AN ASSESSMENT OF THE POLICY FRAMEWORK AND VALUE CHAIN ANALYSIS FOR LIVESTOCK VACCINES IN SOUTH AFRICA

Submitted to the

International Development Research Centre

By

Human and Social Development Programme

Human Sciences Research Council (HSRC)

2018

This study was commissioned by the ARC's Onderstepoort Veterinary Institute (OVI) under the Project Novel livestock vaccines for viral diseases in Africa towards improved food security (CIFSRF 107848). The project is funded by Canada's International Development Research Centre (IDRC), www.idrc.ca, and the Government of Canada, provided through Global Affairs Canada (GAC), www.international.gc.ca. It was prepared by the Human and Social Development unit at the HSRC, Pretoria, South Africa, in collaboration with the Economic Analysis Unit of the ARC, Pretoria, South Africa.

It was prepared by the Human and Social Development unit at the HSRC*, Pretoria, South Africa, in collaboration with the Economic Analysis Unit of the ARC, Pretoria, South Africa.*

COMPILED BY

Prof Sarah Chiumbu– Senior Research Specialist (HSRC)

Mbongeni Maziya – Researcher (HSRC)

Ms Ntombizonke A. Gumede – Researcher (HSRC)

ACKNOWLEDGEMENTS

We gratefully acknowledge assistance received from the project implementation partners at the Agricultural Research Council and their support in this study. Special thanks also go to the smallholder livestock farmers of KwaZulu-Natal, Eastern Cape, Mpumalanga, North-West and Free State provinces for providing us with valuable information, without whom the completion of this study would not have been possible.

Table of Contents

1. Introduction

The concept of value chain for livestock vaccines is linked to a continuum of activities such as production, processing, and delivery of the vaccine to the livestock farmer.[1] Along with this is also the critical aspect of policy and regulation which facilitate the linking of producers to the markets and end-users. In the context of veterinary vaccines for smallholder farmers, the value chain processes are fraught with many challenges. For example, the way the veterinary vaccinology and advances in vaccine technology are developed has in most cases less to do with the role of smallholder farmers in this process.[2] In many cases, there is less consideration of farmer's localised usages of animal vaccines. Thus, in the value chain analysis of vaccine development, a pronounced emphasis must be placed on the geography and unique insights of animal diseases and knowledge of animal medicine which the population of local farmers has. Taking cognisance of farmers as a resource-based population in the vaccine value chain would help better understand their attitudes and willingness to use veterinary medicines.[3] This is especially important in the setting, such as South Africa, where many of the smallholder farmers have little or no formal education and thus may be unaware about the value of vaccines to their livestock. Furthermore, in South Africa many small-scale farmers reside in the rural areas where the provision of veterinary services is mostly constrained, further limiting their understanding of such services.

2. The context of the project

The Agricultural Research Council (ARC)s Onderstepoort Veterinary Institute (OVI), with funding and technical assistance from the Canadian International Food Security Research Fund (CIFSRF) jointly funded by IDRC and Global Affairs Canada, is in the process of developing a variety of recombinant livestock vaccines. The project addresses six diseases, and these are: *peste des petits ruminants* (PPR), lumpy skin disease (LSD), Rift Valley fever

[1] A. Rota (2010) Value chains. Linking producers to the markets. Retrieved from https://www.ifad.org/documents/10180/65cc8da1-d0f9-41d8-acb5-1175850b768f

[2] B.K Dungu, (2011). Assessment of vaccine delivery systems and their impact on the enhancement of immunogenicity, potency and safety of specific livestock vaccines in South Africa. Unpublished Thesis. University of Pretoria. South Africa

[3] A. Peters (2011) A survey of agricultural production, livestock disease treatment and vaccination in rural farming communities in two provinces of Kenya. Retrieved from https://www.gov.uk/dfid-research-outputs/a-survey-of-agricultural-production-livestock-disease-treatment-and-vaccination-in-rural-farming-communities-in-two-provinces-of-kenyaPeters, p. 3

(RVF), sheep pox, goat pox and African swine fever (ASF). However, vaccines for five of these diseases (PPR, LSD, RVF, sheep pox and goat pox) are already available on the market. In this project, the aim is to minimize the cost of these vaccines by producing a single vaccine requiring only one dose that will protect against these five diseases in different combinations (i.e., in sheep and goats the vaccine will protect against sheep pox, goat pox, PPR and RVF, and it will protect against LSD and RVF in cattle). Apart from cost-effectiveness, the vaccine developers are using a live vector platform technology to improve the thermostability of the vaccines, and this will redress the necessity of a cold chain in their delivery.

