

PROTECTING LIVESTOCK - SAVING HUMAN LIFE

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GALVmed

Abstract

[To be completed]

Introduction

Charitable Purpose of GALVmed

To relieve financial hardship and promote good health (including improving food security) amongst livestock keepers in developing countries through the promotion of affordable vaccines, pharmaceuticals and diagnostic products and promoting services aimed at improving the health of their livestock.

The ambition of this project is to contribute to the achievement of the Millennium Development Goals creating **transformational change** in the lives of poor livestock keepers by:-

- Co-ordinating the gathering and dissemination of data for evidence-based decision-making in developing world animal health
- Putting in place communication and networking for key partners additionally merging human and animal health interests around zoonotic diseases
- Driving development and registration of vaccines and diagnostics in four of the most impactful diseases that affect livestock and people in the developing world
- Challenging the systemic failure of access and adoption of such products by poor people and addressing market registration and quality control issues
- Stimulating the growth of value chains

By offering leadership in private public partnerships, our project will create the environment and deliver the products to sustainably improve income, food security and capacity for growth for livestock keepers throughout Africa and Southern Asia.

Why the Global Alliance for Livestock Veterinary Medicines (GALVmed)?

60% of the world's poorest, that's around 600 million people earning <USD\$1/day, depend on livestock for food, for transport, for fertilizer, for trade, for investment. GALVmed's objectives are to make a sustainable impact on poverty reduction by making available livestock animal health products that are appropriate to the needs of the world's poorest livestock keepers. By protecting their livestock we can help save lives and help them break out of the poverty trap. In meeting the challenge of reducing poverty, protecting livestock through vaccines and treatments is one of the few areas of need which has not as yet been challenged.

GALVmed is a not-for-profit organization that is uniquely positioned to leverage the assets and expertise of the Animal Health industry and build partnerships with international and regional donors, NGOs and implementing organizations to develop, register and ensure sustained delivery of animal health products that meet the unique needs of the world's poorest livestock keepers.

GALVmed is designed to meet its targets by 2015. This fits into our commitment to the Millennium Development Goals but also is designed to maintain tension to deliver. Delivery will always be through the creation of partnerships, firstly because to do any other would require massive investment and an unwieldy organization. But more importantly, our intended impact is systemic transformational change, achieved through engagement, buy-in and ownership from the key players. No other organization exists in Animal Health with this remit.

Livestock, Poverty, Human Health and Sustainability

For poor people in the developing world there is a direct link between their livestock, their health and their personal sustainability. Yet the availability of any access to relevant animal health medicines has been in a steady decline for over 30 years. Working with academic groups, donor organizations and regional representatives, GALVmed has made an initial prioritization of those infectious diseases that have the greatest impact on the poorest livestock keepers. These fall into two types:

- Firstly, some diseases cause death or loss of productivity of their livestock, e.g. **East Coast Fever** in cattle, **Newcastle Disease** in poultry
- Secondly, other diseases of livestock can be transmitted to the livestock keepers themselves and cause serious illness and death, i.e. zoonotic diseases such as **Rift Valley Fever** and **Porcine Cystercicosis**
- Our selection criteria are based on the short term availability of potential solutions and their immediate capacity to impact on the world's poor. Nevertheless, we are also continuing to seek solutions for a further nine diseases that have a disproportionate impact on the poor livestock keeper.

New vaccines, but also appropriate use of current technology

Lack of money is not always the issue preventing the development of and use of animal medicines. Many of the needed products are not accessible to poor people in isolated areas or not available in a form that meets the needs of a poor livestock keeper. The key is to make them appropriate - not just cheap, but available in small pack sizes in thermostable forms with convenient methods of administration. We believe that if we develop appropriate technology then the poor livestock keeper will be able to afford them. We recognize that, in many circumstances we will also need the support of government and veterinary services as well as local distribution networks. By doing this we believe it will be possible to develop sustainable markets for these products, something that would never be achieved by simply funding the purchase of current products.

However, there are some diseases which are confined to developing countries, often linked to their transmission by regionalized ticks and insects. Some of these have proved very difficult to control by vaccination, c.f. malaria in people, and it will require us to bring the best expertise and resources from industry and academia together to be successful.

