GLOBAL BENCHMARKING SURVEY 2020

Benchmarking the competitiveness of the global animal health industry

SOUTH AFRICA
AUSTRALIA
BRAZIL
CANADA
CHINA
EUROPE
INDIA
JAPAN
MEXICO
RUSSIA
USA

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Global Benchmarking Survey 2020
Report for SOUTH AFRICA
(Departments of Health and Agriculture)

1. Executive summary

The HealthforAnimals Global Benchmarking Survey (GBS) is run every 5 years and has now grown to include 11 countries in the 2020 survey. The purpose is to examine the interactions between industry and regulatory systems for veterinary medicinal products, particularly the impact of regulations on the animal health industry's ability to access markets, be innovative, continue to commercialise existing products and be competitive.

This GBS report is **the first for South Africa**. It summarises the data from **12 South African companies**, examines key trends and provides analysis, conclusions and recommendations.

Data was collected through questionnaires in Q4 2019, aggregated and summarised to allow discussion in a subsequent workshop. The key points from the workshop discussions are an integral part of the report, which follows the questionnaire structure with 7 separate sections.

Key Conclusions & Recommendations

- The **dual registration system** for Veterinary Medicines and Stock Remedies must be resolved. It is essential for the Ministers of Health and Agriculture's commitment to a common process that would result in **one act for veterinary products.**
- Respondents look forward to changes to be implemented by the new **SAHPRA** and are positive that veterinary product registration will be strengthened through the process.
- **Regulatory predictability and certainty** are a priority. Clear and reliable timeframes are required, with **reliable processes and systems.**
- Measures are required to ensure **Data Protection and Integrity**, as well as **patent protection** for innovator products.
- **Defensive R&D expenditure** is expected to be significant for the foreseeable future. A **risk-based** approach to R&D requirements would be of value in reducing unnecessary research and development costs, particularly for known molecules and species.
- Applications for **transfer of licence holders** should be prioritised as these approvals have commercial impact.
- The **data requirements for Stock Remedies** should be reviewed in discussion with External Technical Evaluators and the industry. Data requirements should focus on current global scientific standards and be risk-based.
- **Evaluation guidelines** are required for External Technical Evaluators to bring consistency.
- The system for **clinical trial protocol and permit approval** should be reviewed and changes implemented to expedite approvals.
- **Regional regulatory harmonisation in sub-Saharan Africa** is critically important for growth of this market. **Common dossier formats**, **common labels** and **mutual recognition** should be encouraged.
- The **compounding legislation** should be reviewed for gaps and to ensure that the rights of innovators are addressed.

- **Illegal compounding** should be stringently addressed by regulatory authorities with offenders being prosecuted. A transparent process is required.
- **Maximum Residue Limits** for Veterinary Medicines and Stock Remedies require review.
- The implementation of a regional **pharmacovigilance and post-marketing surveillance system** is needed.
- **Data requirements for Stock Remedy biological and parasiticide products** should be applicable to the type of product.

Section B - Impact of the South African regulatory environment on ability to innovate

Three-quarters of respondents (75%) consider the regulatory environment in South Africa to be negative (50%) or very negative (25%) for innovation. The long delays to bring an innovator product to market are cited as having significant impact on the investment in new product developments.

Respondents identify the regulatory framework, small market size, weak intellectual property protection, a scarcity of skilled staff available to companies and the regulatory authorities, and lack of available financial resources as being barriers to innovation.

Data protection for new molecules and claims is a determinant for innovation. The absence of emphasis on data protection by regulators deters the launch of innovative products. The absence of data and patent protection and grey areas within South African compounding legislation further impact decisions around innovation and development.

The high level of mandatory defensive R&D spend (41%) has reduced company investment in innovation.

Product development time increased in the period 2015 to 2017 for all product groups (Companion Animal, Food-Producing Animals and Minor Species) and respondents specifically cite the increased R&D costs for pharmaceutical Stock Remedies.

Act 101/1965 (SAHPRA) [Department of Health] – Veterinary Medicines

Act 101/1965 is considered to strongly enforce product quality, certainty, predictability and safety. However, the current regulatory framework does not foster access to, or the development of, new markets or innovation for Veterinary Medicines.

Compliance with the new SAHPRA implemented regulations is time-consuming and is likely to increase the cost of development and divert registration time and focus. The Minor Use / Minor Species (MUMS) guideline was positively received, and respondents are positive that this decreases defensive R&D expenditure for these particular products.

Harmonisation in sub-Saharan Africa is a high priority for South African companies. Most South African offices undertake regulatory functions for the region of sub-Saharan Africa. Initiatives to implement common requirements and review procedures would enhance registration into Africa and grow these markets.

Harmonisation of regulatory requirements with the EU, US and other PIC/S and VICH countries, would speed up registration preparation and review.

The Veterinary Unit is seen to be understaffed, particularly following recent personnel turnover.

Communication with the Unit has been difficult; however, respondents anticipated that this would improve with the new initiatives being implemented by SAHPRA.

SAHPRA has been focussed on the much larger human pharmaceutical backlog and respondents consider this to have impacted the review of Veterinary Medicines. There is an impression that Veterinary Medicines are of low priority compared to other units within the authority. However, the Unit manager was praised for her efforts to improve Veterinary Medicine registration and clear the veterinary backlog.

The review and approval of Veterinary Medicine submissions is reported to take between 5,5 and 6,8 years. Product development time has increased by 1,0 to 1,3 years and product development costs increased by more than 50% for pharmaceutical Veterinary Medicines in the period 2015 to 2019.