The introduction of a single dose may help solve the problem of low usage of animal vaccines among smallholder livestock farmers. Farmers often vaccinate for a while following a disease outbreak but reduce vaccine usage in subsequent years in the absence of disease, resulting in a build-up of a large, highly susceptible livestock population (e.g., RVF). With the use of a single dose combination vaccine, for instance, when they vaccinate for LSD on an annual basis, farmers will get dual protection for both LSD and RVF. These vaccines will impact positively on food security by increasing production efficiency and decreasing animal losses due to disease.

The project also studies the links between vaccine development and social and economic factors to evaluate the economic impacts and ensure the relevance and uptake of the new vaccines by emerging small-scale farmers. Ultimately, the project is directed toward promoting greater food and economic security through improved animal health. To this end, the ARC-OVI has partnered with the Human Sciences Research Council (HSRC), which is working closely with the socio-economic unit of the ARC.

3. Objectives of the legislative analysis and value chain analysis

Value chains do not exist in a vacuum. They are part of larger socioeconomic systems and institutions in a country. These institutions may be formal (i.e., legislation or laws) or informal (i.e., cultural practices) and operate at diverse scales. These larger systems can facilitate, limit or be neutral to the development of the value chain.[4] In this context of this value chain analysis, it is important to assess how these formal and informal institutions affect the participation of small-scale farmers, especially women, in the value chain.

[4] The Value Chain Map. Retrieved at https://www.ser.nl/nl/~/media/894adb278220446bb91e4e0ae41ec753.ashx

This report aims to outline the regulatory, legislative and policy environments into which the 3-in-1 or 2-in-1 vaccine will enter and to explore the new vaccines' value chain (looking at actors, supporters, enablers, and disablers along the value chain) with smallholder livestock farmers as the main end-users. The multivalent vaccine will be manufactured by Onderstepoort Biological Products Ltd (OBP), which is a South African state-owned animal vaccine manufacturing body, which ensures vaccine affordability through varied distribution channels. Specifically, OBP is a subsidiary of the Department of Agriculture, Forestry and Fisheries (DAFF). The overall regulatory framework analysis and the value chain analysis is done to ensure the vaccine's effective manufacturing, marketing, distribution, and eventual roll-out and to inform the development of an effective vaccine delivery strategy.

4. Methodology and Approach

The study uses four main methods for collecting data: (1) a review of secondary information associated with the livestock vaccine policy framework and value chain in South Africa (2) interviews with relevant stakeholders in the field of livestock vaccines; (3) a quantitative and qualitative study on knowledge, attitudes and practices (KAPP) of livestock vaccines by smallholder farmers across five provinces (Eastern Cape, KwaZulu-Natal, Free State, North West and Mpumalanga)[5], and (4) policy and stakeholder engagements held over two years with policy actors and other relevant stakeholders.[6]

5. The significance of the livestock sector to the South African economy

Agriculture plays a crucial role in the broader economy, constituting about 6 percent of South Africa's total labour force. Livestock farming plays an important role in the agricultural sector for most countries. The 2016 *Quarterly Labour Force Survey* from Statistics South Africa revealed that livestock is one of the areas that showed significant job growth.

[5] This study administered a structured questionnaire to 593 livestock farmers who were selected across the five provinces and focus group discussions among a selection of these farmers. The findings revealed crucial information related to legislative and policy barriers and user experiences of the value chain analysis

[6] These dialogues were as follows: 1) "Primary Animal Healthcare in the context of disease prevention and scaling-up for small-scale farmer communities: Research, policy and delivery" held on the 11th of May (2) "New Generation Vaccines and Animal Health in Africa: Research, policy and delivery" held on 1 September 2015 and (3) "Livestock Vaccine Value chains in South Africa: Linking producers to the markets and end-users", held on 8 November 2017.

Livestock, horticulture and crop farming are the largest contributors to agriculture's total labour force, employing 64 percent. Livestock production contributes substantially to the South African economy. Nearly 80% of the agricultural land allows for animal husbandry. Livestock products account for more than 40% of the total value of agricultural output[7]. Furthermore, livestock production is partially rural based, therefore contributing significantly to food security and sustainability. Data provided by the Department of Agriculture Forestry and Fisheries (DAFF) suggest that in 2016, there were about 13.4 million heads of cattle, 20 million sheep and 1.8 million goats in South Africa. It is further estimated that about 40% of this livestock is in the hands of smallholder farmers in rural communities. This represents approximately 240 000 smallholder farmers currently rearing livestock in South Africa.[8]

In addition to livestock's significance to the economy, it also plays several social and cultural roles and functions. Many smallholder rural farmers use livestock both as a 'bank,' whereby cattle can be sold to pay for emergency needs and cultural purposes.[9] With this immense and potentially productive resource, with such influence on household incomes as well as the national economy, it is imperative for South African small-scale farmers to maximize the economic value of their animal assets and vaccinations play an important role in this regard.

