



Protecting Livestock Improving Human Lives

#### **Foreword**

At GALVmed, we know that small-scale livestock producers can, with the necessary support and access to animal health solutions, become engines of financial growth and social transformation in the Global South – boosting incomes, improving lives and strengthening national economies. However, we also know that public services are underfunded and overstretched, meaning governments are unable by themselves to provide the animal health products and veterinary services needed to unleash the development potential of livestock. As a result, livestock vaccination rates remain dangerously low, leaving entire herds and flocks – and livelihoods – vulnerable to repeated disease outbreaks.

This is where GALVmed steps in.

By collecting market data, de-risking commercial investments and working with stakeholders to develop harmonised regulations, GALVmed has supported the public and private sectors and promoted public—private cooperation since its establishment, and I'm pleased to say that we have continued to expand the role of private sector in livestock health in 2024.

Nowhere can this be seen more clearly than in our flagship programme, VITAL (Veterinary Innovations Transforming Animal Health and Livelihoods). Commencing in 2017, VITAL has supported the development and sale of quality, safe and effective vaccines for livestock. A major milestone was reached this year with market authorisations obtained for three combination vaccines. With several companies ready to sell these much-needed vaccines, GALVmed's role in VITAL includes supporting the products' registration and market entry in target countries, ensuring that vaccines reach the small-scale producers who need them most.

2024 has also been a successful year for many other GALVmed initiatives. In September, the <u>AgResults Foot and Mouth Vaccine Challenge Project</u> achieved the registration of the first ever quadrivalent vaccine specifically tailored to East Africa – an important victory in the fight against one of the most infectious livestock diseases in the world. PREVENT (Promoting and Enabling Vaccination Efficiently, Now and Tomorrow) has enjoyed its best year yet, with 8 new hatcheries onboarded and 61.8 million day-old chicks vaccinated – almost double last year's record. And, together with our partners, we have embarked on an ambitious regulatory project: Better Regulation, a three-year initiative to improve the predictability, efficiency and transparency of regulatory processes for new veterinary products across sub-Saharan Africa.

It goes without saying that none of this year's achievements could have happened without the support of our partners and funders, whose unfailing commitment we are deeply grateful for. Together we are creating prosperous, sustainable, private-sector-driven markets for quality animal health products across sub-Saharan Africa that benefit everyone along the livestock value chain. I look forward to continued cooperation in 2025 and beyond in pursuit of this essential goal.

#### Dr Carolin Schumacher

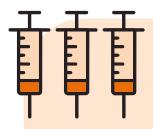
Chief Executive of GALVmed



GALVmed's flagship programme, VITAL (Veterinary Innovations Transforming Animal Health and Livelihoods), has had another successful year. VITAL commenced in 2017 with funding from the Bill & Melinda Gates Foundation (BMGF) and the UK Government Foreign, Commonwealth & Development Office (FCDO) to create effective vaccines for livestock in Africa and the commercial, regulatory and policy support needed to ensure the developed products and other animal health interventions reach the market. It marks a major step forward in the battle against Africa's endemic livestock diseases, which – despite the significant losses they inflict on small-scale producers each year – have historically received very little research and development from the commercial sector.

After several years of research and development, three of VITAL's commercial partners – JOVAC, Hester Biosciences and M.C.I. Santé Animale – have successfully submitted product registration dossiers for combination vaccines and achieved market authorisation for the developed vaccines in Jordan, India and Morocco, respectively. These include combination vaccines for Contagious Bovine Pleuropneumonia, Lumpy Skin Disease and Rift Valley Fever; Newcastle Disease and Infectious Bursal Disease; and Contagious Caprine Pleuropneumonia, Sheep and Goat Pox and Peste de Petits Ruminants (PPR). Dossier submission within the East African Community under the Mutual Recognition Procedure (MRP) and via national procedures in other regions are ongoing. Two other VITAL products are scheduled for dossier submission in 2025.

By catalysing commercial investment in livestock vaccines for transboundary diseases, VITAL aims to lighten the burden of public-sector disease control in Africa, which often has only the resources to provide reactive control of single diseases. The availability and accessibility of these combination vaccines would empower private veterinarians to provide a wider range of high-quality protection, improving the health of herds and the prosperity of their owners.



**3 combination vaccines** achieved market authorisation.



#### First ever registration of a quadrivalent Foot and Mouth Disease vaccine for East Africa

One of the most infectious livestock diseases in the world, Foot and Mouth Disease (FMD) presents a constant global threat to animal trade and national economies. Endemic throughout East Africa, FMD can devastate livestock productivity and severely compromise small-scale producers' livelihoods and food security. Vaccination is proven to effectively control FMD, but farmers lacked a registered quadrivalent vaccine that could protect against all strains circulating in East Africa.

