



ITM Medical Isotopes GmbH  
Lichtenbergstrasse 1 . 85748 Garching/Munich, Germany

**11.04.2024**

Dr. Harald Enzmann  
European Medicines Agency  
Domenico Scarlattilaan 6  
1083 HS Amsterdam  
The Netherlands

**Subject:** Withdrawal of GeGant, 1000, 2000, 4000 MBq, radionuclide generator  
**EMEA/H/C/005165**

Dear Dr. Enzmann,

We would like to inform you that, at this point of time, ITM Medical Isotopes GmbH has taken the decision to withdraw the application for Marketing Authorisation of GeGant, 1000, 2000, 4000 MBq, radionuclide generator, which was intended to be used for *in vitro* labelling of various kits for radiopharmaceutical preparation developed and approved for radiolabelling with such eluate to be used for positron emission tomography (PET) imaging.

This withdrawal is based on the following reasons.

Following the CHMP Day 180 List of Outstanding Issues and the associated timetable, we determined that we will not be in a position to satisfactorily address all CHMP concerns within the procedural timeline.

We reserve the right to make further Marketing Authorisation Application submissions at a future date in this or other therapeutic indication(s).

We would like to take this opportunity to thank the (Co)-Rapporteurs and EMA for their time reviewing this application.

We agree for this letter to be published on the EMA website.

Yours sincerely,

**ITM Medical Isotopes GmbH**

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