MICROECONOMICS MEETS IVDR

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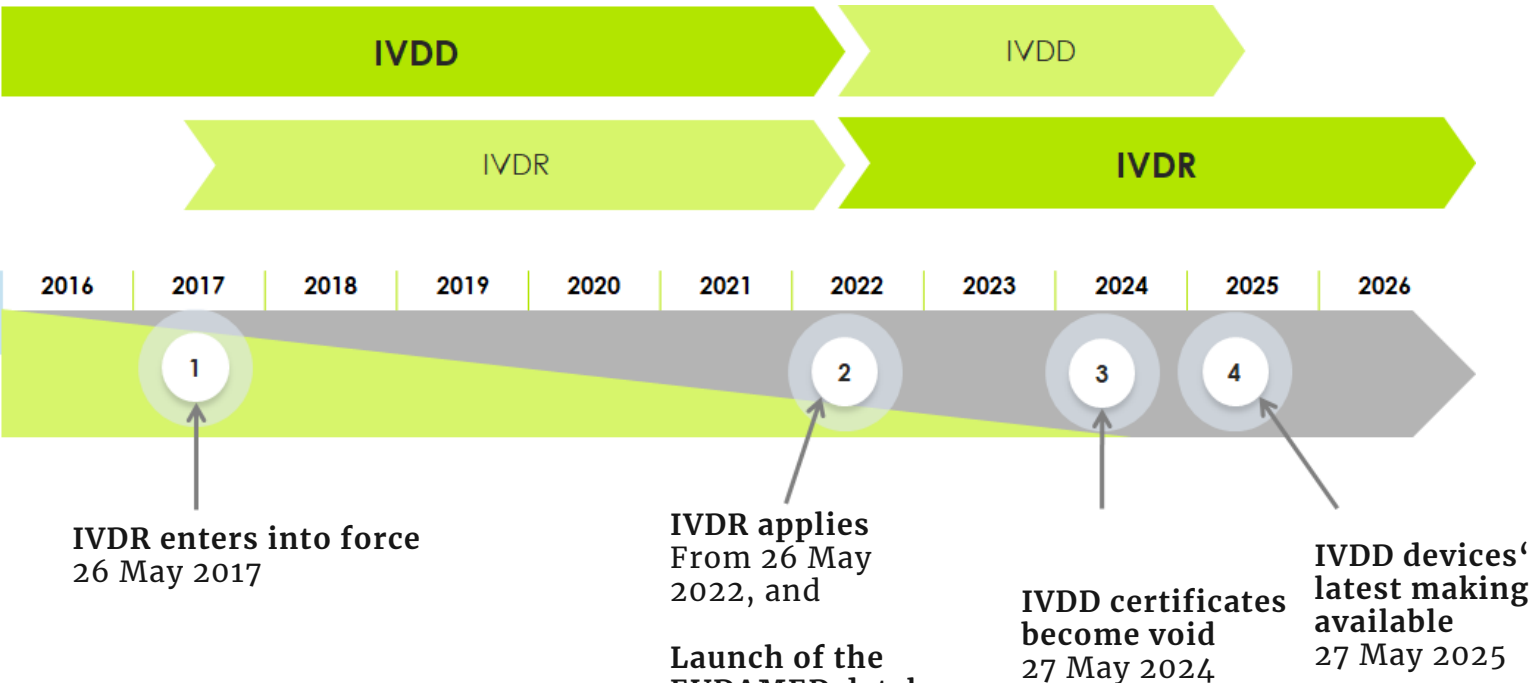
In the European Union, the legislation on In Vitro Diagnostic Medical Devices is undergoing a significant revision. 1.5 years out of the total 5-year transition period from the IVD Directive "IVDD", 98/79/EC [1], to the IVD Regulation "IVDR", (EU) 2017/746 [2], are still available. The Date of Application (DoA) of this regulation didn´t change due to the restrictions of the pandemic situation and is still the 26th of May 2022.

Transition from the IVDD to the IVDR



IVDD: In Vitro Diagnostic Medical Device Directive
IVDR: In Vitro Diagnostic Medical Device Regulation
DoA: Date of Application
IVDR DoA: 26 May 2022

The main changes related to this legislative framework are, but not limited to:

1. Up-classification of the majority of IVD devices [3]
2. Increase of the number of devices requiring the involvement of notified bodies
3. More stringent and detailed assessment of the notified bodies and oversight of the authorities

The implementation of these changes is challenging, due to:

