

MHRA consultation on fee increases

Response submitted on 23 November 2022 by FODO on behalf of Association of British Dispensing Opticians (ABDO); Association of Optometrists (AOP); FODO – The Association for Eye Care Providers

Question 1

Do you support proposal 1, to apply a 10% indexation uplift across Agency statutory fees to match the increased pay costs national average since the last MHRA fees review? Yes/No. If you have any concerns about this proposal, please provide them below.

We are responding on behalf of UK optical businesses, practices and practitioners in all four UK nations.

Increased costs for spectacle lens and frames will adversely affect small manufacturing businesses in the UK. They will also have to be passed on to patients who are already likely to be deterred from seeking the essential eye care they need owing inflation and the cost-of-living crisis. Anything which adds to costs in the short term will exacerbate these public health impacts.

Similarly, UK contact lens manufacturers are often small businesses providing niche healthcare products which cannot be sourced from elsewhere. Increased costs on the scale and at the pace proposed will inevitably impact negatively on supply and patient and public health.

We fully support the submissions made by the Optical Suppliers Association and the Association of Contact Lens Manufacturers on these points and would highlight the impacts such high increases at such a rapid pace will have on patients and eye health across the UK.

Furthermore, under European legislation introduced into the UK under the Medical Devices Regulations 2002, optical practices have to register with the MHRA as assemblers in order to put pre-manufactured spectacle lenses into pre-manufactured spectacles frames for certain patients. This was always a disproportionate regulation in terms of patient safety and, if the UK had followed Europe in adopting the MDR, would no longer apply; nevertheless it was acceptable as long as the UK was part of the EU and registration fees were low. However, the UK is now no longer part of the EU, the requirement itself is obsolete and has been discontinued elsewhere so, faced with such prospective fee hikes, **we would request that this requirement is reviewed as a matter of urgency.** Removing it would save unnecessary work and costs for both the MHRA and optical practices, the latter already struggling under the weight of historically low NHS fees and soaring inflation, wages, fuel and business costs.

Against these backgrounds, we understand the MHRA's case for a 10% indexation increase across statutory fees for 2023/24 given inflation and the fact that the MHRA has control only over numbers of staff, not salaries. As key stakeholders, we would hope however that MHRA staffing levels are regularly reviewed and kept to the minimum necessary to provide an efficient and responsive service which supports and minimises costs on UK healthcare industries which indirectly have adverse effects on ophthalmic public health.

Question 2

Do you support proposal 2, to place a cost-based uplift for 61 significantly under recovering fees to achieve full cost recovery? Yes/No. If you have any concerns about this proposal, please provide them below.

No. The optical sector supports level playing fields as a matter of business ethics and hence the concept of full cost recovery for charges in principle. However, as these costs have to be passed on to patients (see our response to Question 1), for our sector, we are concerned about the impact this would have at the present time and feel that the adjustments should be made over a longer period, say 3 5 years, to give businesses time to plan and adapt to the increased costs.

In our sector, significant fee increases, at such short notice and without prior warning, may force some smaller manufacturers (especially of products for low prevalence diseases) out of the market altogether. This would be contrary to the government's intentions and harmful to patients.

Question 3

Do you support proposal 3 to introduce 22 new fees for services offered by the MHRA? Yes/No. If you have any concerns about this proposal, please provide them below.

No. This would be going too fast, too soon and at the wrong time. It is not clear how this increased burden in costs of regulation will affect a currently pressurised healthcare system.

We would ask whether special consideration might be given to healthcare sectors, such as eye care, where many patients have to pay for care and where the NHS does not fund essential devices in full.

If not, we would again argue for a transition period even if this means MHRA putting some projects on the back burner for a few years during the current recession.

Question 4

Would you consider these proposals to impact certain types of business disproportionately? E.g. small businesses? Yes/No. If yes, in what ways? E.g. costs/time etc. Please provide more detail below.