As many submissions are reviewed and approved in other aligned regions, respondents suggest that mutual recognition could improve registration timeframes in South Africa.

Act 36/1947 (Department of Land Reform, Rural Development) [Agriculture] – Stock Remedies

Respondents do not believe that Act 36/1947 fosters innovation, improves quality or reassures the public of the safety of Stock Remedies. The Stock Remedy registration process is considered to be uncertain and unpredictable. Predictability is particularly important for businesses for financial and resource planning.

Departmental communication was highlighted as being poor. Officials cannot be reached by telephone; mailboxes are full, and companies struggle to obtain responses to submissions and queries.

A multi-agency approach to clinical trial protocol and permit approval drives trial costs up while substantially delaying approval.

To aid the Department to eliminate the Stock Remedies backlog, SAAHA entered into a public-private partnership (PPP) initiative with Act 36 in 2018. External technical evaluators assisted with preliminary evaluation of Stock Remedy applications, while final review was conducted by the Internal Technical Advisors at Act 36. The PPP significantly increased applicant registration costs, but for the most part, sped up external review.

The new data requirements implemented in 2017 for Stock Remedies added substantial quality and clinical trial conditions. The requirements were applied retrospectively to an already substantial backlog dating back to 2014, which further delayed registration approval, and impacted R&D costs and resource requirements within companies. Respondents stressed that they welcomed measures to ensure the quality, safety and efficacy of Stock Remedies, but that requirements should be scientific, reasonable, applicable and risk-based.

The Department did not prescribe evaluation criteria for External Technical Evaluators and the evaluations and application of requirements by Internal Technical Advisors and External Technical Evaluators are inconsistent and open to interpretation.

Respondents recorded a review and approval period of 3,7 to 5,3 years for Pharmaceutical and Pesticide Stock Remedies. These figures considered improved review timeframes for some products in the Public Private Partnership. The registration time for Biological Stock Remedies varies between 4,0 and 6,0 years.

Section C - Commercialisation of existing product

Poor intellectual property protection impacts Animal Health products registered under Acts 101 and 36, creating significant uncertainty for applicants.

The number of products that were not pursued as a result of compounding was unforeseen. While the illegal compounding of autogenous vaccines has historically been contentious, illegal compounding was also reported to impact innovative pharmaceutical veterinary products, in-feed medication, parasiticides and pet foods, and to affect the sale of registered products.

Respondents stressed that compounding legislation while protecting the rights of a veterinarian to compound for a specific patient / herd should still assure intellectual property and patent rights of an innovator product. Companies continue to report illegal compounding activities to the regulatory authorities; however, no action has been taken to date.

The Department of Health's oversight of veterinary Maximum Residue Levels (MRLs) for Acts 101 and 36 are not deemed to be helpful. MRLs are not aligned to international changes in a timely manner nor are they defined for unique animal species encountered in South Africa. This delays the conduct of clinical trials and the review of dossiers. The Department has been focussing on MRLs for Agricultural Remedies, with little attention to Veterinary Medicines and Stock Remedies.

Section D - Regulatory predictability and quality

The necessity for an effective pharmacovigilance system for Veterinary Medicines and Stock Remedies is of concern and is considered to be urgent.

Act 101/1965 (SAHPRA) [Department of Health] – Veterinary Medicines

Regulatory timelines are not predictable, and established timeframes are not adhered to. Applicants find themselves unable to predict an anticipated response or approval time, which is essential for business planning.

Respondents note that scientific assessment of risk and benefit is clear, however review reports for similar products may be inconsistent.

Communication is problematic. Officials cannot be reached by telephone and e-mail queries receive no response.

Respondents expressed concern at the number of lost applications, as well as submissions that cannot not be traced.

The authority is in the process of updating veterinary guidelines. Meanwhile, guidelines are outdated and sometimes impractical. Applicants struggle when human pharmaceutical guidelines are applied across the board to include Veterinary Medicines. Such guidelines may not be directly applicable or relevant for Veterinary Medicines.

The high documentation demand for products that are already registered in recognised or trusted countries is considered to be impractical and unnecessary.

An electronic registration submission and tracking system accessible by product would be highly advantageous.

Act 36/1947 (Department of Land Reform, Rural Development) [Agriculture] – Stock Remedies

There is no regulatory predictability or certainty in terms of timelines for Stock Remedies. The Ministerial Task Team report of 2011 recommended timeframes for the evaluation and review of Stock Remedy applications were not implemented or adhered to.

Evaluations for similar dossiers are inconsistent and varying requirements applied. Internal Technical Advisors should be aligned on requirements and apply the guidelines consistently. Respondents were unanimous that evaluator accountability was necessary. Peer review, which does not currently take place, is strongly encouraged. Prior legal challenges have led to an overly cautious approach by the Department when making decisions, again delaying registration approval.

Respondents were highly critical of, and expressed frustration at, the absence of communication with the Department. Officials cannot be reached by telephone and mailboxes are always full. The Department issues limited official communication relating to policies, processes and requirements, creating an environment of uncertainty.

Act 36 is considered to be under-resourced. While new personnel have been appointed, they lack experience and a scientific understanding of registration requirements for Stock Remedies. Intensive training is essential before these personnel are entrusted with application evaluations, as review is delayed by ill-informed and unreasonable requests. Evaluations should be risk-based and science-based and rely on common sense.

Respondents highlighted that pharmaceutical requirements are rigidly applied to pesticide, and sometimes biological, products, even in the absence of such data in the industry.

