Control Fee Medicinal Products in Norway – Guidelines

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The regulation

In accordance with The Regulation Relating to Medicinal Products of December 18th 2009, the Norwegian Medicines Agency collects a control fee from holders of marketing authorisations (MA).

Why pay the fee?

The fee covers expenses for quality control, supervision of adverse events and information activities by the authorities.

Who shall pay the fee?

MA-holders of medicinal products are responsible for reporting liable turnover and paying the fee.

When to report liable turnover?

Report quarterly and no later than thirty days after the quarter has ended, cf. form for reporting. Send the report by e-mail to: kontrollavgift@noma.no

How is the fee calculated?

The fee is based on the medicinal products' net turnover from each company to the Norwegian market. The fee for 2017 is 0,70 % of the turnover.

How to pay the fee?

The Norwegian Medicines Agency sends an invoice to the MA-holder or his representative according to the information received in the fee-form. The payment is due 30 days after the invoice date. In the case of late reporting, payment is due 14 days after the invoice date.

Swiftaddress:
DNBANOKK

Bank account info:
No. 7694.05.00903
DNB ASA

Account No. IBAN:
NO71 7694.05.00903

The Fee Form

The form (excel) is available at: www.noma.no
Please fill in the colored space. The fee will be calculated automatically on the basis of the turnover.

Yearly report and auditor's confirmation

Each year, the MA-holder's auditor confirms the turnover of medicinal products. The auditor should also confirm whether the company has a system for continuous registration of liable turnover and calculation of control fee (cf. reporting form).

The yearly report with the auditor`s confirmed signature must be received by The Norwegian Medicines Agency within March 1th 2018.

No report – insufficient information

MA-holders who do not report will receive an invoice with The Norwegian Medicines Agency's estimation of liable turnover.

For further information:
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