A need for a focused, systemic approach

So why have products not yet been delivered for these diseases and why are the few existing solutions not being adopted? This is often attributed to "market collapse." But the truth is no one factor is responsible for this.

- There has been a massive decline in many countries in Africa of their Government Veterinary Services and in East Africa, especially.
- Private veterinary services have not replaced them.
- Major pharmaceutical companies have sought more profitable markets and local companies have not yet filled that gap. Neglected diseases have thus remained – neglected.
- Regulation of animal health products and, especially, quality control is poor, leading to counterfeit or ineffective products which have the double impact of reducing consumer confidence and driving away potential producers who cannot compete with rogue imports.
- Many vaccine solutions available right now are dependent upon the availability of a cold chain without which they deteriorate by the time they reach the animal, and poor inaccessible parts of Africa do not have these facilities.

The international AH industry recognizes that, while they have the desire and corporate social responsibility to help these groups of poor livestock keepers, they do not have all of the resources and expertise to target these diseases unique to tropical countries, since it is unlikely to become a major market for them. Their contribution is to work through GALVmed to build Global partnerships that can bring all the resources and expertise to tackle these diseases.

Our contribution is to facilitate the processes that will:

- Focus the international community (researchers, donors and companies) on developing solutions and;
- Building capacity especially in the most affected regions to produce and distribute vaccines and other animal health products.

Requirement for data-driven decision making

The socio-economic impact of the non-availability of animal health products is both undoubted by those in the field and at the same time almost impossible to establish accurately (our proposal to redress this shortfall explains why). The outcome is that “loss” tends to be established by carcass value – the true “loss” to poor people is uncalculated and unimaginable. To a city office worker and a subsistence farmer the cash value of a chicken may be the same but the real value in terms of their personal sustainability is radically different. The loss of a cow to ECF is negligible to a large dairy producer but devastating to a pastoralist with 3 cows. The loss of goats to the economy through RVF in Ethiopia has been roughly estimated, but the loss of a child to the same disease has no recorded value.

Perhaps remarkably, there is no internationally accepted methodology for making an accurate assessment of socio economic impact or animal loss to the lives of poor people.

GALVmed intends to create a consortium of international partners to establish a more robust and evidence based methodology for assessing the socio economic impact of animal health and therefore the impact of development of vaccine approaches. The consortium will seek to engage with the international community (through OIE and FAO) to embed this methodology to inform policy making in future years.

Summary of Disease Impact

The World Bank estimates that in Sub Saharan Africa, the agriculture sector employs 65% of the labor force and produces 32% of GDP growth, but livestock keepers are not only employed in rural agriculture, they are also urban dwellers supplementing their diet and income. Of the 600 million plus poor livestock keepers globally we estimate the diseases affected by geographic reach of this application could have relevance to over 450million. Some will affect far more than others. Newcastle Disease, because it impacts upon poultry, will affect the majority. Porcine Cysticercosis affects fewer in Sub Saharan Africa and South Asia, but like Newcastle Disease, is of Global relevance and is also zoonotic. It has the capacity to infect, sicken and kill, people. The methodology available for measuring impact is imperfect and we intend to address that - currently, impact is more often measured in animal loss than people and income impact. Characteristics of our four top priority diseases are summarized below.

East Coast Fever

Impact:

- Overall susceptible population of cattle = **122 million**
- Estimated annual mortality in the 11 endemic African countries = 1.1 million cattle with carcass loss of US\$168 million.
- Assuming 60% of costs are directly related to mortality, and based on evidence in Tanzania of ITM reducing mortality from 30 – 50% to 2%, the estimated impact > **US\$ 100 million per year** in the endemic countries.
- Additional benefits due to reduction in production losses are estimated to be approximately **US\$ 50 million per year** in the endemic countries alone.