Mutual recognition procedures with other countries in the region would greatly assist dossier evaluation and improve registration timelines.

An electronic tracking system accessible by product is needed. SAAHA funded the development of a submissions database for the Stock Remedies administrative unit, but it has never been used.

Section E - Regulatory trends

The dual registration system with Veterinary Medicines overseen by the Department of Health, and Stock Remedies by the Department of Agriculture, is problematic, influences business decision-making and could ultimately impact the One Health initiative. The Ministerial Task Team recommended that the two Ministers meet, however there has been no progress in efforts to achieve regulatory harmonisation or one act for veterinary medicinal products.

A multi-agency approach to clinical trial protocol approval by the Departments of Health (Act 101/1965 as amended) and Agriculture (Acts 36/1947 and Act 35/1984) has driven up trial costs and substantially delayed approval. Respondents were unanimous in their criticism of the approach, as well as the associated delays, additional requirements and costs. The approval of clinical trial protocols and permits is considered to be a major concern for respondents. The registration and application requirements were described as being tedious and impractical. Respondents cite dossier submission delays of as much as 1 year due to lack of response, and additional requirements.

Act 101/1965 (SAHPRA) [Department of Health] – Veterinary Medicines

The structural transition from the former Medicines Control Council under the Department of Health to the autonomous South African Health Products Regulatory Authority (SAHPRA) took time and created uncertainty in the industry. The Authority also encountered numerous difficulties in 2018

and 2019 due to the closure of their building for health and safety reasons, a prolonged strike and a move to temporary facilities. These factors impacted applicants and the submission and evaluation of submissions.

The survey respondents were unclear on processes to be followed and communication with SAHPRA is problematic. Recent measures to implement electronic dossier submission and reliance for companion animal products were positively received.

Many veterinary guidelines are still under discussion and are not finalised. Initiatives to harmonise guidelines with the EU, VICH and other recognised regulatory authorities, although slow, are under way. The Veterinary Unit for the most part has been able to evaluate submissions within the Unit, which is seen to be of value as the unique requirements of Veterinary Medicines could be considered and addressed.

The Medicines Control Council made good progress after putting together the Veterinary Products Policy Task Team (VPPTT), a multi-agency working group including Acts 101 and 36 as well as industry. The VPPTT was tasked with the review and implementation of VICH guidelines. The VPPTT has not met in 2 years and respondents stressed the need for the Task Team to reconvene.

The Department has indicated its intention to clear its veterinary backlog and reduce registration timeframes for new registrations to 12 months, and major Type II variations and additional claims to 3 – 6 months. These timeframes are not yet being met.

Transfer of licence holders is time-consuming and does not necessarily follow the same process. These delays impact commercial considerations relating to company takeovers and mergers and have a direct impact on the conduct of day-to-day business when licence holder transfers are not processed in a timely manner. Respondents report being unable to continue business while waiting for approvals, with no indication of approval times.

Act 36/1947 (Department of Land Reform, Rural Development) [Agriculture] – Stock Remedies

The Ministerial Task Team recommendations of 2011 have not been implemented. Applicants are concerned by a lack of transparency, urgency and service delivery for Stock Remedy applications.

The PPP assisted to address the Stock Remedy backlog and lack of resources within the Department. Participants note that, while the PPP was rigorously controlled by the industry body SAAHA, a lack of buy-in as well as agreement on requirements from the regulatory authority still resulted in delays. The PPP was intended to clear the registration backlog dating as far back as 2014, but the Department utilised the PPP to retrospectively improve dossier quality. Dossiers submitted many years prior to implementation of these requirements were evaluated against the same requirements, leading to substantial delays in evaluation and approval times.

Project evaluations became increasingly comprehensive and stringent. Some requirements are seen to be overly bureaucratic and are not risk-based. While the alignment of Act 36 Stock Remedy guidelines with VICH and SAHPRA was positively received, the additional regulatory criteria increased the regulatory burden on applicants. Interpretation and application of the guidelines varies per evaluator, and evaluator findings are inconsistent. Companies did not believe that all applicants were treated equally. Adopted guidelines would benefit from mutual review and agreement.

The PPP will require restructuring, and the way forward must be agreed with the Registrar before it can be implemented again.

Section F - Hopes and expectations for the next 5 years

Digitalisation is expected to have a positive impact on business in the next 5 years. Electronic submission and tracking will vastly improve regulatory practice and would be welcomed.

While not a requirement for Veterinary Medicines, respondents indicate that the CTD format is useful in the absence of a global veterinary dossier. A global electronic veterinary dossier format is a priority, particularly for registration focus into African markets.

Pharmacovigilance and globally harmonised post-marketing surveillance is a necessity.

Mutual recognition and the ability to use international data wherever scientifically possible should be encouraged in order to foster growth and innovation.

Communication was identified as an item of critical importance for both regulators, particularly for Act 36.

Act 101/1965 (SAHPRA) [Department of Health] – Veterinary Medicines

A commitment to reliable registration timelines would assist for Veterinary Medicine review and planning.

Act 36/1947 (Department of Land Reform, Rural Development) [Agriculture] – Stock Remedies

A stronger, transparent regulator with increased regulatory capacity and knowledge transfer is required. Predictable and reliable registration timelines are essential.

Personal accountability for evaluators is of importance; regulators should not regulate outside of their scope.

Guidelines and acceptance criteria should be re-evaluated, refined and standardised based on risk category.

