The Laboratory Services Reform Programme

ADVICE NOTE

STEPS TOWARDS COMPLIANCE WITH THE IN VITRO DIAGNOSTIC REGULATION, IVDR (EU) 2017/746

REQUIREMENTS WITH RESPECT TO "IN HOUSE DEVICES"

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The Laboratory Services Reform Programme offers the following advice to HSE and HSE funded laboratories in other hospitals:

1.1 Advice for Laboratories

1. HSE and HSE funded diagnostic laboratories in other hospitals should maintain all essential diagnostic services provided they already have adequate processes to assure the quality of the service, even if those laboratories cannot achieve full compliance with the IVD Regulation by May 26th 2024.

2. If HSE and HSE funded diagnostic laboratories in other hospitals have not identified external service providers that are fully compliant with the IVD Regulation by May 26th 2024 they should continue to use existing external suppliers of essential diagnostic services if they have satisfied themselves that those providers have adequate processes in place to assure the quality of the service.

3. HSE and HSE funded diagnostic laboratories in other hospitals are, or are part of, a "health institution' under the terms of the regulation and **are therefore entitled to use an "in house device" within the terms of the IVD Regulation**.

4. The use of a CE marked product in conformance with the manufacturers recommendations is not an "in house device" and

5. For the purposes of the Regulation an in vitro diagnostic device means
   "*any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, **software** or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally **for the purpose of providing information** on one or more of the following:*
   concerning a physiological or pathological process or state;
   concerning congenital physical or mental impairments;
   concerning the predisposition to a medical condition or a disease;
   to determine the safety and compatibility with potential recipients;
   to predict treatment response or reactions;
   to define or monitoring therapeutic measures.
   Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices"

6. In terms of this definition "*a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, **software** or system"* is not an IVD if it is used **for a purpose other than providing information**.

7. Use of a *"reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system*" in the manipulation of samples in ways that are not "**for the purpose of providing information**" are not addressed by the Regulation

8. Diagnostic laboratories should review, as soon as possible, all of their Standard Operating Procedures to **identify those steps within the SOP using a device that are performed specifically "*for the purpose of providing information***". Aspects of the SOP that do not of themselves "provide information" are not included in the definition of an IVD.

9. Through the process, each laboratory should compile a draft inventory of “in house devices” used in that laboratory that are subject to Article 5(5).

10. HSE and HSE funded laboratories should liaise with other laboratories and the HSE Laboratory Services Reform Programme regarding the draft inventory of “in house devices” subject to Article 5(5) with a view to maximising consistency of approach within the HSE and HSE funded hospital laboratories.

11. After the inventory of “in house devices” subject to Article 5(5) is completed, laboratories should develop a prioritised implementation plan to achieve compliance with the IVD Regulation as quickly as is practical to do so.

12. Laboratories should liaise with other laboratories and the HSE Laboratory Services Reform Programme to share learning, develop common tools and maximise consistency of approach in achieving compliance with the IVD Regulation relating to “in house devices” to which Article 5(5) applies.

2 Background

The In Vitro Diagnostic Directive (98/79/EC) imposed requirements on manufacturers of IVD those requirements did not apply to devices manufactured and used with the same health institution. Devices manufactured and used within a health institution now fall within the scope of the IVD Regulation of May 2022. This imposes very substantial new requirements on laboratories within health institutions although these are less than those that apply to commercial manufacturers.

The Health Products Regulatory Authority (HPRA) is the agency that has responsibility for supporting compliance with the IVD Regulation in Ireland. The HPRA have provided the HSE with significant support in clarifying what is required to achieve compliance with the IVD Regulation. That information has informed the development of this advice note. The HSE Laboratory Services Reform will continue to work with HSE and HSE funded laboratories to progress compliance with the Regulation. It is clear that at this point full compliance with the Regulation will not be achieved in HSE and HSE funded hospital laboratories by May 26th. Based on communication with colleagues to date it appear that this is also in the case in all or almost all other EU Member States. It is not possible to withdraw laboratory services that are essential to patient care until full compliance is achieved without causing very significant harm to patients. For this reason, the HSE accepts that it is essential to continue to deliver essential services while working to achieve compliance as quickly as is practical.

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