Potential solution:

- Registration of ECF-ITM in endemic regions, enabling quality and consistent manufacture and distribution towards wider adoption of the solution.
- Product and process improvements to potentially reduce cost and improve accessibility
- Seek novel vaccine solutions exploiting newer technologies for the longer term control of ECF

Key Partners:

- AU IBAR – co-ordination
- ILRI and Animal Health companies for solutions
- African Manufacturers within Public and Private Sectors.
- Public and Private sector partners for distribution

Key Milestones:

- Registration of ECF-ITM in major markets – 4Q08
- Supply of vaccine to meet urgent demand – 4Q09
- Evaluation and validation of process improvements – 2Q11
- Increase manufacturing capacity – 4Q12

Barriers:

- Biological variation within manufacturing processes
- Capacity of manufacturing sites to meet capacity
- Public and private sector co-operation to improve adoption
- Uncertainty of potential improvements and cost reduction.

Cost **\$3.3m**

Rift Valley Fever / Sheep and Goat Pox / Lumpy Skin Disease

Impact:

- RVF within 13 countries in Africa the susceptible population of Sheep and Goats = **184.5 million**. Losses due to RVF related export ban just from the port of Berbera in Somaliland alone is estimated to be **US\$200 million a year**. There are significant additional losses due to mortality in humans, disease in humans, mortality of young animals, abortions, disease in cattle and the loss of market for livestock meat, which are difficult to measure based on available information.
- Within the 18 countries in Africa that have reported SGP, the susceptible population of sheep and goats = **307 million**. There is evidence that the mortality could be up to 50% when outbreaks occur.
- Lumpy skin disease estimated to affect **250 million** cattle and the economic losses in Africa due to LSD is estimated to be comparable to that of FMD.

Potential Solution:

- Registration and commercialisation of a multivalent, multi species vaccine to protect sheep and goats against RVF, sheep and goat pox as well as cattle against RVF and LSD.
- Registration of a monovalent RVF vaccine for use in outbreak situations
- Validation and delivery of a diagnostic assay for rapid “farm-side” diagnosis of RVF.

Key Partners:

- International research institutes and AH companies for solutions
- African public and private sector institutions for product development and manufacture
- Private and public sector partners in Africa for distribution

Key Milestones:

- Registration of a multivalent vaccine for routine use in Africa – 3Q12
- Validation of a rapid diagnostic assay – 1Q09
- Potential registration of monovalent vaccine suitable for outbreaks – 4Q13

Barriers:

- Bio security required for vaccine development
- Adequate safety and efficacy as well as acceptance of technology by regulators and public
- Adoption of routine vaccination
- Public and Private sector collaboration

Cost **\$4.17m**

Porcine Cysticercosis

Impact:

- **World wide Five million human cases with 50,000** reported deaths each year.
- Figures for Sub Saharan Africa are unreliable
- Programme will also impact on BMGF human health programme,

Potential Solution:

- Registration and distribution of an effective vaccine for pigs
- Registration of a drug to treat pigs that would enable the availability and legal use.

Key Partners:

- International research institutes and AH companies for solutions
- International organisations including WHO and FAO involved in control of neglected zoonoses for policy support and coordination of Human/Animal interface
- African and Asian public and private sector institutions for product development and manufacture
- Private and public sector partners in Africa and Asia including civil society organisations for distribution

Key Milestones:

- Registration of an effective vaccine in the first two countries – 4Q11
- Assessment of proof of concept and ability to register of a treatment option – 4Q08
- Defining a control strategy towards eradication together with global partners – 2Q10

Barriers:

- Awareness of impact caused by *T. solium*
- Technical uncertainty of vaccines, cost of vaccine and acceptance of technology
- Alignment of efforts across multiple stake-holders
- Lack of commercial interest in the monovalent vaccine and availability of public funds for vaccination campaigns

Cost \$5.38m

Newcastle Disease

Impact:

- Number of chickens in African countries, India, Pakistan and Bangladesh = **1573 million**
- Assume 40% of chickens in back-yard = 692.2 millions (likely to be higher than 40% in poor countries).
- Assume 30 – 50% mortality due to uncontrolled ND = 208 – 346 million chickens
- Direct cost of preventable ND (assume US\$ 2 / chicken and 80% vaccine efficacy) = **US\$ 332 – 553 million**
- Additional benefits include increased flock size, increased egg production and improved nutrition.

