



HARNESING THE POWER OF IN-VITRO DIAGNOSTICS:

*UK and EU regulatory
perspectives for their
adoption and increased
market access*



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MANAGEMENT SUMMARY

In an evolving regulatory environment both in the UK and in Europe, the debate surrounding the critical importance of enabling the introduction of more In-Vitro Diagnostics (IVDs) onto the market to “detect and contrast” diseases at their earliest stages is hotting up. Better patient outcomes, less invasive treatments, as well as more cost effective management of diseases are at stake, but the complexities surrounding new regulatory pathways and the availability of Notified Bodies pose a steep challenge.

Will the EU and the UK be able to grasp the opportunity offered by the regulatory shake up of the UK Statutory Instrument No. 618 Medical Device Regulations 2002 (UK MDR 2002) and Regulation (EU) 2017/746 (EU IVDR) to promote innovation while also protecting patient safety? Or will the acceleration of approvals and time-to-market experienced in the pandemic remain an isolated effort?

INTRODUCTION

In the aftermath of the Covid-19 pandemic many national health services have been left with depleted staff resources and long waiting lists for surgeries that in many cases are long overdue. In addition to this, the two-year slow-down in treatment and diagnosis of diseases caused by the pandemic have led to many conditions going undiagnosed or untreated during lockdown with consequent chronicization of diseases that could have been treated more successfully if detected and countered early on. Many more patients that could have been treated with medication and therapy now require surgery.

Early diagnosis in fact plays a critical role in patient outcomes, ensuring sufferers understand how their symptoms will change over time and how this can be changed with treatment. Targeted interventions can also be started earlier, before potentially irreversible damage has occurred, helping to slow or reverse the disease process. Early diagnosis and treatment of often asymptomatic conditions such as type 2 diabetes, hypertension, and hyperlipidaemia could have a huge impact on patients as well as health system budgets. With oncology patients specifically, early diagnosis is closely linked to survival rates: prostate cancer, for example, has extremely high one year survival rates (around 100%) when it is detected in stages 1, 2, or 3, falling to 87.6% if detected in stage 4.[1] Research by McKinsey suggests that the health improvement opportunity in Europe lies mainly in the area of disease prevention and earlier intervention.[2]

IVDs play a critical role in supporting the healthcare system with early diagnosis. The World Health Organization (WHO) reports that between 30% - 50% of human cancers are preventable[3] and several can be screened for using IVDs, and points out: “Diagnosis is a driver of patient, financial and health systems impact, and a critical enabler of universal health coverage, but it is also the weakest link in the care cascade. This is especially true in primary healthcare settings in low- and middle-income countries. These countries often lack an integrated network of laboratories used for such diagnosis; however, a broad set of IVDs is available for testing patients in the primary care setting where laboratories are not available.”

IVDs cover a broad range of areas from pregnancy tests to Covid-19 swabs and are described in the new EU IVDR as: “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 ”.

In addition to better outcomes, early intervention also results in lower treatment costs for health systems, making it imperative for national and international institutions to do as much as possible to improve access to IVDs. The regulatory upheaval in the UK and EU with the introduction of a new regulatory framework in the UK and IVDR are both an opportunity to address the issue and a risk for further bottlenecks in this device area.

This whitepaper looks at the changing IVD regulatory environment in the UK and Europe assessing the degree to which measures are being taken to improve access to IVDs for patients and healthcare systems.

CHALLENGES TO IVD INTRODUCTION IN EUROPE

With some variation, levels of spending by governments on IVD testing during the pandemic were consistently higher across the board: in the UK, NHS Test and Trace (NHST&T) spent £10.4 billion on IVD testing in 2020 and 2021[4], up from £850 million in 2017, while Denmark spent 0.5% of its GDP on testing in 2021[5]. So, while on the one hand the interest in and awareness of the benefits that earlier testing through IVDs can bring are evident, there are also other factors at hand, such as regulatory changes, that are putting the brakes on this acceleration.

The regulatory landscape in Europe is experiencing revolutionary change with the introduction of the EU MDR and EU IVDR. Since the 1990s, in-vitro diagnostic medical devices (IVDs) have been regulated by an EC Directive (IVD Directive (IVDD) (EC) 98/79). Since May 2022, the In-Vitro Diagnostics Regulation (EU) 2017/746 (IVDR) fully applies and demands, among other things: greater transparency, enhanced harmonization and standardization, more regularity scrutiny, increased obligations and oversight of economic operators and notified bodies, more stringent criteria for clinical evidence and performance evaluation as well as heightened traceability across the supply chain through Unique Device Identification (UDI) measures.

Within the EU IVDR, IVDs have been divided into four classes, based on both their intended purpose and its inherent risks. The risk classification system has been established following seven classification rules described in ANNEX VIII of the EU-IVDR.

