One Health Strategy Series - Episode 3

HUMAN VS VETERINARY MEDICINES

TWO LEGAL FRAMEWORKS, PURPOSE-BUILT FOR EACH SECTOR



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Veterinary medicines are no longer an appendix to human pharmaceutical law, they have now their own reference point in Europe. Choosing the correct route is a strategic decision.

SHA partners **Jean-Luc Troch**, **Caroline Chauché**, and **Eric Del Cotto** compare advantages and drawbacks of each route.

DEDICATED LEGAL FRAMEWORKS

Since Regulation (EU) 2019/6 came into force in January 2022, the veterinary medicinal product has its own dedicated legal framework, purpose-built for the sector. It repealed Directive 2001/82/EC and, deliberately broke the historical dependency on the human medicines system. That matters more than it may first appear. A regime designed around veterinary realities (species diversity, food-chain and residue considerations, antimicrobial-resistance stewardship, and the very different economics of the animal-health market) treats a founder's product on its own terms rather than as a derivative of human drug law. For anyone crossing over from human medtech or biotech under a One Health thesis, this is the first thing to internalise: the vet pathway is not a lighter version of the human one. It is a different instrument, with its own committee, its own procedures, and its own logic. The comparison below is where the divergence becomes concrete.

HUMAN VS. VETERINARY: A MAP REDRAWN

Both systems offer a centralised EU route, national routes, and mechanisms to extend across Member States. Table 1 sets out the correspondences and where they break down. The structural symmetry is real, centralised, national, decentralised, mutual recognition all exist on both sides. But three veterinary-specific forces have no human analogue.

> ***Since January 2022, the veterinary medicinal product has had its own dedicated legal framework, purpose-built for the sector.***

TABLE 1 - HUMAN VERSUS VETERINARY MEDICINE FRAMEWORKS

Dimensions	Human Medicine	Veterinary Medicine
Governing law	Directive 2001/83/EC & Regulation (EC) 726/2004	Regulation (EU) 2019/6 (in force 2022)
European Medicine Agency (EMA) committee	Committee for Medicinal Products for Human Use (CHMP)	Committee for Veterinary Medicinal Products (CVMP)
Centralised route	Mandatory for biotech, orphan drugs, advanced-therapies and named categories; EU-wide authorisation	Mandatory for defined biotech-origin and other listed products; EU-wide authorisation
National route	National authorisation in a single member state	National authorisation in a single member state
Coordination body	CMDh (human)	CMDv (veterinary)
Extending a national Market Authorisation (MA)	Mutual recognition procedure	Mutual recognition procedure
Multi-country, first time	Decentralised procedure via CMDh	Decentralised procedure via CMDv
Distinct drivers	Orphan status, paediatric obligations, health technology assessment, reimbursement downstream	Food-chain residues, target-species safety, AMR stewardship, minor-use/minor-species economics

Accessed August 2026: European Medicines Agency, Committee for Veterinary Medicinal Products (CVMP), https://www.ema.europa.eu/en/committees/committee-veterinary-medicinal-products-cvmp; European Parliament and Council, Regulation (EU) 2019/6 on veterinary medicinal products, https://eur-lex.europa.eu/eli/reg/2019/6/oj; European Medicines Agency, Pre-authorisation guidance under Regulation (EU) 2019/6, https://www.ema.europa.eu/en/veterinary-regulatory-overview; EMA / HMA, Coordination Group for Mutual Recognition and Decentralised Procedures – veterinary (CMDv), https://www.hma.eu/veterinary-medicines/cmdv.html; Directive 2001/83/EC and Regulation (EC) 726/2004 (human medicines framework, for comparison), https://eur-lex.europa.eu

The three vet-specific forces are: **the food chain** (maximum residue limits must be settled for food-producing species before a product can be authorised), **antimicrobial stewardship** (2019/6 tightens the reins on antimicrobials markedly), and market economics (many indications are commercially thin, which is why the regulation built in incentives for limited markets). A human-medicines instinct (e.g. chase the centralised route by default) can misfire for veterinary medicine.

Choosing between routes shapes cost, geographic footprint and speed to first sale

CHOOSING YOUR ROUTE

Under the veterinary framework, several authorisation routes are available depending on the product and its intended reach. The centralised procedure, coordinated by the EMA, is mandatory for certain categories, including products of specific biotechnological origin, and yields a single authorisation valid across the EU and much of the European Economic Area (EEA). Alongside it sit decentralised and mutual-recognition procedures,

coordinated through the Coordination Group for Mutual Recognition and Decentralised Procedures for veterinary medicinal products (CMDv), and purely national routes.

- **Centralised (EMA).** Mandatory for certain biotech-origin products; a single application, single evaluation and single authorisation valid across the EU and much of the EEA. Best where the product is pan-European by nature or falls in mandatory scope.
- **Decentralised (CMDv).** Simultaneous authorisation across several chosen Member States for a product with no prior national MA. The route when you want multi-country reach but not the whole Union.
- **Mutual recognition (CMDv).** Extends an existing national authorisation to further Member States. The route when you already hold a national MA and want to grow the footprint step by step.
- **National.** A single-market authorisation, a deliberately narrow, useful for a first market, pilot, or a product with a genuinely local rationale.

Choosing between them is a strategic decision, and it interacts with everything else on a founder's plate: the shape of the asset, the size of the target species population, whether the animals enter the food chain, and the financing round the programme has to reach. The cost of a wrong turn compounds over the life of the programme, such as an over-broad centralised filing burns cash and calendar a smaller product never needed, or an over-narrow national filing caps the commercial story just when it needs to scale. It is a decision worth making deliberately, and with people who have made it before.

HOW STRATEGIC HEALTHCARE ADVISORS HELPS

We work with founders to match the authorisation pathway to their asset, target market and financing stage, sequencing regulatory strategy so investment tracks commercial reality. Where strategically valuable, we also help teams cross between human and animal health, advising on, and where appropriate, executing, the translation of an asset from one market into the other.

> ***The right pathway for an asset is the one that aligns authorisation, market opportunity and commercial reality.***

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