Potential solution:

- Registration of a thermo-stable vaccine produced to appropriate quality with adequate capacity to meet demand and delivered in appropriate vial sizes.
- Models to support sustainable delivery of vaccines enabling high level of adoption

Key Partners:

- International research organisations and AH industry
- African and Asian partners for product development and manufacture of vaccine
- African and Asian private and public sector partners for sustainable delivery of vaccine

Key Milestones:

- Registration in Africa – 3Q09; Establishment of delivery model at pilot scale - 4Q09
- Registration in Asia – 1Q10; Establishment of delivery model at pilot scale – 4Q10

Barriers:

- Awareness of ND related impact among back-yard poultry keepers
- Public - private sector co-operation and policy support to implement models for adoption

Costs \$ 5.49m

Background and Rationale - The need for new approaches

The case for a new approach to allocation of public funding for research into animal health reflects the following key observations:

Involving the private sector

Consultations with the private sector (**developed and developing world companies**) confirm that they have scientific expertise, IP and resources that could be made available to help tackle the diseases faced by poor livestock keepers. However the private sector will not develop the relevant

products on their own because the markets are not large enough to justify the investment. But where the costs and relevant risks can be shared, the private sector is willing to engage on a humanitarian and in some cases semi-commercial basis.

GALVmed ensures that for all projects funded by GALVmed, the benefit will be primarily public and any intellectual property accruing from our funding will be managed for a public good. (Our contracts protect against the development and subsequent storage of IP so that we can ensure that IP leads to products).

Improving existing research models

The Pharmaceutical Research Industry is notable for its success in research and development. One of the reasons for success is its use of a 'portfolio approach' to research management. A portfolio approach to research has three distinguishing features:

- it manages research as a continuum from the discovery of new ideas through to the development of a product;
- it invests in parallel lines of research to develop a new product; and
- it uses stop/go milestones to identify research that is performing, and should be continued, and research which should be stopped.

The use of stop/go milestones is particularly important as well over 90% of early-stage research can be expected to fail. Mechanisms that identify non-performing research at an early stage can greatly increase efficiency of research investments. GALVmed has adopted this approach for its own management processes.

Converting research outputs into accessible products

The diagram below illustrates the key stages in the R&D chain for vaccines.
Stages in the R&D chain (vaccines)



This is the model that GALVmed uses to plan and manage vaccine development. It is adapted from commercial practice and will merge the strengths of CSOs, NGOs and donors into what will be a fully integrated process, our role will be to act as a catalyst and to monitor and evaluate achievement.

Project Objectives

Our strategy for achieving our organizational outcomes consists of four interdependent Objectives

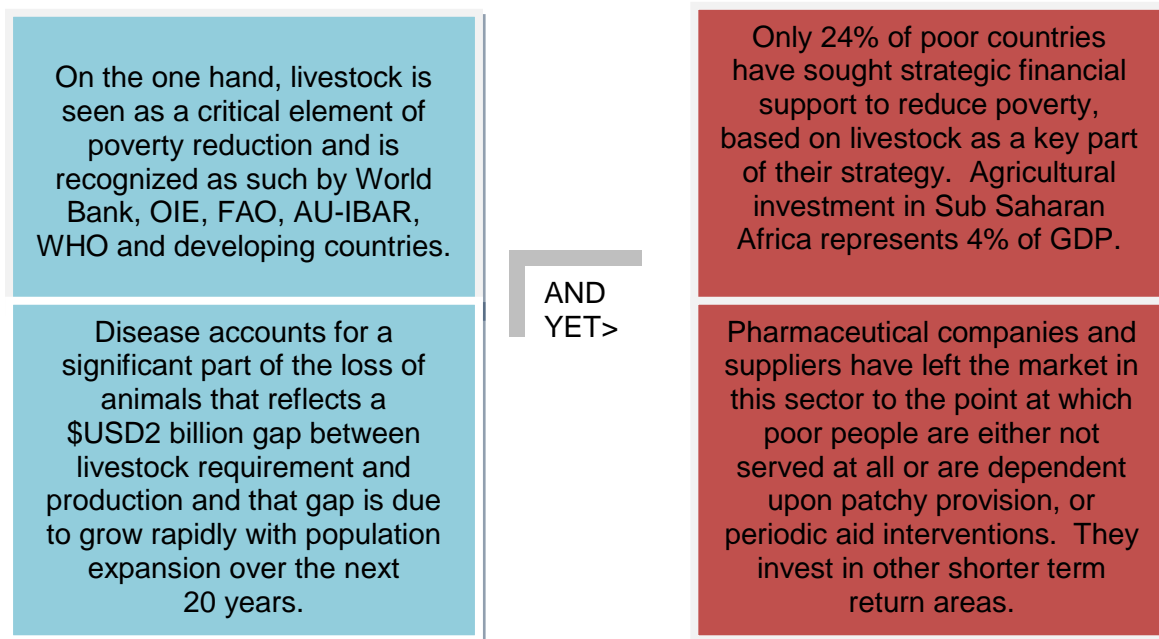
Objective 1: Data Driven Decision Making

