Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Government response to the consultation on decreasing statutory medicines licencing fees and introducing a new fee for online sellers of human medicines to the public

Produced by Medicines and Healthcare products Regulatory Agency

1. The regulatory centre of the Medicines and Healthcare products Regulatory Agency (MHRA) received ten responses to its consultation on decreasing statutory medicines fees and introducing a new fee for online sellers of human medicine to the public.

Part One: Decreasing statutory medicines fees

2. MHRA considers, from the evidence provided by the responses to the consultation, that there is broad support for the decrease in licence fees.

3. Several respondents commented that they do not want to see the quality of the service MHRA provides sacrificed to reduce costs. MHRA will consistently strive to provide the best service possible, whilst ensuring costs remain as low as possible. MHRA will ensure industry's preference to maintain a high quality service is reflected in spending decisions.

4. Therefore the fees proposed in the consultation will go ahead unchanged. Please see Annex A for details.

Part Two: The new fee for online sellers of human medicine to the public

5. MHRA considers, from the evidence provided by the responses to the consultation, that there is mixed support for the introduction of a fee to fund the FMD logo scheme.

6. Two respondents opposed the full FMD logo fee being charged where a company was already signed up to the GPhC voluntary online scheme. They also opposed the full FMD logo fee being charged to community pharmacies due to upcoming economic pressures.

7. MHRA aims to charge businesses a fee equal to the cost of services they have received. In line with *Managing Public Money*[1] principles MHRA will not require businesses or the tax payer to subsidise the cost of the logo for another business. MHRA will therefore be maintaining one fee for all online sellers.

8. The two respondents detailed in paragraph 6 asked whether the General Pharmaceutical Council voluntary online logo could be used instead of the EU common logo. This is a harmonisation measure laid down in EU Directive 2001/83 (as amended) with the common logo designed to be recognisable throughout the EU. As such the Directive does not allow

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1 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/454191/Managing_Public_Money_AA_v2_-jan15.pdf

private registration schemes such as the GPhC scheme to be used in place of the EU common logo. However companies are free to use voluntary online logos in addition to the mandatory EU logo.

9. One respondent requested clarification on whether more than one registration fee would be required if a single seller used the logo to sell medicines on multiple websites. Each seller will be required to apply to register for use of the EU common Logo. As part of that application the seller is required to list all the web addresses (URLs) that they will be selling on. Only one £100 registration fee will be charged regardless of the number of URLs that the seller has listed. If the seller then decides, subsequent to their initial registration, that they wish to sell medicines on additional websites, they can add the additional URLs to their logo registration for no additional fee.

10. No additional information was provided to inform the volumes assumptions for the FMD logo, therefore MHRA will proceed with the fees set out at consultation. These are set out in Annex A.

11. Annexes B and C contain the final regulatory triage assessments. The figures remain unchanged as no new evidence was provided during consultation

Annex A: Summary of new fees.

Annex B: Final Regulatory Triage Assessment for decreasing statutory medicines fees

Annex C: Final Regulatory Triage Assessment for the new fee for online sellers of human medicine to the public