Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Government response to the consultation on increases and additions to current medical devices fees

(Consultation from 24th November 2016 to 13th January 2017)

Produced by MHRA

1. The Medicines and Healthcare products Regulatory Agency (MHRA) received 10 responses to its consultation on increases and additions to its current medical devices fees.

2. The respondents were made up of:

    2 distributors
    5 manufacturers
    3 trade associations – covering 555 members

3. MHRA estimate that there are 8200 companies manufacturing or distributing Medical Devices in the UK

4. There were 5 consultation questions:

    1. We have assumed that there will be no market impacts from these fees. This means we expect no change in the supply of, or demand for, medical devices. Do you agree or disagree? Please provide evidence where possible.
        6 agreed, 1 did not agree.

    2. We have assumed that there are no additional familiarisation costs or administration costs, as fees are already charged in the areas concerned. Do you agree or disagree? Please provide evidence where possible.
        5 agreed, 1 did not agree.

    3. Please provide any relevant comments and evidence on the impact of these fee adjustments.
        2 said the changes were relatively small, 2 were concerned that the increases were being introduced at a time of other commercial pressures

    4. Please provide any additional information on the impact of the fee adjustment on small and micro businesses (1-49 employees)
        2 said the changes were modest, 3 were concerned at the impact of the notified body increases being passed on to them as their clients

    5. Do you have any other comments on the fee changes?
        3 said the increases were fair, 2 were concerned at the notified body increases being passed on to them as their clients, 2 referred to other potential increases in cost unrelated to this proposal

5. The majority of respondents were content with the fee changes proposed. We have noted the concerns over increasing costs and to minimise the burden on businesses MHRA will review its fees regularly to ensure they are set as low as possible, whilst still covering the cost to MHRA of regulation. This approach is intended to make sure that the government neither profits at the expense of consumers or industry, nor makes a loss for taxpayers to subsidise.

Medicines and Healthcare products Regulatory Agency
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