This Objective recognizes the criticality of communicable and authoritative data to drive decision and policy making. Without this, the confidence at macro-level of countries and donors will not be stimulated to invest and without understanding the markets for vaccines better it is difficult to see how companies will make the business case to attract investment for production and supply.

The status of statistical data that can be usefully applied to influence policy, decision making and operational planning in the developing world, is very different in Animal Health than has been achieved in the Human Health context. What exists at present describing Animal Health in the developing world is insufficient not only for planning purposes, but acts as a disincentive to entrepreneurs wishing to invest in what they otherwise see as an area for fast capital growth.

Markets

Viewed from a systems perspective there are some interesting paradoxes in pro-poor animal health provision.



This has become clear in discussion over the last 18 months with researchers, CSOs, Governments , AU-IBAR, Pharmaceutical Companies, Venture Capitalists and Investors in both the West and North as well as in Africa. When assessing why this paradox exists, again vital data is considered to be missing. Some of this (when related to donors and Governments) concerns socio economic impact, but for commercial partners, what is missing is a true understanding of the size, volatility and elasticity of the market.

Objective 2: Product Development

This will form over 80% of our total expenditure and is the central plank of our strategy. These are the vaccine deliverables that will make a difference on the ground

Disease Prioritization

These disease areas have been chosen from 13, defined by an expert committee with experience in development, research and pharmaceutical industry. The four solutions chosen represent low hanging fruit in different ways.

- **Newcastle Disease** is about adaptation of current technologies for a developing world context. Of all of the diseases, it is the most global in its impact, being present in every developing country, and, as the easiest acquired animal group, loss of poultry typically impacts upon the poorest farmers.
- **Rift Valley Fever** has an element of urgency that needs to be addressed. Although it is an episodic disease, it also is spreading and this year has killed a number of people. A combined RVF vaccine, with additional efficacy against Lumpy Skin Disease and Sheep and Goat Pox, has the capacity to benefit very poor people throughout the areas we intend to work within. There are several vaccine candidates ready to take to test and key test partners identified.
- **East Coast Fever** is a disease which we have begun to impact upon through small investments made through our DFID set-up grant. Our work here simply builds upon the basis that this has already been established, but allows us to up-scale and make the product more sustainable.
- **Porcine Cysticercosis** has an experimental vaccine candidate awaiting a process of field testing and up-scaling. Our prioritization also reflected that it is a zoonotic killer disease that has been marked for action moving towards eradication by WHO.

Objective 3: Modeling improved Adoption + Access of Animal Health Products

Two contradictory truths about the animal health market servicing poor people are:-

- There is strong anecdotal evidence and evidence from other sectors that, when offered quality products pitched at an affordable price, poor people will invest scarce funds in order to get a return on their investment, demonstrated by the increased productivity and improved income potential of their animals. Given choices and the opportunity to invest, poor people make good entrepreneurs - it matters most to them.
- Faced with better returns elsewhere, major producers and suppliers have left the market to players who are either unable to meet the quality or unable to meet the sustainable supply needs of consumers – *the result is a 30 year downward spiral of unfulfilled demand, dented consumer confidence and reduced investment, leading to diminishing supply and a situation that meets the ambitions of neither party.*

The result is increased animal health risk, poor food security, increased human health risk and ultimately one of the less visible yet actionable contributions to the poverty cycle.

