# Outcome of the Process – Public Consultation on the Draft Guide for Health Institutions who Manufacture and Use In-House *In-Vitro* Diagnostic Medical Devices in Ireland

## 1 INTRODUCTION

The public consultation on the draft guide for health institutions who manufacture and use in-house *in vitro* diagnostic medical devices in Ireland was closed on 26 January 2024. Inputs to this consultation which were received shortly after this date were also included for consideration. The HPRA would like to thank everyone who contributed to this process.

This guide is intended to provide an overview of the legislation and key concepts relevant for in-house *in vitro* diagnostic medical devices (IVDs). It is targeted at health institutions within Ireland that manufacture and use in-house IVD's. The relevant requirements of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices, as they apply to in house IVDS, are described, including details on when they apply. In addition, this guide provides practical considerations for health institutions that manufacture in-house IVDs and outlines information that must be notified or submitted to the HPRA.

This guide was open for public consultation to gather feedback from stakeholders, with a view to improving stakeholder understanding of the requirements. The content of the guide has been amended, considering the comments received, as appropriate.

## 2 SUMMARY OF RESPONSES RECEIVED

During the public consultation, the HPRA received responses from a range of stakeholders including professionals representing health institutions across Ireland and IVD manufacturers. The HPRA welcomes all suggestions and contributions made; some of the responses received included a mix of queries and comments on the guidance. Where possible the text was revised to provide clarity on the underlying principles. In other cases, the query was addressed by responding directly to the commenter.

## 3 HPRA RESPONSE

Several changes have been made to the document as a result of this consultation which can be summarised as follows.

- Additional terms were included in the glossary for ease of reference.
- Section 4 of the guide was expanded to include additional information and examples of scenarios where the products manufactured would be considered in-house IVD and scenarios where the products would not be considered in-house IVDs.
- Section 5.2 was revised to include the dates each requirement applies; these dates were also presented in Figure 2.
- Some of the information originally provided in Section 5.1 of this guide has been moved to Appendix 1, which contains a checklist that reflects the requirements of IVDR Annex 1.
- In-house self-test IVD's and near patient test IVD's were highlighted.

## 4 CONCLUSION

There was a broadly positive response to the guide for health institutions who manufacture and use in-house *in vitro* diagnostic medical devices in Ireland. Updates to the guide have been implemented based on the informative comments and proposals received. We would like to thank all those who contributed to the consultation process.

Medical Devices Department

Health Products Regulatory Authority