One Health Strategy Series - Episode 2

DEVICES & DIAGNOSTICS MORE FREEDOM THAN YOU THINK

THE EU VETERINARY ROUTE FOR MEDTECH & BIOTECH FOUNDERS



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For **MedTech** and **Biotech founders** with a validated technology, the question is rarely whether the science travels across the species line. It is whether the regulatory and commercial path on the other side is worth taking.

SHA partners **Caroline Chauché, Jean-Luc Troch** and **Vanessa Bensoussan** discuss why the veterinary route can be lighter than the human one.

"OUTSIDE HUMAN MDR AND IVDR"

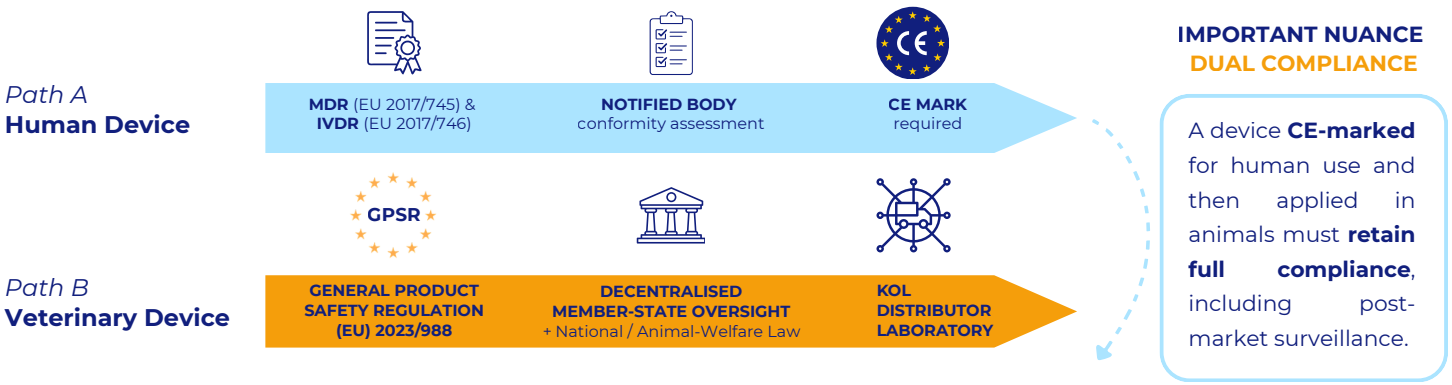
In the European Union, veterinary medical devices and in vitro diagnostics fall outside the two regulations that dominate human MedTech: the **Medical Device Regulation (MDR, EU 2017/745)** and the **In Vitro Diagnostic Regulation (IVDR, EU 2017/746)**. A veterinary device or in vitro diagnostic does not require CE marking under those regimes, and there is no notified body conformity assessment to clear (Figure 1). A product that meets the definition of a veterinary medicinal product under Regulation (EU) 2019/6, whether by presentation, through therapeutic claims, or by function, is regulated as a medicinal product rather than as a device. Where a product is confirmed to be a device, it sits under general product safety regulation (GPSR) (EU) 2023/988, alongside national rules and animal welfare legislation. Furthermore, there is no single harmonised veterinary device classification system across the EU and oversight is decentralised to Member States. Importantly, a device that is CE-marked for human use and then applied in animals must retain its human compliance, including post-market surveillance.

FREEDOM, WITH MODERATION

For a founder, this is freedom with a catch. Removing the notified body removes a familiar external stamp of credibility. In a decentralised market, the true gatekeepers become reference laboratories, distributors and key opinion leaders. Winning their trust, and framing your evidence for a veterinary audience, is where the work actually lies.

> ***Removing the notified body removes a gate. It also removes a familiar external stamp of credibility.***

FIG.1 | EU HUMAN VS VETERINARY MEDICAL DEVICE REGULATION PATHWAYS



*Note: **Veterinary medicinal product** (by presentation, therapeutic claim, or function) falls under Regulation (EU) 2019/6.*

That shift changes the nature of the effort rather than its difficulty: instead of a multi-year conformity assessment, the task becomes market-trust work.

WHAT THIS MEANS FOR YOUR PLAN

The absence of a notified body is an opportunity. As reference laboratories decide whether a new in vitro diagnostic is trusted or ignored, engaging them early via a trusted route is key. Also, distributors control the channel, and access to the clinic is a commercial asset. Like in human health, veterinary key opinion leaders (KOLs) shape adoption and framing existing evidence for a veterinary audience is a distinct piece of work. Two planning notes reside ahead of this. First, confirmation of classification (device or veterinary medicine) must take place before the market-trust plan is built. Second, a human CE-marked device used in animals keeps its human obligations, so planning for dual compliance where it applies is essential.

> ***Confirmed veterinary devices can achieve commercial proof faster in Europe's decentralised veterinary market than the human pathway.***

The teams that succeed are the ones that treat reference-lab validation, distributor relationships and KOL endorsement as the core of the plan, not an afterthought once the product exists. Handled deliberately, the veterinary market allows a validated device to reach commercial proof faster than its human counterpart, provided the market trust work is done with the same rigour a notified body would have demanded, and it is where **SHA**'s expertise and network pay off.

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