Although livestock production plays an important role in the economies of most nations, livestock remains vulnerable to diseases, which sometimes result in outbreaks. Immediate impacts of a disease outbreak include a reduction in the productive capacity of the animals and a subsequent reduction in the supply of meat and meat products[10].

[7] Livestock Development Strategy for South Africa (2006). Department of Agriculture

[8] Department of Agriculture, Forestry and Fisheries (DAFF). 2016. Trends in the agricultural sector. Retrieved at http://www.daff.gov.za/Daffweb3/Portals/0/Statistics%20and%20Economic%20Analysis/Statistical%20Information/.Trends%20in%20the%20Agricultural%20Sector%202016.pdf

[9] Reddy V, Goga S, Timol F and Molefi S (2016) *The socioeconomics of livestock keeping in two South African communities: A black man's bank.* Cape Town: HSRC Press

[10] Pritchett, Thilmany & Johnson, 2005, cited in N. Mdlulwa and K. Klein (March 2015) Socio-economic Impacts of Lumpy Skin Disease and Rift Valley Fever on the South African Livestock Economy

6. The legislative and policy framework for vaccine development

6.1 Legislative Framework

In South Africa, the state is responsible for the development of strategies and legislative frameworks that guide the manufacturing and registration of new vaccines. There are two government departments responsible for regulating vaccine development – the **Department of Agriculture, Forestry and Fisheries** (DAFF) and the **Department of Health**. There is often no synergies between these two departments and as a result the process of vaccine development becomes cumbersome to developers.

The DAFF administers the *Fertilizers, Farm Feeds, Agricultural, and Stock Remedies Act* No. 36 of 1947, which regulates all veterinary vaccines in the country. The Department of Health administers two key Acts - the *Animal Disease Act*, 1984 (No. 35 of 1984) and the *Medicines and Related Substances Control Act*, 1965 (No. 101 of 1965 & Amended in 2008). Before a vaccine is manufactured the manufacturer of a vaccine has to first get permission/authorization from Act 35 (Animal Disease Act).

a. The Fertilizers, Farm Feeds, Agricultural and Stock Remedies Act

The Act makes provision for the control on the trade in and placing on the market and use of fertilizers, pesticides and biological control agents for use in agriculture, products for the feeding of domestic animals or livestock and substances used for the maintenance or improvement of health of domestic animals, livestock, poultry, birds, wild animals or fish. This Act is also responsible for registering livestock vaccines in the country.

b. The Animal Disease Act, 1984

The Act provides for the control of animal diseases and parasites and measures to promote animal health and related matters. The Act provides guidelines on how clinical trials ought to be conducted. All medicine and vaccine manufacturers are required to get permission under Act 35 before they start manufacturing their vaccines. This is to make sure that researchers or vaccine manufacturers follow strict guidelines as dictated by the Animal Disease Act. The Act aims at ensuring that good ethical research practices are followed when conducting

animal trials; from the design to the actual experimentation. In cases where good practices are not followed, this can result in the outbreak of diseases which are unknown and might be hard to cure, and this can result in economic implications for the country.

c. *Medicines and Related Substances Control Act*

The Act aims to provide for the registration of medicines and related substances intended for human and for animal use. The Act was amended in 2008. The Amendment Act of 2008 must be read together with a further Amendment Act, being the Medicines and Related Substances Amendment Act, No 14 of 2015. Both Amendment Acts come into force simultaneously and give effect to numerous amendments to the Medicines Act.[11]

Other Acts that have a bearing on vaccine development, manufacturing and registering are as follows:

- Pharmacy Act, Act No. 53 of 1974
- Trade Marks Act, Act No. 194 of 1993
- Veterinary and Para-Veterinary Professions Act, Act No.19 of 1982
- Patents Act, Act No. 57 of 1978

This legislative framework is supported by the guidelines offered by the following:

- Guidelines as laid out in Fertilizers, Farm Feeds, Agricultural and Stock Remedies Act
- Guidelines offered by the Medicines Control Council of South Africa (MCC)
- Guidelines provided by the International Committee for Harmonization of Veterinary Pharmaceuticals (VICH)

6.2 The Policy framework

Veterinary services are indispensable to the sustained health and well-being of animals and people. The South African state has a long history of involvement in the provision of extension services and the provision of Primary Animal Healthcare (PAHC) to smallholder rural communities. The government has created a policy framework for PAHC, which first

