The Impact of IVD Regulation in the UK: Briefing for Laboratory Professionals

Regulation of the safety and performance of products used in testing services are changing significantly and will continue to change further over the next two-three years. The changes to regulation are already beginning to affect products available on the market in the UK.

The regulations are intended to improve product quality and clinical performance requirements with additional scrutiny before a product can be placed on the market. This should provide greater reassurance that the products will perform as the manufacturer intends and may even reduce the amount of user validation needed prior to commissioning a new product.

However, not all existing products will be able to meet these new requirements and will either need to adapt to the new regulations or be removed from the market. For some manufacturers, the cost of meeting the new requirements may mean that they will not be able to supply them.

There are two major milestones to consider.

Milestone #1 Application of new EU regulations in May 2022
The first regulatory change to apply is the EU regulation on in vitro diagnostic medical devices (IVDs). IVDs placed on the market in the EU need to renew their 'CE mark' to fit the new requirements. May 2022 marks the end of a five-year transition across to the new regulations and many manufacturers will be able to offer a seamless transition without any noticeable effect on availability.

There are some concerns that some manufacturers will not be ready for the new regulations because their attention has been focused elsewhere - not least in providing IVDs essential to tackling the pandemic. There are also significant concerns about the readiness of the EU infrastructure for assessing products for the new 'CE mark'. For some products, manufacturers will decide that some, or all, of their products cannot meet the new requirements in an economically viable way, so will voluntarily remove these products from the market.

There are also significant changes to the exemption for IVDs that are made and used within a single EU or Northern Irish health institution, which means that not every EU or NI health institution will be able to continue using the exemption.

This means that some IVDs and some testing services will not be available to you either temporarily or permanently.

There are calls for a relaxation of the requirements to give more time for manufacturers and the EU system to get themselves ready for the new regulation, though there has been no indication from the European Commission that this could happen.

Milestone #2 Application of new UK regulations in June 2023
Until June 2023 it will be possible for manufacturers to use either the 'CE mark' based on EU regulations, or the new 'UKCA mark' based on UK regulations. From June 2023, it will only be

possible to use the 'UKCA mark' for products placed on the market in Great Britain. (Northern Ireland will continue to allow products with a CE mark.)

The regulations that underpin the UKCA mark for IVDs will be changing too and we expect the transition for these regulations to end in June 2023. We do not yet know what these regulations will be, but we expect them to have similarities with the EU IVDR.

Although we do not yet know what the regulations will be, it is possible that not all IVDs on the UK market will be able to meet them. As with Milestone #1 this means that some IVDs and some testing services will not be available to you either temporarily or permanently.

MHRA is expected to publish a draft of new IVD regulations imminently with a 10-week public consultation.

What can you do about this?
Stay informed. Ask questions.

- Ask your supplier if they are prepared for the IVDR or if they are planning on removing some IVDs from their catalogue.
- If you rely on the exemption for in house manufacturing (either yourselves or a testing service that you use) can the new exemption continue to apply? Do you know what the new exemption requires?
- Will you be able to contribute to the UK consultation? Will you contribute via your Trust or your professional body (or both)? MHRA website for devices regulation and registering for updates may be useful to help you stay informed.
- If you find out or suspect that your testing service will be affected negatively, do you have a plan B?