

Regulatory administration department
Monica Lidberg/ja

The Medical Products Agency's handling of withdrawals and annual fees in connection with the ordinance (SFS 2010:1167) concerning fees for the governmental control of medicinal products

1 January 2011 the ordinance (SFS 2010:1167) concerning fees for the governmental control of medicinal products came into force. One of the changes the ordinance brought is that parts of the annual fee will not be repaid if a product is withdrawn after the end of January current year.

Since the ordinance was decided late 2010 it has been short of time to submit a withdrawal application and have it assessed in time to avoid the annual fee for 2011.

To ease the transition to the new ordinance the Medical Products Agency has decided to apply the following:

Products where withdrawal applications are received on 28 February 2011 at the latest, the annual fee will be repaid after the withdrawal has been completed, at the most three months after the application has been received.

The assessment of withdrawals is not to take more than three months to complete. For products to be withdrawn in order not to be issued an annual fee in the coming years, the applications need to be received before the end of October the year before.

On behalf of the Medical Products Agency,

Monica Lidberg
Head of the Regulatory administration department