South Africa has observed a marked increase in veterinary biological applications in recent years. As many applications are of USDA origin, closer alignment to USDA requirements and formats is important. Applicants currently note that USDA dossiers are rejected as having too little information when compared to the Biological Stock Remedy guideline.

Section G - Regulatory cooperation and special product categories

While SAHPRA engages in regulatory cooperation with several aligned authorities, including the EU, USA, Australia, Canada and Sweden, there is little cooperation within the sub-Saharan region. There is no alignment for registrations held under Act 36.

Many companies manage regulatory functions for sub-Saharan Africa from South Africa. Regulatory cooperation, harmonisation and mutual recognition are important for developing and growing business into Africa.

2. Introduction and background

The purpose of the HealthforAnimals Global Benchmarking Survey is to examine the interactions between industry and regulatory systems, particularly the impact of regulations on the animal health industry's ability to be innovative and competitive. This includes the ability to bring new products to the market, as well as to retain existing products on the market and thus the impact on the availability of veterinary medicinal products.

This report is the **first** for South Africa, summarises the data from **12 South African-based companies, 6 international and 6 local,** examines key trends and draws conclusions and recommendations.

The HealthforAnimals Global Benchmarking Survey originally benchmarked the European and USA regulatory systems but has since evolved to include the main VICH markets and has now grown to include 11 countries in the 2020 survey (see box).

The evolution of the Global Benchmarking Survey

1. 1996: Europe, USA
2. 2001: Europe, USA
3. 2006: Europe, USA, Japan, Australia, Canada,
4. 2011: Europe, USA, Japan, Australia, Canada,
5. 2015: Europe, USA, Japan, Australia, Canada, China, Brazil
6. 2020: Europe, USA, Japan, Australia, Canada, China, Brazil, India, South Africa, Russia, Mexico

The survey is run every 5 years with the cooperation and involvement of the HealthforAnimals member national or regional associations. The purpose expands beyond simple benchmarking, to include monitoring of trends and to identify the emerging issues in the regulatory environment that may have an impact on competitiveness, ability to do business and medicines availability. The survey is also a useful tool to gain insight into expectations of the industry over the next 2-3 years in response to current regulatory dynamics and to provide information that allows development of clear action plans for meeting any identified challenges.

The outcome of this survey provides a wealth of information to support informed policy decisions in the continual search for best regulatory practice and opportunities for improvement.

3. Outline methodology

The previous Benchmarking Survey **questionnaire** was updated to reflect the requirements for the 2020 survey, including: retention of core questions important for global benchmarking and long-term trend analysis; removal of less useful questions; addition of new questions reflecting known new developments within regulatory systems; and addition of selected 'local' questions of importance to an individual country for local versions of the questionnaires.

The survey was divided into two parts. Part 1 covered financial data and product development costs and was sent to the headquarters of each company (so regional offices were not involved). Part 2 covered the regulatory environment and its impact on innovation and competitiveness. The Part 2 questionnaire was adapted to the situation in each of the 11 surveyed markets and was completed by the country offices of companies active in those markets.

The national associations were responsible for requesting their membership to complete the questionnaires, to collect and collate the results using a standard template, and to organise a local 1-day **workshop** with those companies participating in the survey. At the workshop, an aggregated summary of the data for each question was presented and discussed in order to explore and record different views and the local context important for an understanding of the reasons behind a particular outcome.

The assimilated questionnaire data and the workshop 'narrative' explaining the findings formed the basis of each **country report**. The **report structure** follows the list of questions, which are used as sub-headings. The questions are reflected in the subheadings and are reproduced at the beginning of each section in a box below each sub-heading.

The GBS2020 survey covers 11 markets: Europe, United States of America, Japan, Canada, Australia, China, Brazil, India, Russia, South Africa and Mexico.

Final output: The country reports and a global overview report will be published on the HealthforAnimals website: https://healthforanimals.org/global-benchmarking.html

Details for South Africa

In South Africa, SAAHA collected filled questionnaires during September and October 2019. from **12** companies (see below), all of whom participated in the survey workshop on 26th of November 2019.

For more information on the South African membership please visit: https://saaha.co.za/

Survey participants

1. Bayer
2. Boehringer Ingelheim
3. Ceva
4. Elanco
5. Intervet
6. Virbac
7. Afrivet
8. Deltamune
9. Design Biologix
10. Onderstepoort Biological Products
11. Stride Distributors
12. Wildlife Pharmaceutical

