GALVmed

Protecting Livestock – Saving Human Life

Commercialisation Policy Summary

Introduction

Everything that GALVmed achieves, it does so through partnership. In order to succeed in its mission and mandate of facilitating the development of, and access to livestock disease control products for the millions who rely on livestock for livelihood, it is essential that GALVmed has an effective approach to identifying and selecting the most appropriate partners. Building on existing procedures, GALVmed has therefore developed a commercialisation policy to provide guidelines for the selection of commercialisation partners both for internal use and as a reference for potential partners. The policy is available in full, upon request to GALVmed (**info@galvmed.org**) and while the following is not intended to be exhaustive, it offers a flavour of the commercialisation policy's key concepts and considerations.

Interpretation of the policy

GALVmed understands "commercialisation" as meaning all or any of the activities, including development, manufacturing, registration, marketing and/or distribution undertaken by a single or by multiple actors, for introducing a new product, technology or process to the market. The commercialisation policy shall be applied whenever GALVmed intends to facilitate or undertake commercialisation. Whilst the policy sets out principles and policies that form GALVmed's general approach, applicability and appropriateness of the policy will be evaluated on a case-by-case basis.

The policy applies to all types of livestock disease control products that GALVmed is developing, including vaccines, medications, diagnostics, or other forms of technology or processes. In addition to serving as a policy for selection of a commercialisation process, some of the procedures set out in this policy inherently make-up part of the due-diligence process GALVmed may choose to undertake before appointing a partner. Any commercialisation decision made by GALVmed will need to take into account several factors related to the target product type (e.g. public good vs. private good) to determine how this policy will be interpreted and applied.

It is noted that most agreements between GALVmed, the commercialisation partner, and other related third parties, as a minimum, will include proper rights that guarantee adherence to Global Access (as defined in GALVmed's IP Policy).

GALVmed understands Global Access as meaning: a principle applied through the value chain, from research to use, which ensures sustainable access to the animal health products and solutions needed by those for whom livestock is a lifeline, ultimately improving livelihoods.

Generic Criteria for Commercialisation Partner Selection

The generic criteria which follow (1 – 4) will apply in various degrees, depending on the type of product that GALVmed intends to commercialise: 1) **Expertise and capacity**, 2) **Quality and regulatory**, 3) **Sales, marketing and customer service** and 4) **Internal Requirements.**

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Expertise and capacity

The ideal partner should be able to demonstrate experience and success in commercialising a similar product, have the capacity and resources (be they internal or external) to develop, enhance and produce the product, and have commercialisation experience in the markets relevant to the target product. It is also important that a commercialisation partner is committed, and has the capacity to conduct pharmacovigilance in order to ensure product performance and the addressing of potential adverse effects which may appear once the target product is utilised in the field.

Therefore, when considering expertise and capacity, the following criteria will be considered:

a Prior expertise in the field

b R&D capacity and expertise

c Production capacity: internal or contracted

d Regional commercialisation/production capacity and marketing expertise

e Ability in managing and maintaining an effective supply chain, as well as managing the order-to-cash process, both in terms of systems and compliance

f Pharmacovigilance and troubleshooting capacity

g Financial capacity to undertake necessary commercialisation tasks

Quality & regulatory

Suitable partners should have a demonstrated precedent for quality production of animal health products which are fit for purpose and conform to local and international standards for development, manufacturing, marketing and environmental impact.

Therefore, when considering quality and regulatory assurance, the following criteria will be considered:

a Quality standards (certified in the implementation of an internationally recognised quality standard)

b Biosecurity and environment standards

c Regulatory experience and requirements

Sales, marketing and customer service

GALVmed targets the markets of developing countries with a pro-poor approach to achieve Global Access. It is important that commercialisation partners understand the nuances to commercialisation of animal health products in such markets and are willing to commit to making a product available and accessible in the target markets. Such commitments may involve commitment to pricing corridors throughout various stages of commercialisation which will act to promote product and financial sustainability, increased marketing resources, customer sensitisation and support, or reduced focus on other markets which may provide better financial gain.

Therefore, when considering sales, marketing and customer service capacity, the following criteria will be examined:

a Price structure

b Product availability

c Geography: will it cover the areas of interest for GALVmed?

d Existing product range to support "product packages"

e Conflict of interest (potential cannibalisation of existing products)

f Sales targets

g Marketing activities

h Existing customer networks

i Customer and technical support

Other Requirements

Selection of a commercialisation partner also requires GALVmed to evaluate certain criteria which are pertinent to the organisation and its mission, these include:

a Reputation of the partner – GALVmed will consider circumstances under which the reputation of a potential partner may adversely impact stakeholders' or public's perception of GALVmed.

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b Operational ethics – operational ethics refer to the manner in which a potential partner conducts activities across all aspects of its business.

c Financial contribution of parties involved and equitable distribution of benefits generated in relation to such contribution.

d Capacity building – Commercialisation partners which commit themselves to local capacity building and utilisation of local human-capital, for the purposes of sustainability, will be generally favoured by GALVmed.

e Risk distribution and sharing – In selecting a commercialisation partner, GALVmed will attempt to distribute the risk in commercialisation of its portfolio of products across different partners as far as reasonably possible.

f Donor requirements as well as local and applicable legislation will always be considered by GALVmed in order to ensure that appointment of a commercialisation partner, and the overall commercialisation strategy do not conflict.

g Potential partners' commitments to sustainability and willingness to adhere to contractual measures (i.e. obligations or rights) which will support the notion of long term sustainability of the target product.