Approach

- **Value chains.** Create partnerships that can trial and roll out new (and adapted successful approaches from elsewhere) value chain approaches to supporting livestock keepers. Begin with East Africa, learn from Francophone Africa and extend to Southern Africa later in the project. We will trial two approaches to the development of value chains, **the Service Centre Approach** within the Newcastle Disease profile and the second is the **Franchise Project** proposed by Strategic Project Partners Farm Africa. While the Service Centre approach will operate in 12 areas in five countries, the Franchise Project will operate in one country but will create impact (in this funding period) in 25 areas. Together they will impact over 3 million people. The Franchise approach is intensive, multi animal system based and holistic. The Service centre approach begins working through Poultry as a single animal group and puts emphasis upon pull through of increased veterinary provision. It intends to measure experience in a variety of countries and cultures. Both will be monitored and learning will be shared.
- **Ownership and communication.** This is also reflected in our intentions for **the 4th Project Objective**. We intend to build upon the highly successful **CAHNET approach** initially funded by DFID and supported through Farm Africa. This uses traditional and new media approaches to communicate with poor farmers and to give them the opportunity to communicate with decision makers. Currently relevant to the Greater Horn of Africa in the scope of this application, we will extend CAHNET into Francophone Africa with **VSF Belgium** with a view to extending further to Southern Africa in the next phase of GALVmed, post 2011. This approach will allow us the capacity to inform farmers and at the same time, receive feedback from the field (literally) about farmers' experience of vaccines and treatments. It is a two way intelligence system.
- **Distribution networks.** This will build upon and link the successful work undertaken by **AGRA** on Agro dealerships and the work of the **HealthStore Foundation** and **Farm Africa** to develop the village dealership system. Discussions have been held with all partners about the prospect of synergistic program development.
- **Confidence building.** Within the **1st Project Objective** we speak about the need for developing market confidence. Within the **4th Project Objective** we talk about the need for confidence in the regulatory system. Both are critical and both also support the work of Adoption and Access.

The results of the work undertaken above will be feedback through **AU IBAR** to the Council of Ministers to inform at a policy level, as well as to inform through Chief Veterinary Officers, Veterinary Schools and Professional Organizations.

Partners

- **Strategic level**

GALVmed (strategic co-ordination through an appointed Adoption and Access Assistant Director, core funded through DFID); FARM Africa (leading the Adoption and Access element); VSF Belgium (project partners for Francophone Africa and expertise on value chain approaches); NESPOD (project partners in Bangladesh and India); AGRA (project partners dealerships – note early discussion thus far); AU-IBAR (policy level dissemination).

- **Field Level**

Vetaid (project partners in Mozambique); HealthStore Foundation; Kyeema Foundation; BRAC; ANTHRA; Universities of Sokoine and Makerere.

- **Country Coverage**

Burkina Faso; Comoros; Mali; Mauritania; Niger; Rwanda; Ghana; Kenya; Sudan; Ethiopia; Tanzania; Uganda; Mozambique (Service Centre only); Bangladesh; India.

Desired outcome

Steady market growth where products produced to quality standards and delivered in a sustainable and predictable manner are purchased with confidence by poor people well served by professionals and support workers who are able to demonstrate the value of investing hard earned cash for a return that improves their health and life opportunities.

Objective 4: Communicate and Network to improve the paradigm for animal health medicine development to benefit poor livestock keepers.

Communication and co-ordination are cross cutting themes in all of our Objectives. Here we deal with the strategic requirements to improve the paradigm.

There are five elements in our program

i Increase Global Awareness of Animal Health as a pro-poor issue.

This will see the launch of a high profile awareness campaign that will tie animal health to poverty. There are two purposes for this.

