

Global Access Charter

Global Access is an integral part of GALVmed policy which applies to all GALVmed activities. This Global Access (GA) Charter outlines the definition and gives an overview that guides and aligns GALVmed and its partners in order to ensure that Global Access is attained.

The Charter shall be applicable to GALVmed in all dealings with external partners, but is not prescriptive by nature. Adherence to the GA principle and recognition of this Charter is the joint responsibility of all GALVmed staff and management.

GALVmed defines Global Access as 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.

GALVmed considers Global Access at every stage

Research and Development:

GA is intrinsic in stages of research and development as it ensures that all upstream activities can ultimately be translated to globally accessible downstream solutions. Much forethought is given to implementing GA in these stages—requiring that both technical and legal aspects are evaluated and strategies are created which result in solutions appropriate for the target market. GALVmed commits to:

- apply GA when designing a Target Product Profile i.e. considering need/demand/socio-economics, including understanding the local cultural contexts.
- perform freedom to operate (FTO) and patent landscaping to mitigate risks which may impede downstream GA.
- evaluate and ensure that technological improvements will provide added value to GA.

- apply GA when in-sourcing technologies i.e. looking beyond only technical characteristics and conducting due-diligence to ensure that optimal access can be gained both for development as well as downstream activities. This can be done through identification of complementary, substitute technologies which may be available under better licensing terms.

Registration and Regulatory Affairs:

The registration of animal health products is central to making such solutions accessible. GA will be considered and implemented in this stage through activities which ensure that all steps are reasonably taken and all necessary regulatory information is collected in order to increase the likelihood of regional registration and ultimately, market accessibility. GALVmed shall work to:

- ensure, as far as reasonably possible, that products are fit for registration, when applicable, in target markets.
- make documents and resources available and mobilise effort required for product registration.
- facilitate local partners to manage registration processes.

Manufacturing:

The assurance that there is a sustainable supply of physical product through a manufacturing process is a key step towards guaranteeing access to such products and/or solutions downstream. The GA charter aims to support the manufacturing of the right product, at the right time, in appropriate quantity in order to meet demand/need. The following steps will be taken:

- Potential manufacturing partners should be selected in accordance with fair, transparent and equitable criteria, considering their capacity to produce (with respect to the Target Product Profile) and promoting sustainability through implementing standards in QA and QC.





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- > GALVmed will facilitate where appropriate, capacity building support, in order to ensure the sustainability and quality of the manufacturing process where necessary.
- > Promote sustainability through the use of commercial incentives and benefits to engage manufacturers which are compliant with environmental, welfare and industry standards.
- > In order to ensure long term continuity of manufacture, GALVmed will encourage the transfer of production capability, through local capacity building in order to stimulate self sufficiency in production.
- > Consider a strategy for managing partner ‘obligations’, including the retraction of certain benefits and incentives enjoyed by partners when such obligations are not fulfilled.

Distribution:

Sustainability cannot be achieved in the absence of well-developed distribution systems. Similarly, commercialisation of animal health products is enhanced when distribution partners/channels have been empowered with the right business and technical skills. GALVmed activities will support this in developing countries by:

- > promoting fair competition and free markets within the countries to the advantage of the ultimate beneficiaries.
- > selecting distributors according to fair and clear criteria and supporting those who want to be involved through formal commitment to raise their capacity and ensure GA.
- > seeking to ensure that all established distribution networks are sustainable by encouraging participants to realise profits in order to stay involved.
- > supporting the delivery of products/solutions in the most viable methods and to the highest quality standards.
- > supporting the delivery of GALVmed facilitated products to end-users at affordable prices by adopting appropriate pricing strategies.

- > assisting end-users in making informed decisions about their livestock by making available the latest technical information in relation to GALVmed products.
- > considering a strategy for managing partner ‘obligations’, including the retraction of certain benefits and incentives enjoyed by partners should such obligations not be fulfilled.

Policy and Support:

Stimulating and creating a conducive or enabling environment is essential with regard to the GA Charter. The supportive functions need to work in synergy to promote product/solution adoption and uptake in a holistic manner which harmonises and drives the principles of the charter. Key areas include:

- > alignment and synergy with global trends, local and regional initiatives, strategies and policies, with support to areas where these could be used as an advantage to the charter.
- > engagement with and support to policy and decision makers in addressing constraints in order to stimulate an enabling environment.
- > facilitation of evidence based clear messaging and targeted advocacy through appropriate product/solution communication strategies, stimulating beneficiary collaboration and empowerment thereby enhancing global access principles.
- > ensuring compliance with laws and regulations in respective countries whilst lending financial support and other resources to partners and beneficiaries in order to encourage active participation in the value chain.
- > considering that while the product is available, the proper supporting infrastructure is also required. E.g., making a product available and complementing that with community health workers trained in its use and handling.