Yes. We have significant concerns about the impact on

- small UK spectacle lens and frames manufacturers
- small UK manufacturers of specialist contact lenses and prosthetic products, and
- optical businesses which provide essential healthcare to the public but are already struggling with the effects of inflation and recession.

Moreover, increased fees will have an impact on eye care patients because the NHS does not fully fund medical devices for eye care patients. This means costs added to the supply chain have to be passed to families, and those impacted the most will be people on means tested benefits.

Without consideration of how these changes will impact smaller manufacturers and eye care providers and some mitigation of these effects such as a reduced fee system, or some form of exemption or phasing, there is a risk that patients and public health will be adversely affected and essential specialised products disappear from the market.

Question 5

Do you think any of the proposals in this consultation could have an impact on the development and access to medicines or devices for (1) rare conditions or (2) minority groups with smaller patient populations? Yes/No. If yes, please provide more detail below.

Yes. These new fees and increased fees could place patients who have low prevalence eye conditions at a significant disadvantage and in extreme cases may mean there is no viable product available in the UK market. For example, prosthetics and contact lenses for patients with corneal scarring and contact lenses for patients with corneal ectasias such as keratoconus could find that they are unable to obtain essential treatment devices. As the market for many of these products is small, it is unlikely that another manufacturer will enter the market.

Question 6

Do you think any of the proposals in this consultation pose a risk to existing products being withdrawn from the UK market? Yes/No. If yes, please provide more detail below.

Yes. If the additional burdens of the UK system mean that it ceases to be viable for small manufacturers, they may well withdraw from the market altogether. This will result in UK patients being unable to access products that are readily available in other parts of Europe. At the same time, for some patients, access to spectacles which better meet their needs than off-the-shelf are likely no longer to be available to them or only at prices they cannot afford in the current financial climate.

Medical devices like spectacles are not funded by the NHS in full and this means patients will have to pay more. Supply chains are already trying hard to reduce costs and provide people on means tested benefits with access to vision correction within the NHS funded

voucher system. This system is already under pressure and even small increases in costs could result in restricted choice and access for these patients, in effect removing patient access to an essential product even if the actual product is accessible to people with more ability to pay.

Question 7

Do you think any of the proposals in this consultation could have an impact on research, clinical trials or clinical investigations in the UK? Yes/No. If yes, what could be the impact? Please provide further detail below.

Yes. Significant and sudden charge increases may flip the balance away from essential but low volume products in favour of volume, mass market applications which can cover the sudden extra costs burden.

Question 8

With reference to the protected characteristics covered by the Public Sector Equality Duty set out in section 149 of the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998, we do not consider that our proposals risk impacting different people differently with reference to their protected characteristics. Do you agree? Yes/No. If no, please provide more detail below.

[Public Sector Equality Duty set out in section 149 of the Equality Act 2010

<https://www.legislation.gov.uk/ukpga/2010/15/section/149>

Section 75 of the Northern Ireland Act 1998

<https://www.legislation.gov.uk/ukpga/1998/47/section/75>

Yes. Sudden and high charges increases will impact on people with visual disabilities and older people.

Question 9

In Northern Ireland new policies must be screened under Section 75 of the Northern Ireland Act 1998, <https://www.legislation.gov.uk/ukpga/1998/47/section/75> which places a statutory duty on public authorities, to mainstream equality in all its functions – so that equality of opportunity and good relations are central to policy making and service delivery. In addition, new or revised policies must be rural proofed in line with the Rural Needs Act (NI) 2016 <https://www.legislation.gov.uk/nia/2016/19/contents> which requires public authorities to have due regard to rural needs.

We do not consider that our proposals risk impacting different people differently with reference to their protected characteristics or where they live in Northern Ireland. Do you agree? Yes/No. If no, please provide more detail below

Yes. Please see our answer to Question 8. The greatest negative effects will be on the most vulnerable and those with least resources, especially those living in areas of urban and rural deprivation and poverty.