The first is to ensure that the issue of livestock is considered by policy and decision makers as an issue of global importance. There are several good reasons to do this. One is to highlight, as has recently been done by the World Bank, that actually investing in Agriculture gives an excellent return for poverty reduction. We wish to be specific about the role of livestock. Another is to inform decision makers at a national level. Finally we also wish to educate about the potential impact of “exotic” diseases should they reach the shore of the developed world. Some already have - Bluetongue is having a devastating effect. Rift Valley Fever is moving north and is showing (as of early November 2007) a disturbing trend to the most devastating form of the disease in human beings. (Whereas RVF had been seen as a relatively mild disease killing 1-2% of humans, the hemorrhagic version of the disease kills in far higher percentages – around 40%-50%. It is exclusively this strain it seems that has moved into Sudan). Bluetongue is midge born; RVF is blood, tissue and mosquito borne. The inference is clear.

The second is to provide a rallying point for other agencies and companies who wish to emphasize their commitment to working with livestock issues. Major companies will not see this market as a natural market for them - profit can be made faster elsewhere. However they will commit to support if

we can offer CSR advantages. This is a part of the deliverable for them. But to be seen as valid, we need to establish this awareness campaign as companies will not do this for fear of criticism.

ii Network with Key Agencies

Both in the USA and in Europe there are annual “Global” conferences and meetings of concerned parties who focus on livestock in the developing world. The US conference tends to be all-USA agencies with token European representation; the European Conference (which GALVmed hosted in 2006) tends to be all-European with token US representation! Neither have a paid secretariat - both had remarkably similar agendas in 2007. Both have minimal attendance by people from developing countries (and in the European case in 2006, non-existent). Neither wants it to be this way.

It would be our intention to encourage these two groups to join forces, possibly with mirror groups in the USA, Africa and Europe, by offering a secretariat function and by enabling the travel funding of African and Asian representatives - presently the major obstacle to their attendance. We would seek to include FAO, OIE, PANVAC and AU-IBAR, as well as World Bank and the South Asian Ministries. The desired outcome would be shared learning with duplication avoided - much higher representation of farmer stakeholders, less reinvention of the wheel, and more wheels turning. Also, to provide more opportunity to capture enthusiasm and give it application. Working, as we know we would be, with exceptionally highly motivated people, we see this as an opportunity to make a real difference - quickly.

iii Support to key agencies to simplify and co-ordinate regulatory issues.

This is about two absolutely crucial areas of work – Regulation and Quality Control. In Africa especially, neither meet the requirements of the market or for that matter, replicate global standards.

Some issues are worth mentioning here.

- At a plenary session in the recent IFAH meeting in London, a question was put by GALVmed to several major Animal Health Pharmaceutical Companies. The question was

“other than opportunity cost, what is the major disincentive to you investing in serving the developing world markets?”

The universal response was “**risk**”. Not risk of loss but risk of unfair competition and having their products illegally reproduced and marketed by pirate companies as theirs, and risk also of competing with cheap alternatives (especially from China) which claim they do the job, but offer less efficacy. Risk clearly would be mitigated if the products imported were tested and regulated.

- In a study tour undertaken in October to three countries in Africa – chosen because they are a key market for all of the products we mention, we found the following. In all cases, Animal Health product registration was within a non-animal health agency. One country admitted that of the 56 staff dedicated to registration and regulation, three (one of whom was administrative), were dedicated to animal health products.
- Some animal health products on the market simply have never been registered. This is true for instance for the ECF ITM product, and is why we have prepared a dossier for it to be registered. The issue here is a little opaque, but in this instance it restricts who might buy the product - only a government can afford to have a batch tested; what farmer could? Hence commercialization of this product has been hampered.
- Theoretically, Quality Control of all products is undertaken by PANVAC. To the best of its ability PANVAC does its job dutifully. It has very few staff and when paid to test products, does so by commissioning this process through a supplier, often NVI, which is the closest laboratory to them. We have heard anecdotal evidence of PANVAC delivering a negative result to governments who receive it, file it and pass the product fit for use. No-one, for obvious reasons, is prepared to confirm this.

We need to make a very important point here - in none of the above did we find poorly qualified or poorly motivated people. In fact, the exact opposite. We found staff who took their jobs very seriously indeed, were prepared, had they the opportunity, to apply exacting but appropriate standards, but who had token resources.