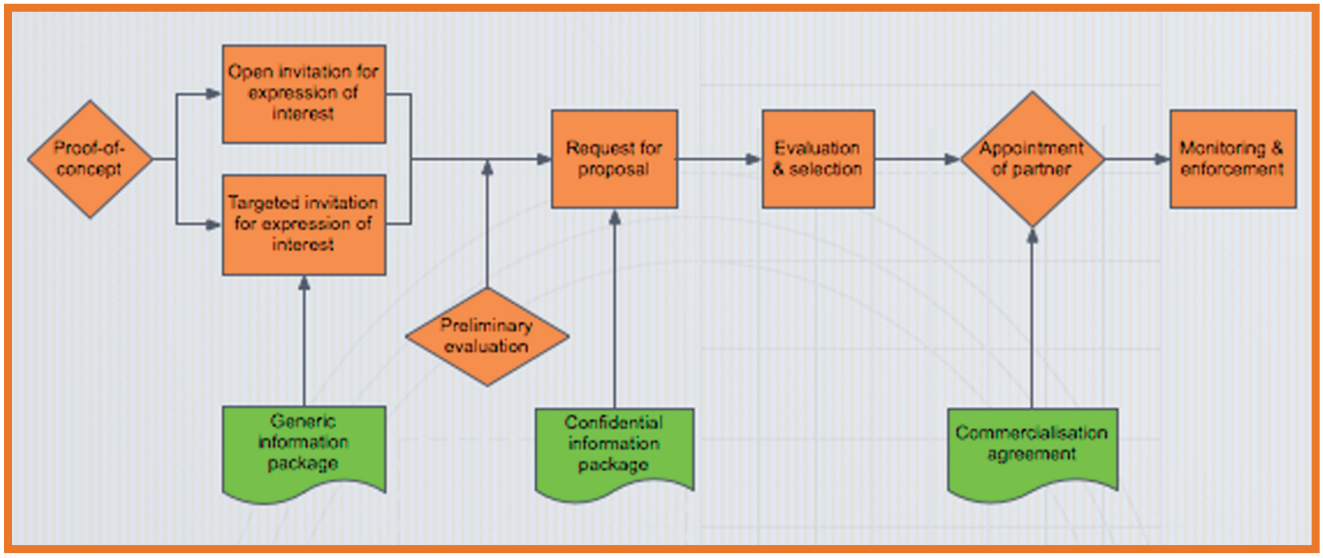
h Global Access Charter – the guidance provided by the Global Access charter should always be considered when selecting a commercialisation partner as well as throughout the process of commercialisation.

i Equitable distribution of generated benefits – ensuring that the benefits generated through commercialisation of a target product, be it financial or otherwise, are fairly distributed amongst all those who contributed to the creation of the target product (e.g. technology suppliers).

j Management of Market Authorisation licences – Commercialisation partner, when necessary, should be able to become Market Authorisation Holders (MAH) for a specific product. This should be balanced however, with Global Access obligations.

Partner Selection Process

The process which GALVmed will typically undertake in partner selection is outlined in the figure below.



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Partner Selection Process

Commencement

Engagement of a commercialisation partner will begin as soon as reasonably possible when a commercialisation opportunity is identified, or shortly before or after reaching PoC in relation to a target product.

Expression of Interest

An open-invitation for expressions of interest will be made through various outlets, e.g. GALVmed website, newsletter, etc.

GALVmed will also send out targeted invitations for expressions of interest to a list of organisations which it feels may prove to be appropriate commercialisation partners for the target product.

Organisations which express an interest will undergo a preliminary evaluation in which they will be rated on certain minimum requirements, including at the very least:

a Reputation

b Relevant capacities which are required

e Willingness, understanding of markets, and commitment

Request for Proposal

Applicants deemed to be appropriate potential commercialisation partners, will be requested to submit a thorough commercialisation proposal to GALVmed. Ahead of submitting such a proposal, each potential partner will be eligible to receive a confidential information package providing technical details on the target product. This package will describe the various obligations and requirements to which the potential partner must commit (specific to the target product) and may also include information which is proprietary to GALVmed and/or GALVmed partners.

A proposal submitted by a potential commercialisation partner should provide detailed descriptions on how the potential partner aims to achieve parameters set in relation to any of the generic criteria defined under Section 6 above (for example the price structure and the intended countries or area to be covered) as well as how it aims to fulfil any pro-poor performance indicators which may have been set by GALVmed.

Appointment of partner

Following a decision by GALVmed, the selected commercialisation partner will be notified of GALVmed's decision and contracting and negotiations will commence immediately. Any commercialisation agreement should include provisions in line with the GALVmed Intellectual Property Policy and Global Access Charter.

The commercialisation policy complements existing, enduring documents including:

- GALVmed Constitution
- GALVmed Global Access Charter
- GALVmed Intellectual Property Policy
- GALVmed Partnership Policy
- Any other GALVmed policy