SmartPractice (DK) ApS

From: Helena Rinda Christensen <HRC@smartpractice.dk>
Sent: 14 September 2012 15:18
To: SANCO FEES PHARMACOVIGILANCE
Cc: Ziogas Constantinos (EMA); Kirsten Paulsen; Michael Nielsen
Subject: Public consultation on the Pharmacovigilance fees_September 2012

To whom it may concern,

I hereby send you our comments to the "Introduction of fees to be charged by the EMA for pharmacovigilance".

We (SmartPractice Denmark ApS) are concerned what kind of impact introduction of this new "Pharmacovigilance Service Fee" will have on our part/company.

SmartPractice Denmark ApS is a "Small and medium-sized enterprise" which manufactures TRUE Test. SmartPractice Denmark ApS holds a MA for the product. The product is only registered under national procedures and under MRP.
TRUE Test is a niche product for determination of contact allergy. The product consists of up till 36 different allergens. Some of the allergens are combinations of several active substances.
Our concern is whether we will be subject to one fee for this product or to several fees (i.e. a fee for each of the active substances)? Further, is this fee going to be charged by EMA or by the respective NCAs?

We would very much like you to consider these apects when you move forward with these fee introductions. Further, would it be possible for you to respond directly to us regarding an answer to our questions or would it be possible for us to contact you in order to clarify these questions?

Best regards/Med venlig hilsen

Helena Christensen

QA Chemist

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From: Ziogas Constantinos [mailto:Constantinos.Ziogas@ema.europa.eu]
Sent: 4. september 2012 15:03
Subject: Public consultation on the Pharmacovigilance fees

Dear SMEs,

We would like to remind you to provide your contribution to the public consultation released by the European Commission in June 2012 on the Pharmacovigilance fees (http://ec.europa.eu/health/files/pharmacovigilance/2012-06_concept_paper_en.pdf).

The document sets out the new fees for pharmacovigilance activities and fee incentives for SMEs which are planned to be introduced in 2014.

The consultation will contribute to the regulatory impact assessment and be used to amend the fees regulation.

The pharmacovigilance fees will cover **both** centrally and non-centrally (mutual recognition/decentralised/nationally) authorised products (medicines for human use only).

SMEs and particularly micro-sized enterprises (<10 staff; turnover or balance sheet total <2 million €) are particularly advised to provide contributions.

The deadline for comments is **15 September 2012**.

Best regards,

On behalf of the SME Office,

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