There is a global reason why this is important. With Avian Influenza and other diseases threatening pandemics, and northward drift possibly because of climate change, International Organizations are making global policy based upon assumptions about the efficacy of products. If that efficacy is an illusion, then so too is the policy.

We believe that two courses of action are viable to improve this situation.

The first is to communicate and conference the issues of regulation in Africa (initially) - our first action here is to sponsor the OIE conference on African regulatory processes in March 2008. But this needs to drive down to and reach out to decision makers within countries to make the case for greater investment in regulation and progress needs to be reflected through the Council of Ministers at the AU.

The second is to support the role of PANVAC. Our ambitions here are to baseline the issues with PANVAC and AU-IBAR, and to prepare a business case for development support to donors. Their role needs to be both self sustaining and independent. In terms of offering a route to the radical simplification of issues of quality, a solution that has been discussed with GALVmed is the development of an inviolable “**kitemark**”. This would be the sole stamp of approval for all animal health products in Africa. The logistical issues relating to this have not been explored and this remains an idea rather than a proposal.

iv Facilitate global learning in pro poor vaccine, diagnostic and medicine development

This is a portal based concept, both actual and virtual. It relates to the need to develop a learning consortium of key stakeholders around the issues of Animal Health Product development. GALVmed's experience over the last 2 years is that there are large comprehension gaps between Research and Animal Health Company product development, and this has led to misunderstanding, miscommunication and in some cases, bad feeling, all of which act as a barrier to future developments.

Our intention here is to:

- Hold seminars around specific issues of mutual interest that are topic-based not relationship-based.
- Develop a web-based approach to create self-sustaining forums of interest for people from different backgrounds.

Prior to establishing this however, we will research best practice from other areas so that we do not make mistakes that others have avoided.

v Support current and develop new methods of communicating with poor farmers

As has already been said this is a cross-cutting theme. However our ambition here relates less to specific products and issues, and more to establishing how poor farmers receive information and how they are motivated towards action, and in this case, adoption. This will be work that is undertaken by consultants and in liaison with already established agencies in Africa (especially) who have experience in this area.

Section 4 Project Design and Implementation Plan

4.1 Design

The four elements of our Project, expressed through our objectives, are designed to complement one another as a strategic approach to putting vaccines, diagnostics and treatments in the field and ensuring that they are used.

Experience (and a self-evident lack of product) shows us that research alone, however exceptional, cannot be relied upon to ensure that results leave the laboratory and reach the farmers' shelves. Likewise products, without a value chain to ensure delivery and support by governments, do not predictably make it to the farmer, and livestock keepers need information and advice and guidance to be sure that the products they use are the right ones. Within all of these, there are also the systemic disincentives to deal with around issues of regulation, poor quality goods, and policy drift.

This is why the project design is holistic and the elements (objectives) are inter-linked.

4.2 Implementation

Some of the implementation will be through staff but much will be through contracted services.

It is proposed that our Organization will have three divisions:

- Operations
- Finance and Audit
- Policy and External Affairs

The Operations Division will take much of the responsibility for the activities within Objectives 1 and 2. This will include operational and milestone monitoring. Some of the financial contracting arrangements will be monitored through the Finance and Audit Division who will also be responsible for reporting against financial expenditure to our donors.

4.3 Replication

The lessons learned through this project will be applied globally by GALVmed. Although this project works within Sub Saharan Africa and South Asia, we also intend to work in South Eastern Asia and Latin America.

We are however very well connected to the key organizations who are able to disseminate learning.

- OIE
- FAO
- DFID
- The European Union
- The African Union

All are represented as Observers on our Board.

GALVmed intends to open regional offices in Nairobi and New Delhi in mid and late 2008. At present the plan is to base our Policy Division in Nairobi, along with at least one Project Manager and support staff, and with a Project Manager and support staff in New Delhi. We wish to keep the exact arrangements flexible to reflect the qualities of the staff we are able to attract. It is also our intention to seek wherever possible staff from developing countries.

ⁱ Doherty Building, Pentlands Science Park, Bush Loan, Edinburgh, EH26 0PZ, Scotland, UK.