The four classes are:

- Class A: low individual risk and low public health risk
- Class B: moderate individual risk and/or low public health risk
- Class C: high individual risk and/or moderate public health risk
- Class D: high individual risk and high public health risk

It is the manufacturer that is responsible for applying the right risk class to its IVD, and to provide a justification for this decision. Higher risk devices will of course be subject to more regulatory scrutiny, however wrong classifications that result in a deviated conformity assessment route are likely to end up causing delays to market entry, stopping patients and healthcare providers from accessing the tools they need for speedy diagnosis.

Estimates suggest that the entire certification process could take up to 18-24 months, depending on risk class, status and maturity of the technical documentation and QMS, as well as on the availability of a Notified Body. There are in fact only 12 appointed Notified Bodies for IVDs in Europe as of 31 October 2023, so ensuring that a NB takes on a new device is not an easy feat.

An ongoing survey by Gesundheit Österreich GmbH (Austrian National Public Health Institute) with Areté and Civic Consulting reported that only 950 applications have been received, and 331 IVDR certificates have been issued in October 2022. With over 80% of self-certified IVDD devices that will need Notified Body involvement under the IVDR, 1,551 valid IVDD certificates were recorded in October 2022. Specifically, the IVDR application refusal data show that manufacturers appear to struggle with their applications. Typical reasons for refusal are incomplete data, wrong qualification and/or classification. The time it takes to get an IVDR QMS and product certificate issued in 60% of the cases is 13-18 months, and 19-24 months in 30% of the cases[6].

Despite this, frequent pushing back of deadlines and lack of access to EUDAMED have lulled manufacturers into a state of inactivity with many failing to make contact with an NB in good time for an 18 months regulatory approval pathway. As a result the much needed instruments to help national health systems make early diagnoses, improving patient outcomes and system efficiency, may not be on the market when they are needed.

THE UK LANDSCAPE FOR IVDs

Early diagnosis is a topical thread for UK industry experts and government departments. In the most recent bid to spot disease before it becomes more complex and expensive to treat, the NHS has recently announced staff will be given the latest artificial intelligence (AI) technology to diagnose and treat patients more quickly thanks to a new £21 million fund.[7] This move resonates with government plans to make the UK the global home of medical technology and a breeding ground for innovation, as set out in the Medical Technology Strategy, but also with a recent roadmap by Cambridge Design Partnership, drawn up in partnership with CPI and the Association of British HealthTech Industries (ABHI).

Estimates from the report suggest the UK accounts for just 3% of the £90 billion IVD industry and that, while it excels at research, it is held back by the commercialisation process. As a result, many UK inventions are commercialised by overseas companies. The report concludes that for the UK to take the lead in developing specific technologies in materials, enzymes, Artificial Intelligence (AI)/data, optics and photonics, microfluidics, and sensors, the UK needs to adopt the following strategies:

- Boost the IVD industry's profile in the UK
- Create a focused government-led strategy for the UK IVD industry
- Support access to NHS resources during development and commercialisation
- Assist IVD companies through a well-defined and harmonised regulatory pathway
- Develop partnerships for high-risk IVD developments that have defined pathways to clinical use.

From a regulatory standpoint, following Brexit, the UK now has the freedom to look at innovative and new ways to increase IVD products on the market and reduce the regulatory burden, whilst maintaining high patient safety standards. The development of a new UK-only regulatory system therefore represents a key opportunity to ensure that more IVDs are able to make their way onto the market.

For the time being, while the MHRA is increasing its engagement with industry and industry bodies (BIVDA, ABHI, etc.), extended use of CE marking for IVDs in the UK market has been taken up to June 2030 (date to be confirmed). In addition to this, as the UK is working towards dual country approvals and supporting the UK's intention to be a hotbed for innovative technology and IVDs, the MHRA announced in September 2023 the introduction of the Innovative Devices Access Pathway (IDAP) to “bring new technologies and solutions to the National Health Service (NHS) to help with medical needs that are not currently being met.”[8]

It is not possible, however, to increase use of IVDs in healthcare unless these are making their way through regulatory pathways steadily and successfully. In this complex international scenario, the role of the regulatory consultancy takes on critical importance in informing, advising and supporting IVD manufacturers so that their devices can be safely commercialised in the shortest time possible. Cutting down time-to-market grants national health services speedy access to a range of IVDs to help catch disease at the early stages, when these can be treated with drugs or minor procedures that are not particularly expensive and are minimally invasive for patients.

As healthcare moves away from a “pill for all ills approach” and towards a more proactive form of prescribing that aims to “detect and contrast” early on, IVDs are no longer seen as simple tests but as tools to protect the healthcare system and society from a range of known and new pathogens.

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