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Research and Development Division (human use)

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Circular No. 650
For the attention of the DG PRE authorisation employees, Research and Development Division (human use)

Your letter from	Your reference	Our reference	Annex	Date
				08.07.2020

Processing clinical trial applications COVID-19

Dear Sir
Dear Madam

COVID-19 clinical trials are our highest priority. This is why we are implementing an accelerated evaluation for clinical trial applications (CTAs) related to COVID-19. This means that the main objective of the clinical trial is either the therapeutic treatment or the prevention of COVID-19.

Consequently, I request my services to apply shorter deadlines for the evaluation of these trials, as set out in this circular.

1. Deadlines for clinical trial applications (CTAs) with medicinal products other than those referred to in Article 17, subparagraph 3 of the Experiments Law 2004[1]

My services are requested to apply a shorter deadline, and therefore to communicate a final decision or reasoned objections to the sponsor/applicant within this deadline, when the application concerns:

- the normal procedure contained in Article 13, § 1 of the Experiments Law 2004 (without prejudice to the provisions of Article 17, § 1 of the Experiments Law 2004);
- the procedure foreseen for pilot projects, as referred to in Article 34/1, § 1 of the Experiments Law 2004.

In both cases, my services are requested to give the sponsor/applicant a final decision or to communicate reasoned objections within **four working days** following receipt of the application that meets the formal requirements. My services are requested to process the application, regardless of whether the fee referred to in Article 30 of the Experiments Law 2004 has been paid – it remains due insofar as it is not a pilot project as referred to in Article 34/1, § 1 of the Experiments Law 2004, but will be recovered afterwards.

If Article 16 of the Experiments Law 2004 is applied, or if for any other reason additional information is requested from the sponsor, the final decision of the FAMHP will be communicated to the client within **four working days** following receipt of the modified application or additional information.
The above instruction is without prejudice to the provisions of Article 17 of the Experiments Law 2004. A clinical trial with a medicinal product for which a marketing authorisation in the sense of Article 6, § 1,

[1] Law of 7 May 2004 on experiments on the human person, hereafter "Experiments Law 2004".

subparagraph 3 of the Law of 25 March 1964 on medicinal products (MA) has not yet been granted, can therefore only start after the explicit authorisation has been obtained from the minister.

Exclusions: These shorter deadlines are explicitly **not** imposed on my services for applications for medicinal products as referred to in Article 17, subparagraph 3 of the Experiments Law 2004, namely medicinal products for advanced therapy (somatic-cell therapy medicinal products, tissue-engineered products or gene therapy medicinal products) or for medicinal products containing genetically modified organisms (GMOs).

In summary: I request my services to process the above-mentioned applications within four working days following receipt of the application that meets the formal requirements, or within four working days following receipt of the requested additional information.

Current shorter deadlines are without prejudice to the requirement of an explicit written authorisation, contained in Article 17 of the Experiments Law 2004.

2. Deadlines for clinical trial applications (CTAs) with medicinal products referred to in Article 17, subparagraph 3 of the Experiments Law 2004

My services are requested to apply a shorter deadline, and therefore to communicate a final decision or reasoned objections to the sponsor/applicant within this deadline, when the application is submitted under the procedure laid down in Article 13, § 1, *juncto* § 3 or Article 34/1, § 1, and concerns:

- clinical trials with advanced therapy medicinal products (somatic-cell therapy medicinal products, tissue-engineered products or gene therapy medicinal products);
- clinical trials for medicinal products containing genetically modified organisms (GMOs), insofar as the GMOs are intended for contained use, as referred to in Article 2, 3° of the Royal Decree of 21 February 2005 regulating the deliberate release into the environment as well as the placing on the market of genetically modified organisms or products containing them, and the relevant legislation of the federated entities.

In both cases, my services are requested to give the sponsor/applicant a final decision or to communicate reasoned objections within **ten working days** following receipt of the application that meets the formal requirements. My services are requested to process the application, regardless of whether the fee referred to in Article 30 of the Experiments Law 2004 has been paid – it remains due insofar as it is not a pilot project as referred to in Article 34/1, § 1 of the Experiments Law 2004, but will be recovered afterwards.

The above instruction is without prejudice to the provisions of Article 17 of the Experiments Law 2004. A clinical trial with a medicinal product as referred to in Article 17, subparagraph 3 of the Experiments Law 2004 can therefore only start after the explicit authorisation has been obtained from the minister.

If Article 16 of the Experiments Law 2004 is applied, or if for any other reason additional information is requested from the sponsor, the final decision of the FAMHP will be communicated to the sponsor within **four working days** following receipt of the modified application or additional information.

Exclusions: These shorter deadlines are explicitly **not** imposed on my services for applications for clinical trials with medicinal products containing GMOs for deliberate release into the environment, as referred to in Article 2, 3° of the Royal Decree of 21 February 2005 regulating the deliberate release into the environment as well as the placing on the market of genetically modified organisms or products containing them.

In summary: I request my services to process the above-mentioned applications within ten working days following receipt of the application that meets the formal requirements, or within four working days following receipt of the requested additional information.

Current shorter deadlines are without prejudice to the requirement of an explicit written authorisation, contained in Article 17 of the Experiments Law 2004.

3. Pilote projects – College

Within the framework of the pilot projects referred to in Article 34/1, § 1 of the Experiments Law 2004, the Clinical Trial College of the FPS Health, Food Chain Safety and Environment has confirmed to me that the ethics committees participating in these pilot projects are also committed to the aforementioned shorter deadlines.

Yours sincerely,

Xavier De Cuyper
General Administrator