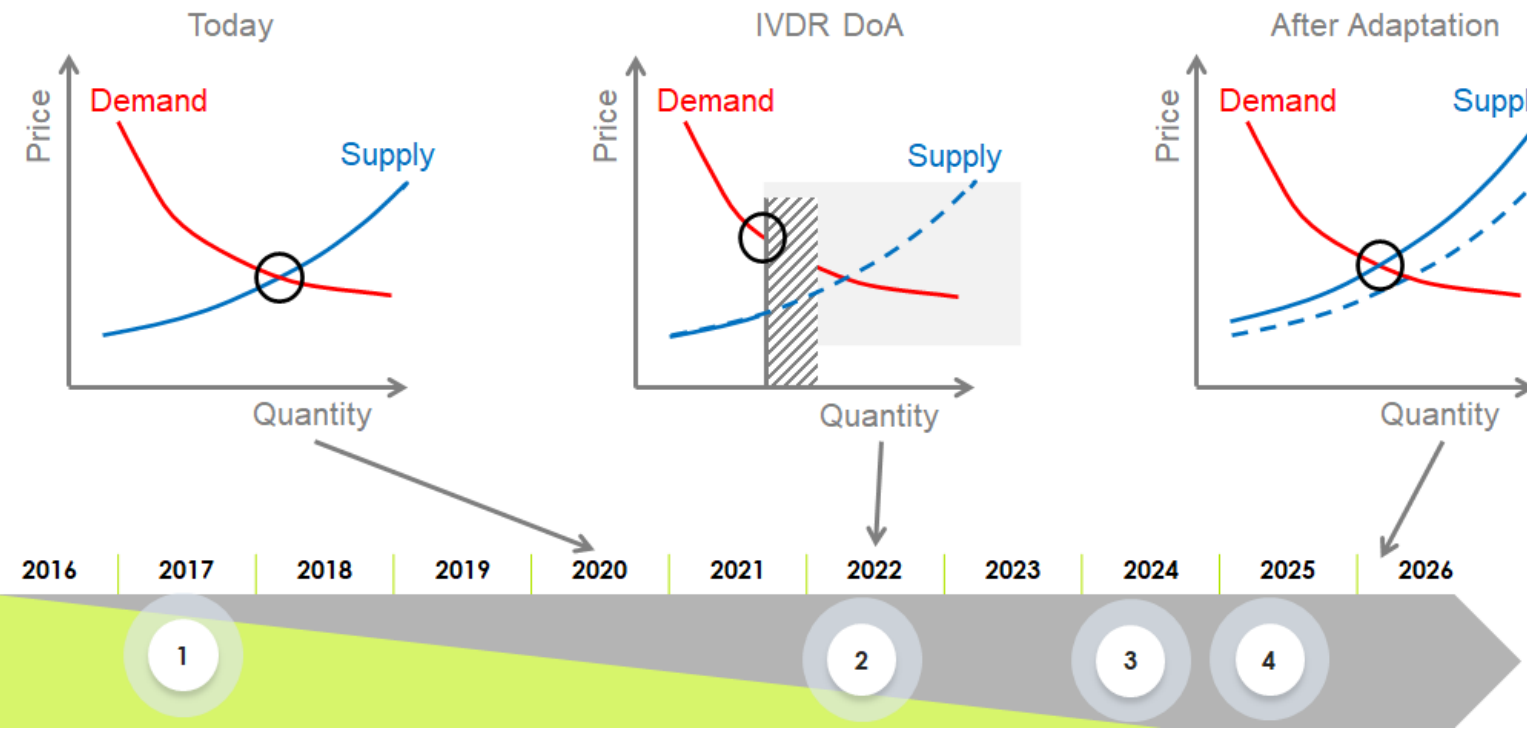
1. Limited number of notified bodies
2. Limited capacities of notified bodies for the various IVD Scopes when compared to the market need
3. Limited experience of the IVD Industry which didn´t need a third party in the past and need now to involve a notified body to ensure timely certification of their devices

Solutions for IVDs currently on the European market respecting the boundary conditions above will NOT work out for all devices. There is the danger that it will not be possible to bring them into compliance with the IVDR in time for the DoA on the 26th of May 2022. In consequence, such IVDs will need to be withdrawn from the market, unless the EU member states will apply their joker and offer special release to ensure continuity of the healthcare system in a period full of challenges.

From a microeconomic viewpoint, assuming perfect competition, we may apply the supply-and-demand model to the IVD market.

Today, patients and healthcare professionals consume the IVDs, while consumers and/or insurances pay for the devices and services and drive the system towards its equilibrium (spot where the supply and demand curve intercept).

Supply and Demand of IVD Medical Devices



By implementing the IVDR, the legislative authority (European Commission) wants to increase device safety for patients and users, maintain clarity regarding device's performance, increase the involvement of notified bodies towards better scrutiny and oversight, and allow for more transparency for the national competent authorities.

On the DoA, with the IVDR becoming applicable, a shock will shake the system, as supply may be cut (unless a reasonable approach may be applied). Demand exceeds supply, and the manufacturers can profit from the willingness of customers to pay higher prices.

This distorted market situation will not last for long as manufacturers will adapt to address the market need by fulfilling the new obligations. They are forced to consider safety and performance of their devices, with the IVDR even more than before. Their manufacturing is ready, but access to the IVD market also depends on other elements (such as technical documentation and performance data to support claims), which will require more effort under the new legislation.

This adaptation on the supplier side will take time and increase costs. Obviously, this also means that some devices will be discontinued.

Consumers and payers will then push the system into its new equilibrium at a higher price and lower quantity compared with today's (and all else hold equal).

There are only 18 more months left till the IVDR DoA. Let's use them wisely to secure the supply of IVDs, on which patients and healthcare professionals depend!

To know how to benefit from these last 18 months to the fullest and achieve compliance for your IVD, get in contact with the QUNIQUE team through www.quniquegroup.com or on info@quniquegroup.com

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References:

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3. MDCG 2020-16: https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020_guidance_classification_ivd-md_en.pdf