4. The findings for SOUTH AFRICA

Section A – FINANCIAL DATA

Global context

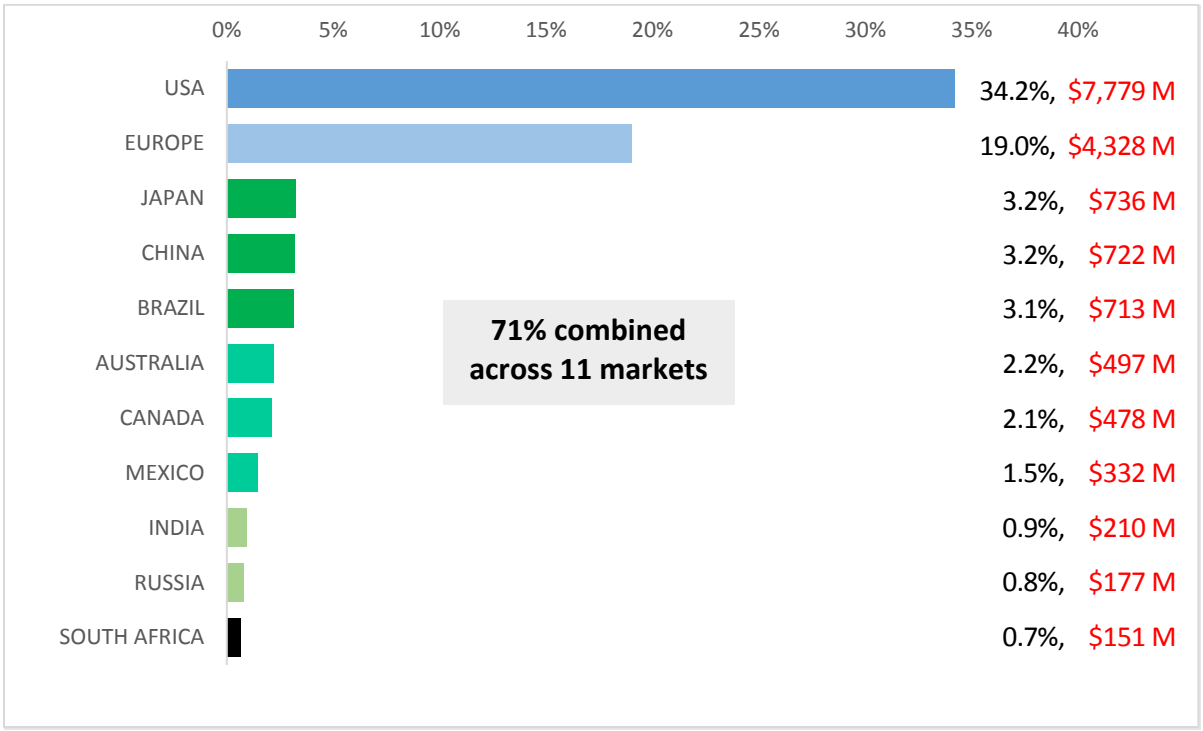
The financial data covers the 2018 full financial year. All data is presented in US dollars ($).

The GBS2020 Part 1 report on financial data is published separately. Key findings from that report are cross-referenced where relevant in this report for South Africa, such as in the sections on product development trends and defensive R&D.

In 2018 the global animal health market was estimated to be worth $45.8 billion[1]. The 10 HealthforAnimals company members held over 50% of that market with a combined revenue of $22.7 billion, and an average of $2,274 million, of which 7% was invested in research and development (R&D).

The 11 benchmarked markets accounted for 71% of HealthforAnimals companies' global revenues (Figure 1), with South Africa representing less than 1% of that revenue.

Figure 1: Revenue distribution of HealthforAnimals companies across 11 markets in 2018



Overall, top international companies directed their R&D spending mostly towards pharmaceutical (62%) and biological (24%) products. Parasiticides developed and registered under pesticide-based regulatory regimes remained a small segment of product portfolios (4%). Companion animal products represented 51% of R&D spending and major food species 49%.

[1] Market Research Reports - https://www.marketremsearchreports.com/blog/2019/09/05/world%E2%80%99s-top-10-animal-health-companies

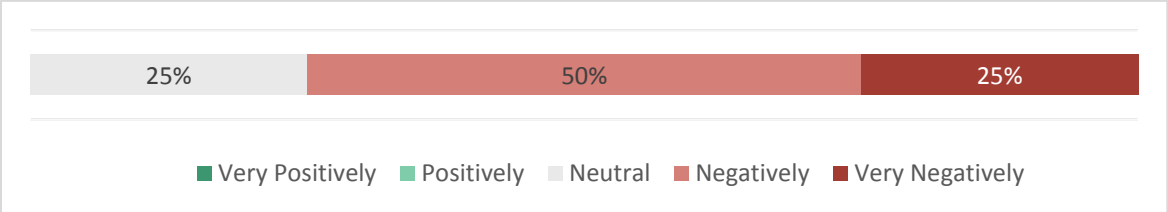
Section B – IMPACT OF REGULATIONS ON INNOVATION

1. Impact of the South African regulatory environment on innovation

How does the regulatory environment in SOUTH AFRICA impact your ability to innovate?

75% of respondents consider that the South African regulatory environment negatively or very negatively impacts on innovation. Delegates noted that, because of the long delays to implement, or bring to market new innovations, there is less motivation to innovate or try new concepts.

Figure 2: Impact of the South African regulatory environment on ability to innovate



2. Factors relevant to innovation in the animal health industry

Below is a list of 10 factors relevant to innovation in the animal health industry in SOUTH AFRICA. Which of these, if any, are significant for innovation in your business?

Respondents identified 5 of the 10 factors as being the 'most relevant' (i.e. it was ranked as the top factor by one or more companies) to innovation in the South African animal health industry (Table 1).