[11] Neil Kirby "A new regulatory regime for medicines comes into force in SA" Sunday Times, Retrieved at https://www.timeslive.co.za/news/2017-06-15-a-new-regulatory-br-regime-for-medicines-br-comes-into-force-in-sa/, accessed 15 June 2018

started with an Animal Disease Management Plan (2015) and later developed into the South African Veterinary Strategy (2015-2020).

a. The Animal Disease Management Plan (2015)

The animal health management plan was developed with the mission "to ensure that human and animal well-being is optimized through strategic livestock development in respect of food security, agrarian transformation and rural development, and in supporting industrial development.[12]

b. The South African Veterinary Strategy (2015-2020)

The Strategy was developed in 2015 to improve the performance of Veterinary Services in South Africa. Its development followed an evaluation of Performance of Veterinary Services of South Africa conducted by the Office of International des Epizooties (OIE) – [the World Organization for Animal Health] in October 2012 and June 2014. The purpose of the evaluations was to assess Veterinary Services in relation to international norms and to advise and assist South Africa in developing strategies to overcome challenges faced by Veterinary Services. [13] The current veterinary strategy has been developed with the mission "to ensure that human and animal well-being is optimized to strengthen the internal market and the competitiveness of the livestock sector value chain."[14] The purpose of this veterinary strategy is to provide direction for the improvement of the delivery of veterinary services (VS) to higher standards in South Africa. It will facilitate the establishment of priorities that are consistent with agreed strategic pillars and the revision of, and agreement on, acceptable and appropriate standards.

7. Value chain processes

[12] Ibid
[13] "Livestock and Small-scale Farmers: Policy Perspectives, Department of Agriculture, Forestry & Fisheries", presentation by Tembile Songabe Director Veterinary Public Health at the DAFF at the HSRC Policy Dialogue, "Primary Animal Healthcare in the context of disease prevention and scaling-up for small-scale farmer communities: Research, policy and delivery" held on the 11th of May 2015 in Pretoria.
[14] The South African Veterinary Strategy, p.6

A value chain is a key framework for understanding how a product is brought together and how the product then moves physically from the producer to the customer; and how value increases along the way.[15] The value chain perspective provides an important means to understand -business relationships that connect the chain, and ways to increase/add value along the chain.

7.1 Stages in the value chain

Apart from legislation discussed above, the following are the other stages in the value chain of livestock vaccine.

- Production
- Marketing
- Distribution (cold chain processes)
- End-user/Reception

7.2 Value chain map/actors

In the animal vaccines value chain in South Africa, the actors are as follows:

- Developers
- Manufacturers
- Suppliers/Sellers
- End-users

7.2.1 Vaccine development/production

Vaccine development is a long, complex process, often lasting 10-15 years and involving a combination of public and private involvement. The process is also complex and costly. Other key challenges include identifying suitable antigens, adjuvants, regulatory approvals, technical and manufacturing hurdles.[16] Public vaccine innovation and development in South Africa is mainly done by the Veterinary Research Institute (OVI) that falls under the Agriculture Research Council.

[15] McCormick and Schmitz 2001, p. 155
[16] Vaccines for Africa. Retrieved at http://www.vacfa.uct.ac.za/vaccine-development-process

7.2.2 Vaccine manufacturing

Vaccine manufacturing in South Africa is done by Onderstepoort Biological Products Ltd (OBP) and other smaller companies such as AfriVet, Deltamune, and Zoetis South Africa. OBP, the state-owned company, manufactures a range of vaccines for cattle, sheep and goats, horses and poultry. While OBP is a subsidiary of the Department of Agriculture, Forestry and Fisheries, its primary aim is to "prevent and control animal diseases that impact food security, human health, and livelihoods." Its mandate is to "ensure vaccine affordability and accessibility through diverse distribution channels". As a state-owned company, OBP believes they "have a responsibility to provide for the public as stakeholders".[17] Currently, OBP manufactures 52 different animal vaccines.

The following organogram shows the macro-structure of the company, showing the close alliance of the company to the Department of Agriculture, Forestry and Fisheries and the natural alliance between the ARC and OBP in working together to promote vaccine use

[17] http://www.obpvaccines.co.za/Cms_Data/Contents/OBPDB/Media/downloads/OBP%20Annual%20Report%202015.pdf

among smallholder livestock keeping communities:

The fit between the ARC and OBP in working together in the manufacture and roll-out of the vaccine on this project is further underlined by the fact that OBP aims to "contribute to government priorities concerning food security and economic growth."

OBP has since the 2014/2015 financial year implemented international manufacturing practices, often referred to as GMP (Good Manufacturing Practices).[18] These principles and practices coincide with an upgrade of the manufacturing facilities and are meant to "[cover] all aspects of production from the starting materials, premises, and equipment to the training and personal hygiene of staff." GMP certification is meant to open international markets for

[18] OBP 2014/2015 Annual Report, pages 22-23.