In response, the <u>AgResults Foot and Mouth Disease Vaccine Challenge Project</u> – an eight-year, \$17.34 million pay-for-results competition – was launched in January 2020. Funded by AgResults (a collaborative initiative between the governments of Australia, Canada, the United Kingdom and the United States, as well as BMGF and the World Bank) and managed by GALVmed, the competition supports the development and uptake of high-quality quadrivalent FMD vaccines tailored to meet the needs of East Africa. In September 2024, the competition announced the first ever development and registration of a quadrivalent FMD vaccine tailored for East Africa. The vaccine was registered in Rwanda by Biopharma, a vaccine manufacturer based in Morocco. By successfully registering the vaccine in one of the competition's six target countries (Burundi, Ethiopia, Kenya, Rwanda, Tanzania and Uganda) and meeting the technical requirements, Biopharma qualified to become the project's first official competitor.

The second phase of the project, the <u>Vaccine Distribution Cost-Share Phase</u>, formally kicked off on 1 October 2024. This phase aims to increase the distribution and adoption of high-quality FMD vaccines by funding a portion of the selling price of registered and approved vaccines. AgResults provides the cost-share funding to manufacturers on behalf of public- and private-sector buyers, enabling them to better combat FMD through improved access to more effective vaccines.

The first quadrivalent Foot and Mouth Disease vaccine for East Africa has been successfully registered.



## PREVENT surpasses target for hatchery-vaccinated chicks in record year

This year has seen continued progress for PREVENT (Promoting and Enabling Vaccination Efficiently, Now and Tomorrow). Funded by BMGF and implemented by Ceva Santé Animale and GALVmed, this project is introducing vaccination to medium-sized African hatcheries and encouraging small-scale producers to purchase pre-vaccinated poultry as a way to strengthen their sustainability and commercial enterprises. In 2024, 8 new hatcheries were onboarded, bringing the total to 40 and surpassing the original target of 36. PREVENT also expanded into Gambia, Mozambique and Zambia; these increase the project's reach to 11 countries, joining Burkina Faso, Côte d'Ivoire, Ethiopia, Ghana, Nigeria, Rwanda, Tanzania and Zimbabwe.

In 2024, a record 61.8 million day-old chicks were vaccinated – almost double the previous year's figure – bringing the project total to 148.2 million. Vaccine administration also increased this year, with 131.5 million administered doses raising the project total to 408.2 million. On market development, 210 field technicians were trained across 7 countries, with Ghana and Burkina Faso completing biosecurity and troubleshooting training modules and a further 12 people benefitting from a field technical mentorship programme in Tanzania. In addition, GALVmed's Monitoring and Evaluation (M&E) team, in collaboration with partners, interpreted and analysed experimental baseline data from Tanzania and Nigeria and produced a learning brief on the findings.

To better understand the currently circulating strains of disease-causing organisms in hatcheries, PREVENT field technicians collected 262 tissue samples, of which 165 were screened for viruses, bacteria and antibiotic resistance. In October, the 'PREVENT Event' was successfully held in Kigali, Rwanda. Bringing together public- and private-sector poultry stakeholders from across West, Central and East Africa, the event raised awareness of the concept of mid-size hatchery vaccination. In recognition of the project's considerable achievements, a no-cost extension was approved for PREVENT this year, moving the project end from December 2024 to June 2025.



#### **61.8 million day-old chicks vaccinated** – almost double the previous year's figure.





## Game-changing market intelligence platform in development

A persistent lack of data about the size and potential of the animal health market in sub-Saharan Africa significantly restricts industry investment across the continent. In response, GALVmed has partnered with AgNexus Africa – a Kenya-based market research company – to develop the first integrated market intelligence platform for Kenya, Tanzania and Uganda. The subscription-based market intelligence platform will include current market size reports and market simulations for all three countries.

To gather detailed customer requirements for the platform, GALVmed conducted an online survey of over 100 participants at the start of the year, followed by an in-person workshop in Nairobi, Kenya, in March 2024. Since then, GALVmed and AgNexus have developed the platform's system architecture, classification systems (including therapeutic, species and region classifications) and reports associated with 18 prioritised key performance indicators for the platform. AgNexus is also on track to develop a market simulation system that will allow users to build market estimation scenarios based on their inputs. This is projected to be ready by the end of March 2025. Once complete, the market intelligence platform will transform the animal health sector's understanding of the African livestock health market – enabling more investment from international businesses and improving small-scale producers' access to quality veterinary products.

Over 100 stakeholders surveyed to inform the development of the market intelligence platform.



