



Response to consultation on: MHRA (Medicines and healthcare products regulatory agency) Regulatory fees– proposals for 01 April 2016

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PSNC welcomes the opportunity to respond to the consultation on regulatory fees.

PSNC wishes to express its concern at the proposed introduction of a one-off application fee of £100 and the proposed annual service fee of £97. The NHS is faced with making efficiency savings of £22bn. As pharmacy owners derive about 90% of their income from their NHS services, they expect difficult times ahead and the introduction of what we believe is an unnecessary fee, is unwelcome.

In Great Britain, the General Pharmaceutical Council (**GPhC**) already operates a voluntary internet pharmacy logo scheme which provides for a logo linked to a verification facility (as does the EU logo). Unlike other retailers of medicines, pharmacies must register with the GPhC and are regulated by that body. If these pharmacies have been registered by GPhC and validated and verified for the internet pharmacy logo then the public interests are safeguarded.

As a result of the new EU logo, the GPhC is to review the use of the current voluntary logo. We believe that it is more important for patients to be able to verify that an internet business is a registered pharmacy than it is for patients to be able to verify an internet seller of medicines, since the pharmacy site will be one where expert professional advice on medicines can be obtained from a pharmacist. It follows that the internet pharmacy logo authorised by the GPhC is, in our opinion, more important to patient safety than the EU logo.

If it is necessary to also display the EU logo we would suggest to MHRA that there need not be costs associated with that for pharmacies in Great Britain because there is no additional burden for the MHRA over and above checking that the premises is a pharmacy with an internet pharmacy logo that is regulated by the GPhC.

We agree that it may be reasonable for the MHRA to seek to recover its costs if they arise from an obligation by the Agency to undertake costly investigation into the legitimacy and identity of online retailers, but that is not needed for regulated GB pharmacies.

The GPhC as the pharmacy regulator requires a single one off payment of £57, with no ongoing charge (clearly there is no need for an additional annual charge as the GPhC is not required to undertake additional verification after the first grant of the rights to use the logo, whilst the pharmacy remains on the register of pharmacy premises – if the premises were no longer suitable, the authorisation to use the logo would cease with the removal of the pharmacy from the GPhC register).

We are firmly of the view that a registered retail pharmacy which already has the GPhC internet logo, should be authorised to use the EU logo without charge, since the MHRA will not incur any significant costs of verification.

In light of the above, PSNC responds to the consultation questions below in the order in which they are raised in the consultation.

Question 1. Do you agree or disagree with the proposed fee reductions in Annexes A & B?

No comment

Question 2. Are the proposed fee levels tolerable, or will they cause a significant impact on your business's finances?

For the reasons above, PSNC consider that the proposed fee levels are inappropriate and would create an intolerable additional burden on the NHS which would be unwelcome at this point in time.

Question 2 (a). Are you a small/micro business?

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Question 3. Do you have any data or information that will improve the registration volumes estimates?

No.

Question 4. Do you have any data to inform our assumption on how many businesses will register beyond year one?

No.

About PSNC

PSNC promotes and supports the interests of all NHS community pharmacies in England. We are recognised by the Secretary of State for Health as the body that represents NHS pharmacy contractors. We work closely with Local Pharmaceutical Committees to support their role as the local NHS representative organisations.

Our goal is to develop the NHS community pharmacy service, and to enable community pharmacies to offer an increased range of high quality and fully funded services; services that meet the needs of local communities, provide good value for the NHS and deliver excellent health outcomes for patients.