OBP, reduced production costs and increased efficiency, preventing batch failures occurring at late stages.

To ensure the quality of its products, OBP is ISO 9001-2000 accredited, and all its quality assurance processes and procedures are maintained and overseen by the Quality Assurance department.[19]

OBP has two departments dealing with quality control; Quality Control (QC) laboratory and Experimental Animals (EA). "Both these departments are dependent on each other and are mainly responsible for quality control testing of intermediate and final products. For the release of products OBP complied with set international specifications according to the *Office de international des epizooties* (OIE) manual, the *European Pharmacopeia* as well as the *British Pharmacopeia*."[20]

Regarding quality control and assurance then, OBP is following the highest international standards, and the EA department ensures that the use and treatment of animals in trials and testing occurs according to these standards. The company's annual report shows that the EA department has been responsible for:

- Management and welfare of all animals within the facility "to the highest ethical standards."
- Ensuring that all relevant staff handling animals are registered with the South African Veterinary Council (SAVC)
- Ensuring conformity with DAFF requirements through weekly inspections ("to date, there have never been any findings of non-conformances against the department")
- Quarterly inspections by the NSPCA (the National Council of SPCAs, the councils aimed at preventing cruelty to animals and promoting the welfare of animals) ("all their recommendations were implemented as suggested").[21]

[19] OBP 2014/2015 Annual Report, page 31.
[20] OBP 2014/2015 Annual Report, page 31.
[21] OBP 2014/2015 Annual Report, page 31.

7.2.3 Vaccine Distribution

Distributors of vaccines play an important role in the value chain by ensuring that the cold chain is maintained from supplier to end-user. Prominent distributors and wholesalers of animal health care products in South Africa include TWK Agriculture, Senwes and Obaro. Obaro, in particular, offers after-sales vaccination training to farmers and visit them regularly to ensure that the products are used correctly. Distribution of livestock vaccines in the country is done by a variety of actors as shown as follows: Cooperatives, wholesalers, government and veterinarians.

OBP has increased access to vaccines in rural areas by recruiting Black Economic Empowerment (BEE) partners who are distributing vaccines. The distributors are trained on how to handle vaccines and are given discounts, and this has improved access to vaccines in rural areas. These BEE distributors are monitored to make sure that they keep the vaccine cold chain.

Key commercial distributors of livestock vaccines are as follows:

- Obaro
- ANB Vet
- Senwes
- Afgri
- Intervet South Africa
- Midlands Veterinary Wholesalers

7.2.4 Suppliers/Sellers

Suppliers in the value chain are the retailers responsible for selling the vaccine to local farmers. As distributors above, they are also responsible for maintaining the cold chain. In the local shops, farmers are also advised on how to use best the vaccine (i.e., maintaining the cold chain and instructions on the general use of the vaccine). In most cases the sellers often sell vaccines to farmers which are packaged in a manner that keeps/maintains the cold chain.

7.2.5 End-users

The end users of the vaccines are the livestock farmers. The effectiveness of the vaccine solely depends on the handling (i.e., maintaining the cold chain) and correct application of the vaccine. These farmers work hand in hand with State Vets and Animal Health Technicians whose purpose is to provide advisory services regarding Primary Animal Health Care (PAHC).

8. Supporting actors and services in the cattle value chain

Although supporting actors such as farming cooperatives, NGOs, and some private business and professional associations are not included in value chain core stages, they nonetheless occupy a critical role in the functioning of the value chain and enable the chain to operate efficiently. These public or private sector partners can provide support at critical points of the core stages. In chains that do not function efficiently, these actors are often missing. In South Africa, we see that these actors do not play a meaningful or visible role in the chain, as will be explained later. Some of these actors are as follows:

- South African Veterinary Association
- African Farmers Association of South Africa
- Livestock Health and Production Group
- Milk Producers Organization
- Red Meat Producers Organization
- National Animal Health Forum
- National Wool Growers Association

9. Challenges and Opportunities in the livestock vaccine value chain

Although South Africa has strong systems and actors along all the points of the value chain, there are challenges that exist, especially in regards to small-scale farmers. There are also opportunities to be harnessed from the whole process.

9.1 The legislative environment

South Africa has an adequate legislative and policy environment for both livestock vaccine development and primary animal health care. Also, the country has a range of veterinary services to support livestock production and trade. However, despite the existence of strong policies, access to vaccines at the end-user level remains a challenge. Several issues cause the challenges as outlined below:

- **Fragmented policy environment:** There seems to be a breakdown in the chain of command between the central and provincial government. Constitutional arrangements regarding animal health have in part caused this problem. The Constitution of the Republic of South Africa (Act No. 108 of 1996) decentralised veterinary services, making it a concurrent function to be performed by both national and provincial veterinary authorities. As a result, the regime of veterinary public health services is fragmented and divided among a largely uncoordinated multitude of government agencies.[22] This then creates challenges along the value chain.

