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Research and Devolopment

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Circular n° 593
To the attention of sponsors of clinical trials

Your letter from	Your reference	Our reference	Annex	Date
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This document is a translation of the official and signed versions in Dutch and French

Dear Madam, Dear Sir,

We wish to draw your attention to the publication of the Royal Decree of 16 July 2012 laying down the fees for the execution of the tasks of the Federal Agency for Medicines and Health Products (FAMHP) pursuant to Article 30, § 8, of the Law of 7 May 2004 concerning experiments on the human person.

Since October 18, 2012, a fee of 650 euros is payable for each submitted annual safety report ("Development safety update report" – DSUR). The legal basis for this is Article 28, § 2 of the Law of 7 May 2004:

> **§ 2. Once a year, during the entire duration of the experiment, the sponsor provides the Minister and the Ethics Committee in Belgium and those of the Member States on whose territory the trial is conducted in the case of multicenter trials a list of all suspected serious adverse events that have occurred during that period as well as a report on the safety of the participants.**

The amount due is calculated in function of the number of ongoing trials in Belgium per investigational medicinal product (IMP) at the time of submission of the safety report:

1 trial with the IMP: 650 €
2 ongoing trials: 1.300 €
3 ongoing trials: 1.950 €
4 ongoing trials: 2.600 €
5 or more ongoing trials: 3.250 €

Based on the experiences with these DSUR reports at the national and European level, these amounts and the terms of payment may be revised. A first consultation with the pharmaceutical industry is foreseen four months after the publication of this circular.

The fees must be paid no later than 14 days after the submission of the report to the bank account BE84 6790 0015 1459 (BIC PCHQBEBB) of the FAMHP.

Reminder:

The "development international birth date" (DIBD) is used to determine the start of the annual reporting period. The safety report should follow the international structure (DSUR), as described in the ICH

guidance E2F. The DIBD is the date of the first authorization (worldwide) of a trial with the investigational medicinal product. The "DSUR data lock point" is the last day of the reporting period of one year. When testing an investigational medicinal product in a trial, the safety report should be submitted within 60 days after this DSUR data lock point.

The annual safety report is submitted to the FAMHP and the Ethics Committee responsible for the single opinion from the initial approval by the FAMHP of a clinical trial with the IMP and up until a trial with the IMP is ongoing in Belgium, i.e. until the last visit of the last patient ("Last patient last visit") in Belgium, or until the "End of Trial" criteria as specified in the protocol are met.

When the submission of the annual safety report to the FAMHP is no longer required, for example because the last clinical trial with the IMP in question was completed in Belgium, but this trial is still ongoing elsewhere, the agency will be notified by letter.

Circular 586 (Annex 1), which among other things clarifies the procedures for the submission of the annual safety report, continues to apply.

Concretely, this means that:

1. The annual safety report is sent in digital form (unprotected pdf format) on CD-ROM.
2. A cover letter mentions the EudraCT number (numbers) of the clinical trial(s) to which the report relates.
3. The fee based on the number of ongoing trials per IMP is paid to the bank account mentioned above.
4. For each payment, the concerned EudraCT number(s) is (are) mentioned.
5. A proof of payment is added.
6. The documents are sent to the following address: Federal agency for medicines and health products, division Research and Development, Place Victor Horta 40/40, 1060 Bruxelles.

Thank you for noting the contents of this circular.