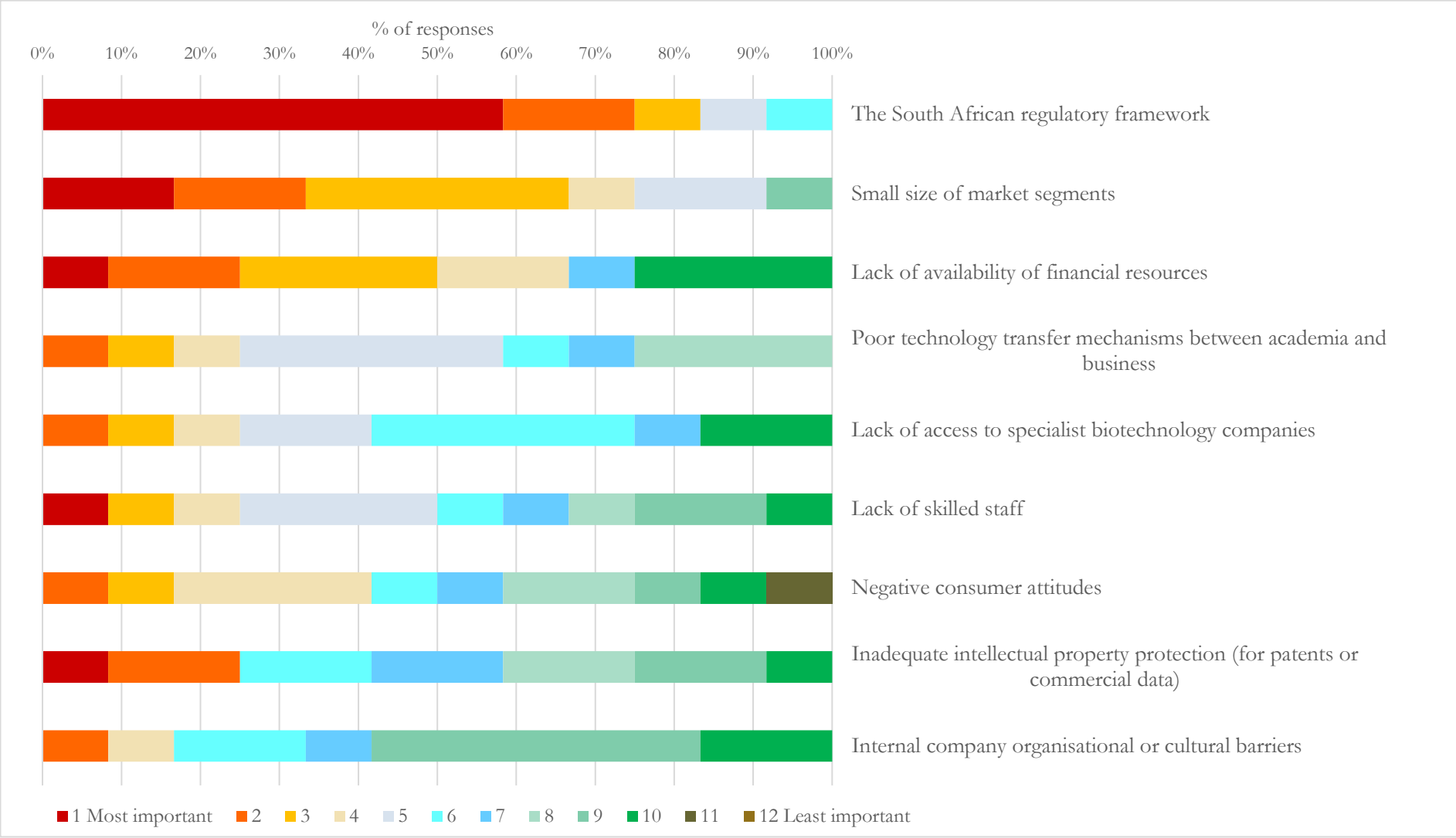
Table 1: List of factors that were voted 'most important' to innovation (% of votes)

Factors relevant to innovation	% of votes
1. The South African regulatory framework	58.3%
2. Small size of market segments	16.7%
3. Inadequate intellectual property protection (for patents or commercial data)	8.3%
4. Lack of skilled staff	8.3%
5. Lack of availability of financial resources	8.3%

- The South African regulatory framework was overwhelmingly considered to be the greatest impactor (58,3%) on innovation in the Animal Health market. The absence of consequences for non-performance by the regulators was of major concern.
- The small size of market segments, lack of financial resources and lack of skilled staff were considered together, as they impact one another.
- An absence of suitably skilled staff is a problem encountered by Animal Health companies, as well as the regulatory authorities, as is the ability to retain them.

When all the individual company ranking scores (ranking from 1 to 10) are summated, the order of importance, and the spread of the voting, is illustrated in Figure 3. This overall ranking also identifies poor technology transfer mechanisms between academia and business and lack of access to specialist biotechnology companies as being areas of importance. The areas of least importance were closure of South Africa and/or other geographic markets for certain products, and internal company organisational or cultural barriers.

Figure 3: Factors relevant to innovation in the South African animal health industry



3. Regulations' impact on competitiveness

Have Government Regulations in South Africa HELPED to improve the competitiveness of your business in any of the following ways?

Respondents ranked a list of factors related to competitiveness, citing half of them as helpful to improved competitiveness in the South African market. The results are summarised in Table 2.

Table 2: Ranking of factors relevant to competitiveness (Act 101)

Factors relevant to competitiveness	Average ranking score
Improved product quality	3.5
Prevented dangerous products entering the market	4.0
Provided confidence to invest (added to certainty and predictability)	4.6
Provided a stable business environment	4.8
Reassured the public about the safety of animal health products	5.1
Protected investments in innovation	6.5
Triggered innovation in new production processes	7.1
Improved access to other geographic markets	7.3
Helped redirect resources to innovation	7.4
Speeded up time-to-market	7.9
Created new market segments	8.3

Following discussions in the survey workshop, participants agreed that:

- Act 101 is well legislated with stringent regulations that provide good control.

- The Act 101 legal framework had a positive impact on:
  - Product quality
  - Certainty and predictability
  - Safety and control of dangerous products
  - A stable business environment

- The Act 101 regulations do not assist in:
  - Creating new markets or improving access to other markets
  - Triggering innovation
  - Time to market

Similarly, respondents ranked a list of factors related to competitiveness for Act 36, citing half of them as helpful to improved competitiveness. The results are summarised in Table 3.