- **Strong state role:** The state is responsible for the development of strategies and legislative framework that guides the manufacture, registration of new vaccines, including access of these vaccines to small-scale farmers. The state is therefore accountable for the implementation of the relevant control measures. The tensions lie in diseases that are important at the farm or village level but not theprioritised for State intervention. For instance, Rift Valley fever, Lump Skin Disease (LSD) and Blue Tongue are diseases that are categorised as notifiable, meaning that they should be reported to the State, but all control measures including vaccination are the responsibility of the owner/s. The government provides advisory services and in certain areas vaccines. There needs to be a more thorough interrogation particularly of the state's role in PAHC given that any large-scale intervention in PAHC for smallholder livestock farmers and keepers will necessarily require the involvement of the state at national, provincial and local levels.

[22] R Morane (2015) Primary animal health care: Issues and challenges. Presentation to Policy Dialogue on Primary Animal Health Care in the Context of Disease Prevention and Scaling-up for Small-Scale Farmer Communities: Research, Policy and Delivery, Pretoria, 11 May 2015

- **Lack of agreed principles on Primary Animal Health Care:** Although the country has finally adopted a Primary Animal Health Care Policy (PAHC) and Strategy, there are no agreed principles of primary animal health care between the different stakeholders. For example, the term "primary animal health care" and its roles and responsibilities need a proper definition. At the moment, meanings of "primary animal health care are contested. An evaluation of the performance of The South African veterinary services conducted by the Office of International des Epizooties (OIE – the World Organisation for Animal Health) in October 2012 and June 2014 confirmed the challenges facing PAHC, which found that animal health interventions are poorly defined due to policy fragmentation.[23]

- **Regulatory barriers in vaccine development chain:** There appears to be regulatory and legislative barriers to testing, registration, field trials, production and manufacture of the vaccine. This chain is riddled with limited coherent and cohesive policy direction.

- **Gender neutral policies:** Most social policies are written in gender-neutral language, but their effects are frequently different for men and women. Currently, the policies on PAHC and vaccine development in South Africa seem to be gender-neutral. Moreover, there's no point along the value chain where there is a consideration for gender dynamics, i.e. manufacturing a vaccine which women can use easily. Also, existing policies and programmes and initiatives supporting small-scale livestock farming do not seem to take into account the impact, role, and effects of gender on intra-household and inter-household dynamics to differing degrees.[24]

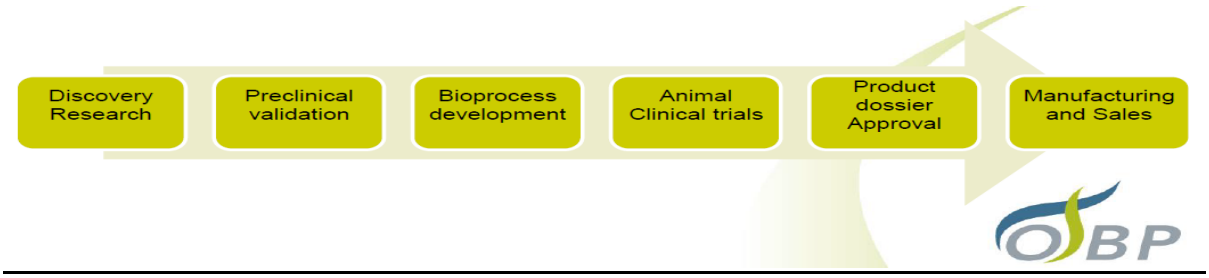
9.2 The production and manufacturing chain

South Africa has a comprehensive vaccine manufacturing value chain which matches international standards and this offers great opportunities for the vaccine value chain. But challenges exist that need overcoming. For instance, the registration process and approval timelines are too long and cumbersome. For example, the following shows the process:

[23] T Songabe (2015) Livestock and smallscale farmers: Policy perspective. Presentation to Policy Dialogue on Primary Animal Health Care in the Context of Disease Prevention and Scaling-up for Small-Scale Farmer Communities: Research, Policy and Delivery, Pretoria, 11 May 2015

[24] V Reddy, S Goga, F Timol S Molefi, A Mather, T Chetty and D Wallace (2015) Gender, small-scale livestock farming and food security: Policy implications in the South African context. *HSRC Policy Brief*, March 2015

- Long review times (>600 calendar days)
- GMO approval
- Clinical trials (safety and efficacy) required with the final product
- Field studies (2 geographical sites)
- Animal Health Act Section 20 approval
- Real-time stability studies on 3 consecutive batches (final product)
- No phased review