## More than 1,200 agrodealers in Kenya and Tanzania receive digital point-of-sale devices

In conjunction with the development of the market intelligence platform, GALVmed and AgNexus Africa are also providing digital point-of-sale devices to agrodealers in Kenya and Tanzania and offering them bespoke training from the International Finance Corporation. In addition to supporting business growth in East Africa, this digitisation of agrodealers automates the collection of retailer-based market data, ensuring that the market intelligence platform will provide up-to-date information for many years to come. To date, digital point-of-sale devices have been issued to 731 agrodealers in Kenya and 550 in Tanzania.



731 agrodealers in Kenya and 550 in Tanzania issued with digital point-of-sale devices and training.

#### A step closer to a new solution to African Animal Trypanosomiasis

African Animal Trypanosomiasis (AAT) is a devastating parasitic livestock disease that costs Africa at least \$3 billion each year. Despite the potentially enormous impact of new solutions to AAT, commercial interest is guarded because they can be very expensive to develop. As a result of this commercial neglect, existing drug compounds are old and increasingly ineffective as the parasites responsible for AAT develop resistance.

GALVmed, in partnership with BMGF, FCDO and Boehringer Ingelheim, is conducting research and collaborating with other projects to create a new solution to AAT before 2030. This unique collaboration is the world's only programme to develop a new, commercially available solution for AAT. In 2024, GALVmed continued to develop its capacity and internal processes to support the technical and regulatory components of this AAT programme. It also secured commitments from BMGF and FCDO to provide the necessary funds for GALVmed to complete the development phase of the programme. Crucially, 2024 also saw important technical progress in the development of a potential new solution, allowing the programme's commercial partner to advance their contribution to the programme. GALVmed also engaged with key African regulatory authorities to identify potential regulatory issues associated with the primary registration of a new solution to AAT in Africa. These developments are a major achievement in the fight to control one of Africa's most destructive livestock diseases.



BMGF and FCDO have committed to providing funds for GALVmed to complete the next phase of the AAT programme.

#### Digitising animal health across Africa

Livestock producers in sub-Saharan Africa contend with inadequate animal health services due to logistical challenges and a relatively low number of service providers, leading to avoidable losses of livestock productivity associated with morbidity and mortality. Access to medical data by government policy bodies, which would otherwise support disease surveillance efforts and inform responses, is also patchy. To address this, GALVmed is working with the National Animal Disease Information Service, the African Veterinary Technicians' Association and VetNOW, a veterinary healthcare technology company, to develop two transformative apps for sub-Saharan Africa: a telemedicine app that enables remote livestock care and a clinical sign recognition app that uses images of livestock diseases and symptoms to increase the accuracy of diagnosis. In 2024, both apps were developed and deployed in Kenya's Kiambu and Nakuru counties. Two hundred products for ruminant diseases have been added to the diagnostic tool with full data to help ensure prescribed drugs are genuine and registered; 4 engagement specialists employed to drive farmer recruitment; and 32 veterinarians and 255 veterinary paraprofessionals have been trained to use the apps. The two apps will be introduced to other counties in Kenya in 2025 before expanding to other countries within sub-Saharan Africa in subsequent years. By reducing the need for time-consuming and expensive travel to seek veterinary assistance, these two apps hold the promise to revolutionise veterinary service delivery – increasing access to animal health expertise, improving livestock health, enhancing farm productivity and boosting producers' incomes.

**200 products** for ruminant diseases added to the diagnostic tool.





# Mutual Recognition Procedure's veterinary vaccine registration guidelines to be used across Africa

The variety and complexity of national regulations across Africa, which prevents the quick and effective registration of animal health products across multiple countries, has been a major barrier to commercial development of livestock vaccines in the continent. The East Africa Community (EAC)'s Mutual Recognition Procedure (MRP) is a revolutionary multinational regulatory system designed to tackle this issue. Established with GALVmed's support in 2014, it allows companies to apply for product licences in multiple EAC countries simultaneously by harmonising animal health product registration in the region. Harmonised guidelines for the registration of veterinary vaccines and pharmaceuticals were developed and applications for product registrations submitted in 2017 and 2020 respectively. In 2024, the African Union, on the recommendation of a pan-African regulatory meeting hosted by the Pan African Veterinary Vaccine Centre, directed that the vaccine registration guidelines developed under the MRP will now be used to register all PPR vaccines in Africa in readiness for a global eradication campaign against this disease. This is a monumental step towards harmonisation of regulatory requirements in Africa.



Vaccine registration guidelines developed under the MRP will now be used to register all Peste des Petits Ruminants vaccines in Africa.

