Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Regulatory Triage Assessment

Title of regulatory proposal	FMD logo statutory fee
Lead Department/Agency	MHRA
Expected date of implementation	April 2016 SNR 5
Origin	EU
Date	01/12/2015
Lead Departmental Contact	rose.geeson@mhra.gsi.gov.uk
Departmental Triage Assessment	Low-cost regulation (fast track)

Rationale for intervention and intended effects

Due to an EU Directive, MHRA must provide a registration and logo system for the UK's online medicine sellers. MHRA will not be able to recover its full costs unless it introduces a new fee for services provided to online sellers of medicine. Legislation is required to introduce a statutory fee.

Viable policy options

Option 1: Do nothing: This would mean that the online logo scheme would need to be subsidised. This is contrary to managing public money principles.

Option 2: Legislate to enable MHRA to recover the costs of implementing the Directive, in line with managing public money principles and the organisation's status as a trading fund.

There is no alternative to regulation, as MHRA must ensure full cost recovery through charging fees for its services.

Initial assessment of business impact

Online sellers will be required to pay a fee to obtain their logo from MHRA. This fee will be set at a best estimate of full cost recovery. If MHRA does not introduce a fee the costs would be passed on to UK businesses, as it is a Government Trading Fund. Therefore the benefit of the policy is to UK businesses, and it is directly equal to the costs. We estimate the cost of running the scheme to be between £0.3m-£0.5m annually.

One-in, Three-out status This is a fee to fund an EU regulation with no gold plating, and therefore it is out of scope.
Rationale for Triage rating This is a zero net cost EU measure with a low impact on business.
Departmental signoff (SCS): Patience Wilson **Economist signoff (senior analyst): Keith Derbyshire** **Better Regulation Unit signoff: Frank Brown**