Adopted this day of 2012

GALVmed is a not-for-profit global alliance of public, private and government partners. By making livestock vaccines, diagnostics and medicines accessible and affordable to the millions for whom livestock is a lifeline, GALVmed is *protecting livestock and saving human life*. It is currently funded by the Bill & Melinda Gates Foundation and the UK Government's Department for International Development (DFID).

GALVmed launches Global Access Charter

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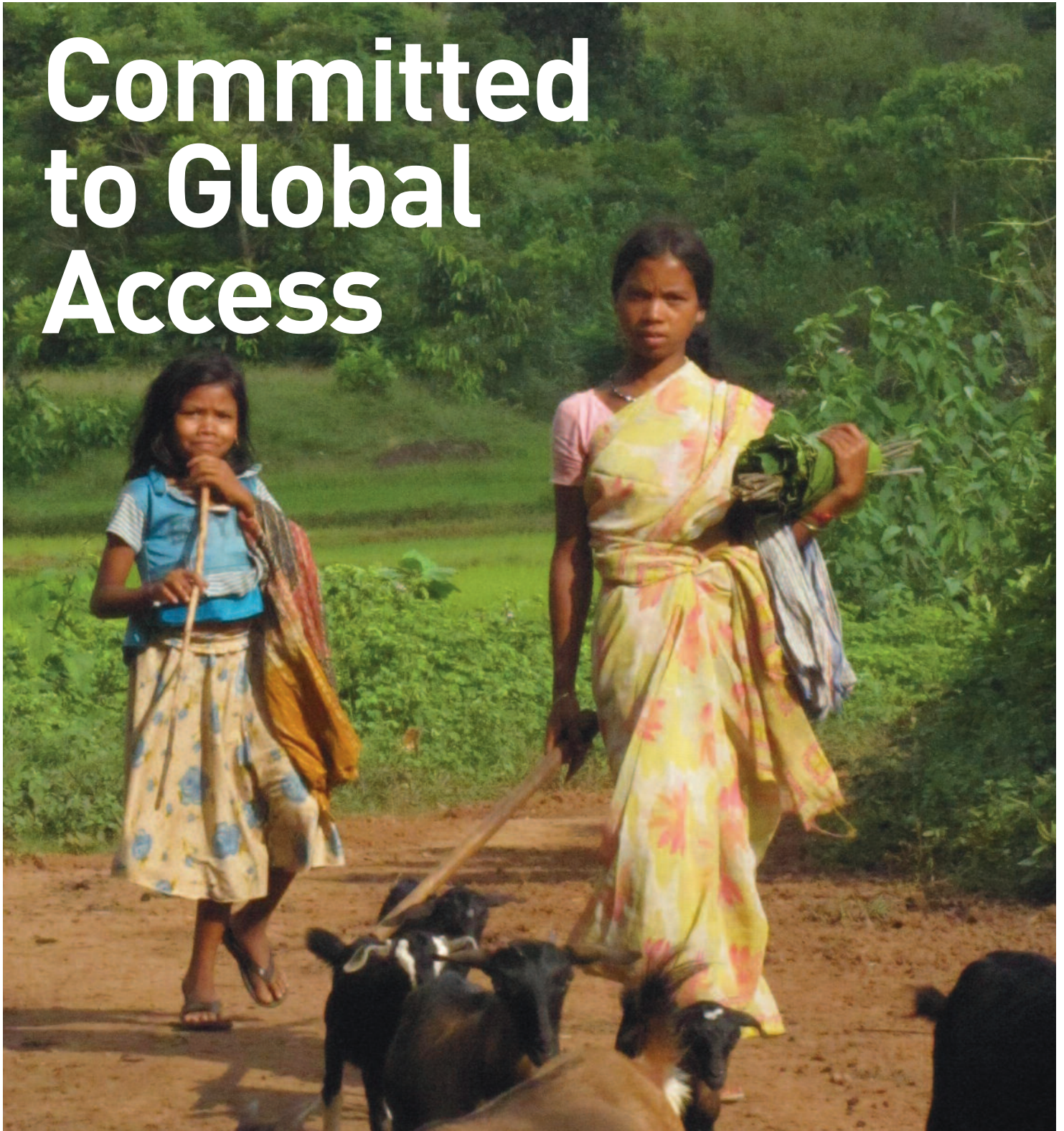
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GALVmed

Protecting Livestock – Saving Human Life

Committed to Global Access



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