9.3 The marketing and distribution chain

The animal health industry in South Africa is worth around R6.8 billion, and vaccines account for one-third of the market value.[25]OBP dominates this market, and it currently manufactures 52 different animal vaccines. To maximise profit, in 2001 OBP partnered with private actors, but this has created problems. The distribution of vaccines was concentrated on commercial farmers, and smallholder farmers struggled to access them (vaccines). The reality is that most users of animal health products are commercial farmers who contribute more than 80% of revenue to companies while emerging or small-scale farmers contributes less than 20% of the total revenue. Thus, most companies/distributors focus only on the lucrative commercial market[26]. The OBP has ended its partnership with the private sector and has come up with a direct sales strategy to improve accessibility to vaccines. Because of this strategy, selling points have increased from eight to 555, and this has resulted in an increase of OBP's market share locally to 28%. OBP has also increased accessibility to vaccines in rural areas by recruiting Black Economic Empowerment (BEE) partners who are distributing vaccines directly to smallholder livestock farmers. The distributors are trained on how to

[25] A Report of the Stakeholder Engagement Workshop on: Livestock Vaccine Value chains in South Africa: Linking producers to the markets and end-users. The Human Sciences Research Council, 8 November 2017
[26] Bethuel Nthangeni (2016) Animal health challenges in SA - industry perspective. Presentation given at the HSRC Policy Dialogue on New Generation Vaccines and Animal Health in Africa: Research, policy and delivery, 30 August 2016, Pretoria

handle vaccines and are given discounts. According to OBP, this strategy has improved accessibility to livestock vaccines, but not to a meaningful extent. There are still challenges in the marketing and distribution as follows:

- **Cold chain processes:** Some vaccines are not accessible by farmers (sometimes including commercial farmers) because of stringent cold chain requirements. High distribution cost to maintain cold chain is becoming too expensive for most distributors and suppliers of livestock vaccines.

- **Creation of 'artificial' vaccine shortage:** Another obstacle results from the rationalization of vaccine access by distributors, making some vaccines inaccessible, as they choose which vaccine to sell or not, thus creating an "artificial" vaccine shortage.[27]

9.4 The end-user chain

Communal or small-scale farmers form an important core of the livestock value chains. In the five provinces surveyed by the HSRC-ARC KAPP study, for example, livestock keeping is integral to the communities.[28] The KAPP study surveyed five provinces and 593 households and the following challenges were identified:

- **Transport problems**: Most small-scale livestock owners find it difficult to acquire access to veterinary clinics and veterinarians. The main reasons given for this are related to the distances to the service and poor road and transport networks. As a result, many farmers have no contact with state veterinary personnel.

- **Inadequate cold chain processes:** Although in the KAPP study mentioned above, most farmers indicated that they own and have access to refrigerators (82% of households have fridges), due to unstable supply of electricity, the efficacy of the vaccine is compromised. Also, the study observed that smallholder livestock farmers store their vaccines in the same fridge where they store household food items. This poses a danger especially in households where there are children.

[27] A Report of the Stakeholder Engagement Workshop on: Livestock Vaccine Value chains in South Africa: Linking producers to the markets and end-users. The Human Sciences Research Council, 8 November 2017
[28] The study surveyed 593 households in 5 provinces, 8 Districts.

- **Inadequate knowledge:** There is lack of understanding of the value of healthy animals by most small-scale/ communal farmers". Most farmers (85.3%) indicated that they have never received any form of training relating to primary animal healthcare. This is an indication of bottlenecks in the delivery of animal healthcare services in rural areas.

- **Dwindling extension services:** After 1994, the ANC government curtailed national veterinary provisions. Since then less money has been invested in regular dipping or systematic vaccination, and as a result, many South African smallholders are increasingly reliant on their strategies to cope.[29] The rolling-back of veterinary extension services in the country is also due to privatisation and government cutbacks over the past decade and this is a worrying trend. The following factors compound the South African animal health environment:

    - A general shortage of available veterinary professionals
    - The skewed distribution of the few available veterinary professionals in favour of urban areas and "lucrative" career paths.
    - Deterioration of the veterinary infrastructure
    - Declining resources and budgets for veterinary services[30]

- **Gender dimensions:** Women play important roles in the livestock value chains. When women own livestock, it constitutes an important component of their asset portfolio, being an asset that they can easily own, and that is not bound by most of the legal and property rights issues. However, culturally, livestock ownership in rural areas is skewed in favour of men. In cases where women own livestock farms, men often frown upon them. This is a clear indication of the deeply rooted cultural views on livestock farming. Women usually own livestock when the household head (man/husband) has died, but the knowledge of how to correctly vaccinate livestock dies with the husband.