### Ectoparasiticides added to the Mutual Recognition Procedure

Mites, ticks and other ectoparasites severely impact the wellbeing of animals and cost producers billions of dollars each year, holding back the African livestock sector. In 2024, in a bid to reduce the high cost of registering parasiticides, GALVmed supported the EAC Secretariat to develop and validate harmonised guidelines for ectoparasiticides. These guidelines and related technical documents were approved in June 2024, meaning that veterinary pharmaceutical companies can now register veterinary ectoparasiticides via the MRP, signifying a major expansion for the multinational regulatory system. In preparation for this expansion of the MRP, 21 senior assessors were trained by the Australian Pesticides and Veterinary Medicines Authority.

Plans are now underway to further expand the MRP initiative to incorporate safe and effective aquatic animal medicine – supporting the rapid growth of aquaculture in the EAC. In preparation for validation, East African countries, with support of the World Organisation for Animal Health (WOAH), reviewed aquatic animal medicine registration guidelines.

**21 senior assessors** trained to review ectoparasiticides submitted to the MRP.

## GALVmed jointly establishes pioneering project to coordinate product regulation across Africa

In 2024, GALVmed was awarded a grant for a new product regulation project in recognition of its work establishing and supporting the EAC MRP. The Better Regulation project is an ambitious three-year initiative to significantly improve the predictability, efficiency and transparency of regulatory processes required to bring new veterinary products to market in sub-Saharan Africa. Currently, there is no overarching framework or governance structure for cooperation between agencies responsible for veterinary medicines in Africa. This significantly slows the flow of new and high-quality livestock medicines into the hands of African small-scale producers.

In response, Better Regulation will build on the accomplishments of the MRP to support the development of a long-term governance structure that will improve access to high-quality veterinary medicines through improved, coordinated regulation. This will simplify the registration process, save time and resources, and help to ensure the quality, safety and efficacy of veterinary products. Better Regulation will also increase products' availability, contributing to improved animal health and livestock production throughout sub-Saharan Africa. The project will be implemented by GALVmed, WOAH, the UK Veterinary Medicines Directorate and the EAC, with the support of BMGF.

Better Regulation project will improve the predictability, efficiency and transparency of regulatory processes across sub-Saharan Africa.



# GALVmed's governance receives clean bill of health for sixth consecutive year

GALVmed received a clean external audit report in 2024 for a sixth successive year, with no control weaknesses or suggestions for improvement identified. The recent due diligence exercise, conducted on behalf of FCDO, was a very worthwhile exercise with numerous examples of good practice identified. Another governance milestone was reached this year: there are now as many staff employed in our Global South offices as in our Head Office in Edinburgh, reflecting GALVmed's commitment to increase our presence in our countries of operation.



There are now as many staff employed in GALVmed's Global South offices as in its Head Office in Edinburgh.

## Monitoring and evaluation captures GALVmed's long-term impact

How can GALVmed gain a broader, more holistic understanding of its impact? This is the challenge that our M&E team addressed in 2024. GALVmed's impact model for the market-led distribution of animal health products, published last year, has proved instrumental in estimating the impact of our current initiatives. The M&E team is now expanding its modelling efforts to better align with GALVmed's newer interventions. This includes the development of dynamic production models, which, by more accurately reflecting how animal health products impact farms, will allow GALVmed to capture a wider range of factors that affect impact, such as production losses, product quality improvements and growth accelerators.

This year also saw the development of a Transformational Market Systems Change framework – a new tool that expands GALVmed's M&E focus from evaluating individual projects to also surveying broader systemic changes in the markets the organisation influences. This will help assess how GALVmed is catalysing impact at a systems level, which is crucial for sustainable impact at scale. To better understand how GALVmed-supported products and projects continue to influence markets and improve livestock health beyond the project cycle, M&E has also focused on capturing GALVmed's legacy impact. This has already yielded important findings, such as the sustained profitability of community vaccinators and substantial increases in sales of GALVmed-supported products following commercialisation.

The new market systems change framework expands GALVmed's M&E focus from individual projects to broader market-level changes.



#### 2025 and beyond

GALVmed's many achievements in 2024 have set the organisation on a promising path for 2025 and beyond. The year ended with the fantastic news that BMGF and FCDO had approved GALVmed's funding proposal for VITAL2, a follow-on project to our flagship VITAL initiative that has been two years in development. Over the next five years, VITAL2 will continue to build the portfolio of available ruminant vaccines and focus on raising the notoriously low vaccination rates of small and large ruminants across sub-Saharan Africa, using private-sector-driven initiatives to transform the market for high-quality animal health products. This project will ensure continuity for GALVmed and its partners' efforts to unlock the enormous and much-needed development potential of livestock for small-scale producers.





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