- The Act 101 legal framework had a positive impact on:
  - Improved product quality
  - Reassuring the public about the safety of Act 36 animal health products
  - Preventing dangerous products entering the market

- The Act 36 regulations do not assist in:
  - Helped redirect resources to innovation
  - Speeded up time-to-market
  - Created new market segments

Table 3 Ranking of factors relevant to competitiveness (Act 36)

Factors relevant to competitiveness	Average ranking score
Improved product quality	3.1
Reassured the public about the safety of animal health products	4.0
Prevented dangerous products entering the market	4.1
Provided a stable business environment	4.9
Provided confidence to invest (added to certainty and predictability)	5.6
Protected investments in innovation	6.7
Triggered innovation in new production processes	6.9
Improved access to other geographic markets	6.9
Helped redirect resources to innovation	7.5
Speeded up time-to-market	7.5
Created new market segments	8.9

4. The effects of Regulations on business

Do government regulations in SOUTH AFRICA have any of the following effects on your business?

Respondents were asked to rank certain factors that had impact on their business linked to government regulations. The results are listed in Table 4.

Table 4: Ranking of factors relevant to business (Act 101)

Factors relevant to business	Average ranking score
Create significant uncertainty or unpredictability	3.4
Increase product development time	3.8
Increase costs of product development	4.4
Limit the use of innovative marketing methods	5.0
Divert management time	5.5
Re-direct resources into defensive R&D	6.1
Reduce access to new ideas, particularly in biotechnology	6.1
Close markets for specific products	6.1
Reduce cash flows from existing products	6.5
Restrict collaborative R&D ventures	8.9

Act 101 regulations were considered to

- create significant uncertainty or unpredictability
- increase the time and costs of product development,
- impact cash flow and
- divert management time.

Act 101 regulations were not considered to restrict collaborative R&D ventures.

With only a slight variation in ranking score, the results for Act 36 largely mirrored those of Act 101 and are listed in Table 5 below.

Table 5: Ranking of factors relevant to business (Act 36)

Factors relevant to business	Average ranking score
Create significant uncertainty or unpredictability	3.1
Increase costs of development	3.3
Increase development time	3.3
Divert management time	5.8
Re-direct resources into defensive R&D	6.1
Close markets for specific products	6.4
Reduce access to new ideas, particularly in biotechnology	6.7
Reduce cash flows from existing products	6.7
Limit the use of innovative marketing methods	6.9
Restrict collaborative R&D ventures	7.2

- **The uncertainty and unpredictability of registering products under Act 36** was a common theme, most frequently being linked to unclear and unpredictable registration requirements.

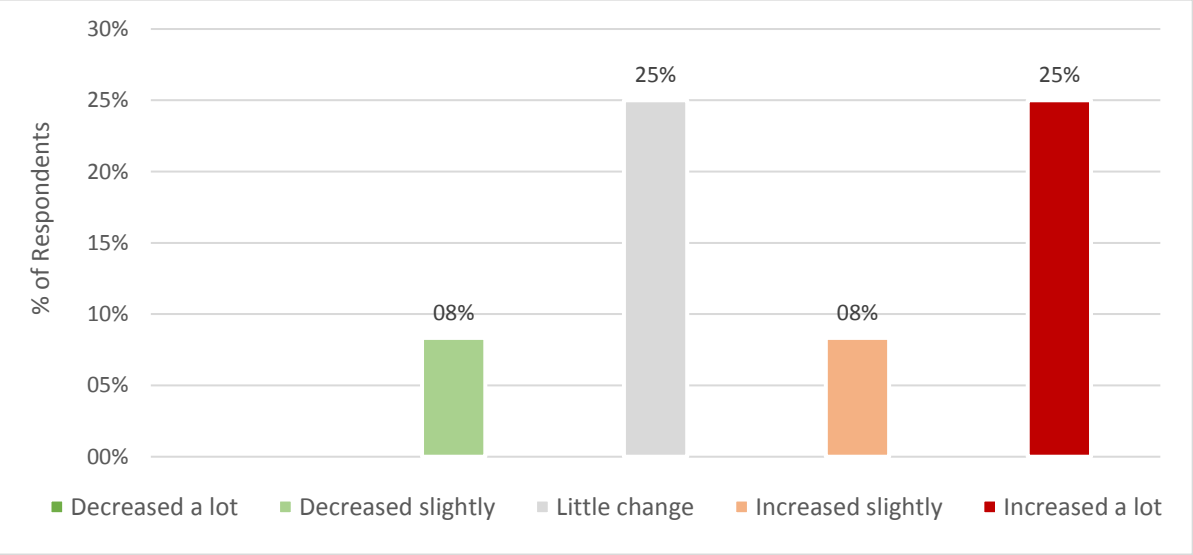
- **The increased costs of development for Act 36 products since 2017** were of concern to participants, particularly in relation to more stringent quality and clinical trial requirements. These requirements are controlled through guidelines, rather than regulations, and application is inconsistent.

5. Expenditure on mandatory defensive R&D

Which of the following statements best indicates how your expenditure on MANDATORY DEFENSIVE R&D in South Africa has changed since 2015?

When companies were queried on the changes in their expenditures on Mandatory Defensive R&D, the results were mainly spread between 'little change' and 'increased a lot' as shown in Figure 4. (N.B. Some companies did not answer the question thus resulting in total figures less than 100%.)

