



02 March 2020

[REDACTED]  
European Medicines Agency  
Domenico Scarlattilaan 6  
1083 HS Amsterdam  
The Netherlands

**Subject Withdrawal of Doxorubicin hydrochloride pegylated liposomal Tillomed 2mg/ml concentrate for dispersion for infusion, Doxorubicin Hydrochloride, 2mg/ml, Concentrate for dispersion for infusion - EMEA/H/H0005194**

[REDACTED]

I would like to inform you that, at this point of time, Tillomed Pharma GmbH has taken the decision to withdraw the application for Marketing Authorisation of Doxorubicin hydrochloride pegylated liposomal Tillomed 2mg/ml concentrate for dispersion for infusion, Doxorubicin Hydrochloride, 2mg/ml, concentrate for dispersion for infusion, which was intended to be used for:

- As monotherapy for patients with metastatic breast cancer, where there is an increased cardiac risk.
- For treatment of advanced ovarian cancer in women who have failed a first-line platinum-based chemotherapy regimen.
- In combination with bortezomib for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for bone marrow transplant.
- For treatment of AIDS-related Kaposi's sarcoma (KS) in patients with low CD4 counts (< 200 CD4 lymphocytes/mm<sup>3</sup>) and extensive mucocutaneous or visceral disease.

Doxorubicin hydrochloride pegylated liposomal Tillomed may be used as first-line systemic chemotherapy, or as second line chemotherapy in AIDS-KS patients with disease that has progressed with, or in patients intolerant to, prior combination systemic chemotherapy comprising at least two of the following agents: a vinca alkaloid, bleomycin and standard doxorubicin (or other anthracycline).

This withdrawal is based on the following reasons:

- Identification of major GCP issues at Panexcell Clinical Lab Private Limited.

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

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Amtsgericht Lübeck  
Geschäftsführer: Ajit Chand Srimal,  
Tajuddin Shaik & Massimo Berzigotti

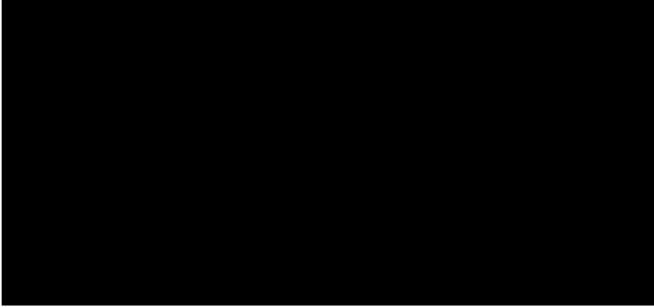
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Yours sincerely,



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