AHNTI ANIMAL HEALTH, NUTRITION & TECHNOLOGY INNOVATION

FDA U.S. FOOD & DRUG ADMINISTRATION

zoetis

SESSION SPOTLIGHT:

Reimagining Regulatory Pathways for Animal Health Innovation

The importance of flexibility and early collaboration

At AHNTI EU, Kristin Peck, CEO of Zoetis, sat down with Tim Schell, Director of the FDA's Center for Veterinary Medicine, for a candid fireside conversation on one of the most consequential questions facing animal health innovation: how regulation must evolve to keep pace with science.

The discussion explored the role regulators can play not just as gatekeepers, but as active enablers of innovation, particularly at a time when biotechnology, data-driven medicine, and new therapeutic modalities are reshaping the industry.

Schell outlined an ambitious vision for modernising the regulatory system governing veterinary medicines. His goal is simple but transformative: cut the time it takes to bring new animal health products to market in half.

> *"Please don't stop a product because you think we're going to say no. We can look at risks differently and move products forward."*
>
> – Dr. Timothy Schell, Director for the Center for Veterinary Medicine (CVM), FDA

> *"The question for the industry is not just what regulators can do differently, but what we can do together to support that agenda"*
>
> – Kristin Peck, CEO, Zoetis

Today, it can take around ten years to move a new veterinary drug through the regulatory process in the United States. Schell believes that with the right reforms, tools, and collaboration with industry, this timeline could be reduced to five years, dramatically accelerating the delivery of new treatments to veterinarians, producers, and pet owners.

Achieving this will require structural change. During the conversation, Schell highlighted several areas where the FDA is actively exploring reform, including expanding conditional approvals, modernising outdated regulatory processes, and piloting new review mechanisms such as “stop-the-clock” reviews to allow a more continuous dialogue between companies and regulators.

A major focus of the discussion was conditional approval pathways, which allow promising therapies to reach the market while additional evidence is gathered. Schell described how extending these pathways and introducing more flexible regulatory tools could be particularly valuable for innovative therapies and smaller biotechnology companies.

Another priority is improving pathways for minor species and minor uses, areas that have historically struggled to attract sufficient commercial investment. Schell suggested the agency aims to significantly increase the number of products approved under these programmes, unlocking innovation in underserved areas of veterinary medicine.

The conversation also touched on the growing opportunity for global regulatory collaboration. As innovation becomes increasingly international, Schell highlighted the potential to leverage approvals from other countries to accelerate access to products in the United States.

Throughout the discussion, a central theme emerged: regulatory reform cannot happen in isolation. Industry collaboration, regulatory experimentation, and willingness to rethink long-standing processes will all be required to deliver meaningful change.

For the audience of innovators, founders, and industry leaders at AHNTI EU, the message was clear. The regulatory environment is evolving, and those who engage early with regulators will be best positioned to shape the future.