



Eric Abadie, Chairman of the CHMP
European Medicines Agency
7, Westferry Circus,
Canary Wharf
London E14 4HB
United Kingdom

Hoofddorp, 20 July 2011

**Subject: Withdrawal of
Doxorubicin SUN 2mg/ ml Concentrate for solution for infusion**
Procedure number: EMEA/H/C/002049/0000

Dear Sir Abadie,

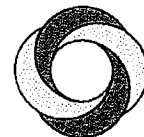
I would like to inform you that, at this point of time, Sun Pharmaceutical Industries Europe B.V. has taken the decision to withdraw the application for Marketing Authorisation of

Doxorubicin SUN 2mg/ ml Concentrate for solution for infusion
EMEA/H/C/002049/0000

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/mm³) and extensive mucocutaneous or visceral disease.
- Doxorubicin SUN 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 reason:
Sun Pharmaceutical Industries Europe B.V. has decided to discontinue this application since the major objections raised cannot be answered within the available time frame.



At the present time, there are no ongoing clinical trials with
Doxorubicin SUN 2 mg/ ml Concentrate for solution for infusion.

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

I agree for this letter to be published on the EMEA website.

Yours sincerely,