

ASI ANIMAL HEALTH COMMITTEE FDA UPDATES

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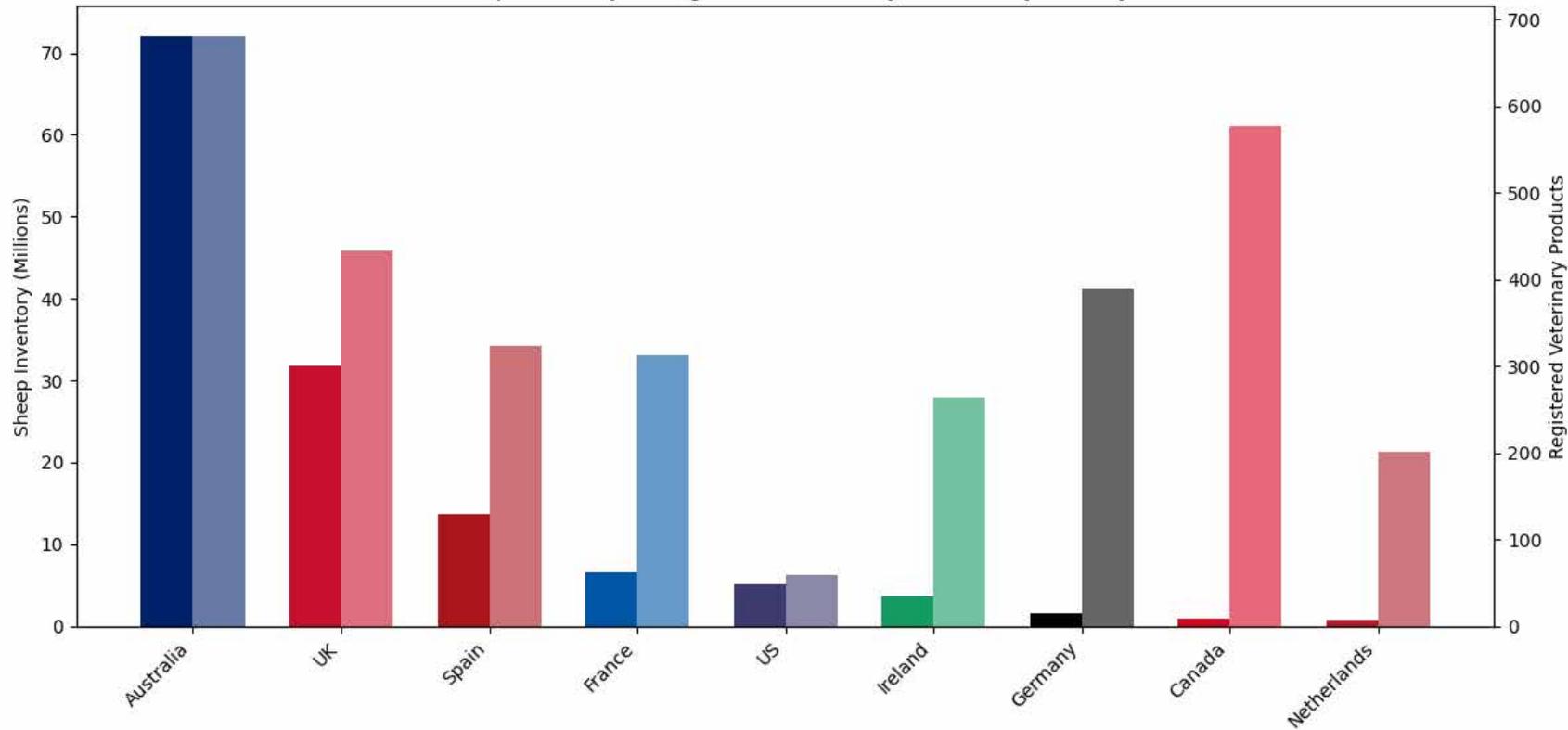
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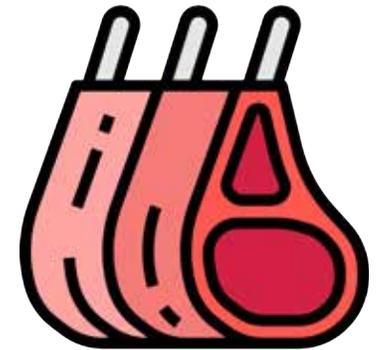
January 2026

Availability of Sheep Health Products

Sheep Inventory vs Registered Veterinary Products by Country



73%
of lamb consumed
in the US is imported



Animal and Veterinary Innovation Agenda

- GAO Third Party Audit → Reagan-Udall Report: June 2025

“Transforming Animal Health in the US for the 21st Century”

- Modernize regulatory pathways for animal health products
- Explore pathways that are “risk-based” rather than “risk-averse” particularly in areas like minor species
- Time is money: the review process should utilize external expert review panels to improve FDA’s ability to make timely, informed decisions
- Systemic reform and appropriate incentives are necessary to motivate change of review priorities from investment based solely on profitability rather than needs.
- Imported lamb benefits from import tolerance limits for veterinary drugs. Congress should amend AMDUCA and/or the MUMS legislation to permit the use of related species tolerances or Maximum Residue Limits (MRLs) for minor food animal species.

AVMA MUMS Roundtable

- MUMS act passed in 2004
 - Allows marketing as a conditional approval for up to 5 years
 - Incentives including exclusive marketing right for seven years after approval
 - Indexing (but not for food animal species)
- 27 drugs have been approved in 20+ years
 - Drug companies say it costs \$10-25 million to add a species to a label



New World Screwworm

- Emergency Use Authority and Conditional Approval pathways
 - Cannot use these “off label”
- List of injectable, oral, and topical veterinary products that exist in the world to treat and prevent New World Screwworm
- Evidence-based withdrawal intervals necessary
 - Interstate movement critical for feeder lambs and fat lambs
- Investigational New Animal Drug Exemptions?
- Communication

