can therefore result in severe and fatal toxicity.

France triggered a referral under Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data, requesting the PRAC to assess the need to take action at EU level regarding the detection of DPD-deficient patients.

Risk minimisation activities

To minimise the risk of increased toxicity, the PRAC recommended DPD-deficiency testing to be conducted before initiation of treatment and new warnings to be introduced in the SmpC and PIL for 5-fluorouracil and fluorouracil-related substances (capecitabine, tegafur and flucytosine).

ELC Group provides a full range of Medical Writing services and also ensure that all of the requisite Pharmacovigilance activities are duly taken into account.

Concept to Compliance

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