Outcome of the Process - Public Consultation on proposed Clinical Trial Fees for 2022

1 RESPONSE TO THE CONSULTATION

The HPRA received four responses, one from an industry representative group and three from organisation engaged in clinical research.

The HPRA & the National Office for Research Ethics Committees welcomes all the suggestions and contributions made as part of our fee consultation. This document is a summary of the outcome of the consultation.

2 SUMMARY OF RESPONSES RECEIVED

One response was received from the human medicines industry representative group and three from organisations involved in clinical research.

The response from the industry group noted that there is a significant change in fees but accepted the proposal on the basis that there would be no further increase in fees for some years.

The responses from the clinical research entities included one that agreed with the proposed small fee for academic studies but asked that the proposal be publicised for budget purposes. One academic respondent objected to the proposal on the basis that the HPRA was a publically funded organisation. One respondent raised specific questions regarding the fees and we have responded directly to this response.

3 HPRA RESPONSE TO THE SUBMISSIONS RECEIVED

In relation to the proposal that the fees be fixed for the coming years, this does not reflect the HPRA commitment and process of reviewing fees annually. When fees are set in advance of new legislation with new approaches and processes, the fees represent out best estimate of the work involved. Once the regulation is experienced in practice, we will review the fees to see if they are fit for purpose and as result of that, review fees may go up or down. This review will be part of the annual review and will be transparent and subject to a public consultation.

In relation to the academic fee proposal, while the HPRA has sympathy for this view, the fee proposed is minor and will not cover the cost of delivering this work. The HPRA is fee funded and has been and will continue to subsidise academic trials to encourage research in Ireland. In relation to the suggestion that we publicise the proposal to allow researchers include the fee in their budget proposal, we will look at options to communicate to these researchers.

4 CONCLUSION

Overall, the responses were positive to the new fees. When proposing the new fees, the HPRA reviewed the fees in other Member States where they are published. While we are sympathetic to the view of not applying a fee to academic and non-commercial trials, we consider it appropriate to introduce a small fee to cover some of the time and assessment work involved. The HPRA's primary objective is the protection of public health but in delivering this we are committed to providing a first class service to the industry we regulate. We will continue to review the cost base of the HPRA and related fees. As always we commit to reviewing our fees annually to ensure that the fee levels are appropriate to the functions and costs of the HPRA.

Consequently, we propose to submit the fee structure as outlined in the original consultation document to the Minister for Health for approval.

We would like to thank all those that contributed to the consultation process.

HPRA
Finance, Corporate and International Department
2nd November 2021