[29] William Beinart (2015) Between traditional and biomedical knowledge on animal health: implications for policy and practice. Presentation given at the Policy Dialogue on Primary Animal Health Care in the Context of Disease Prevention and Scaling-up for Small-Scale Farmer Communities: Research, Policy and Delivery, Pretoria, 11 May 2015

[30] Songabe presentation

10. Conclusion and Recommendations

Although South Africa has made great strides in developing policies on animal health and disease prevention management, there is a need for further policy development, underpinned by evidence-based interventions. There is also a need for policy re-alignment. For instance, livestock production and veterinary services are treated separately. This gap needs to be addressed. Still in the policy arena, there is also the need for policy debate to define and decide whether South Africa has small-scale (subsistence) farming. This is controversial, but a necessary discussion that needs to take place. There are also contested meanings of "primary animal health care." There is currently the absence of definition/policy/strategy.

The livestock vaccine value chain – from policy to the end-user – should take into consideration the needs of the small-scale farmer, especially in resource-constrained rural areas. There is a need to initiate a dialogue with smallholder livestock farmers so that stakeholders can have a shared vision or a model for developing both appropriate livestock vaccination and the smallholder livestock farming sector. This will enable the stakeholders to form solutions on the current challenges facing farmers jointly. There is also a need to improve access to information, whether its product-related, technical or concerning primary animal health care. The information must be accurate so that it caters to the interests of smallholder livestock farmers. This can be done through a variety of channels such as study groups, farmers' days, social media and local radio stations. There must be a central point of information dissemination within local areas, and stakeholders should engage farmer organizations and get cooperatives to work together. All these interventions meant to help smallholder livestock farmers should consider gender and migration dynamics in rural areas.

The 3-in 1 and 2-1 vaccines being developed by ARC-OVI provides an opportunity for re-orientating the relationship between the ARC and OBP; the ARC/OBP relationship to DAFF's national developmental priorities, and through this, ARC/OBPs relationship to most of smallholder livestock keeping communities that have thus far been largely left out of policy picture since they are not seen as job creators or profitable or well-integrated into the formal market economy somewhere along the livestock production value chain.

11. Action Plans to deal with Constraints and Obstacles

- The government, in conjunction with relevant stakeholders, need to develop an effective vaccine delivery strategy;
- Communication between different actors should be enhanced by all stakeholders involved
- Foster synergies among livestock value chain actors through establishment of innovation platforms for information sharing and learning in order to enhance efficiency along the vaccine value change. Farmers should also be shown the real impact of vaccination to motivate them to vaccinate their animals (farmer-to-farmer influence, creating suitable media material).
- Government should identify entry points or key leverage points to improve the value chain
- There is need to create platforms for private-private or public-private dialogue and decision-making. NGOs, private business and professional associations need to play a more visible and active role in value chain core stages.
- Government should support the development of cost effective ways to increase farmers' access to vaccines
- Government interventions should consider the needs of woman livestock keepers
- Interventions should factor in the needs of neglected groups such as communal women livestock farmers

References

Dungu, B. K. (2011). Assessment of vaccine delivery systems and their impact on the enhancement of immunogenicity, potency, and safety of specific livestock vaccines in South Africa. Unpublished Thesis. The University of Pretoria. South Africa.

Mdlulwa, N and Klein, K (2015) Socio-economic Impacts of Lumpy Skin Disease and Rift Valley Fever on the South African Livestock Economy. Retrieved at http://www.arc.agric.za/Economic%20Impact%20Assessment%20Studies/Socio-Economic%20Impacts%20of%20%20Lumpy%20Skin%20Disease%20and%20Rift%20Valley%20Fever.pdf

Peters, A. (2011). A survey of agricultural production, livestock disease treatment and vaccination in rural farming communities in two provinces of Kenya. Report of a survey carried out for GALVmed by Biotechnology Trust Africa. Retrieved from https://agriknowledge.org/downloads/q524jn78d

Pritchett, J, Thilmany, D. and Johnson, K. 2006.Understanding Broader Economic Effects of Livestock Insurance and Health Management: Impacts of Disease Outbreaks on Allied Industries. The Economics of Livestock Disease Insurance 17:207-221

Rota, A. (2010). Value chains. Linking producers to the markets. Retrieved from https://www.ifad.org/documents/10180/65cc8da1-d0f9-41d8-acb5-1175850b768f

Wallace, D. B., Mather, A., Chetty, T., Goga, S., & Babluk, S. (2014). Five diseases, one vaccine – a boost for emerging livestock farmers in sub-Saharan Africa. WRENmedia