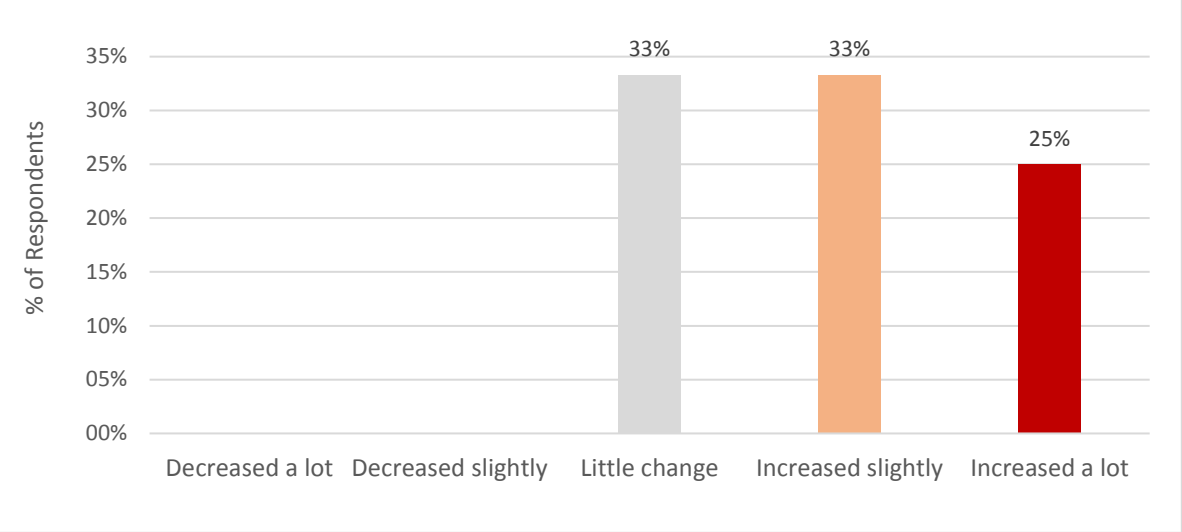
Figure 4: Companies' perception of the burden of mandatory defensive R&D spending (Act 101)



Most participants noted no change, or a slight increase in R&D expenditure for Act 101 products over the period 2015 to 2019, while 3 companies reported a substantial increase in R&D expenditure for Act 101 Veterinary Medicines. Only one company noted that their expenditure had decreased.

In contrast to Act 101 results, companies were much more critical of Act 36 and its effects on the increasing expenditure on mandatory defensive R&D. As seen in Figure 5, more than half of respondents cited slight or considerable increases in mandatory defensive R&D spending.

Figure 5: Companies' perception of the burden of mandatory defensive R&D spending (Act36)



Participants agreed that the current registration requirements applied for Act 36 Stock Remedies have increased their R&D expenditure over the past 4 years.

6. Factors causing the change in expenditure on mandatory defensive R&D

What factors have caused the change (a decrease or an increase) in expenditure on mandatory defensive R&D

The factors causing the change in expenditure on mandatory defensive R&D for both Act 101 and Act 36 are summarised in Tables 6 and 7 below.

As would be expected, very few reasons for decreases were cited by the companies while factors causing increases were numerous and varied for both Acts. Where there were reasons for expenditure decreases, these were for Act 101.

The factors causing an increase covered both the product development phases (particularly clinical trials) and the scientific assessment phase.

The negative factors affecting the scientific assessment phase were related to both lack of resources and stability in personnel (e.g. lack of regulatory assessors and experts, high staff turnover, inexperienced new staff) and lack of stability in the requirements.

The companies felt that it would be beneficial to have greater alignment with international standards (e.g. VICH) or with well-established and respected (and adequately resourced) regulatory agencies (e.g. USDA or APVMA).

Table 6: Factors causing a change in expenditure on mandatory defensive R&D (Act 101)

Factors causing a decrease in expenditure on mandatory defensive R&D
Act 101 ▪ One company makes extensive use of the Minor Species / Minor Use exemptions, which resulted in decreased defensive R&D expenditure ▪ Harmonisation of regulations with EU and other PIC/S countries ▪ Post-marketing pharmacovigilance
Factors causing an increase in expenditure on mandatory defensive R&D
Act 101 ▪ **Clinical trial requirements** - Approval requirements for clinical trials and importation of trial material, requiring review by up to 3 Government Departments (2 in Agriculture and 1 in Health) with additional costs and delays exceeding a year. ▪ **Cost of additional clinical studies** - External R&D companies to conduct residue studies for withdrawal period changes - Trial subjects ▪ **Cost of experts for:** - Preparation of experts to run studies and prepare clinical trial report ▪ **Change in requirements** - Change in regulatory requirements for specific molecules - New technology requirements - New guidelines - Extensive and more stringent regulations are being adopted - eCTD requirements for submission of an electronic CTD dossier - The Minor use / Minor Species Guideline is not clear ▪ **Personnel** - Increase in regulatory staff turnover, and the appointment of unskilled staff - Newly appointed SAHPRA staff require more comprehensive training on performing reviews, and to gain experience ▪ **Communication** - Poor communication and lack of clarity from the regulator ▪ **Timelines** - Extended time to market - Delayed registration timelines ▪ **The Veterinary Unit at SAHPRA needs to align** more with VICH, USDA and APVMA requirements

Table 7: Factors causing a change in expenditure on mandatory defensive R&D (Act 36)

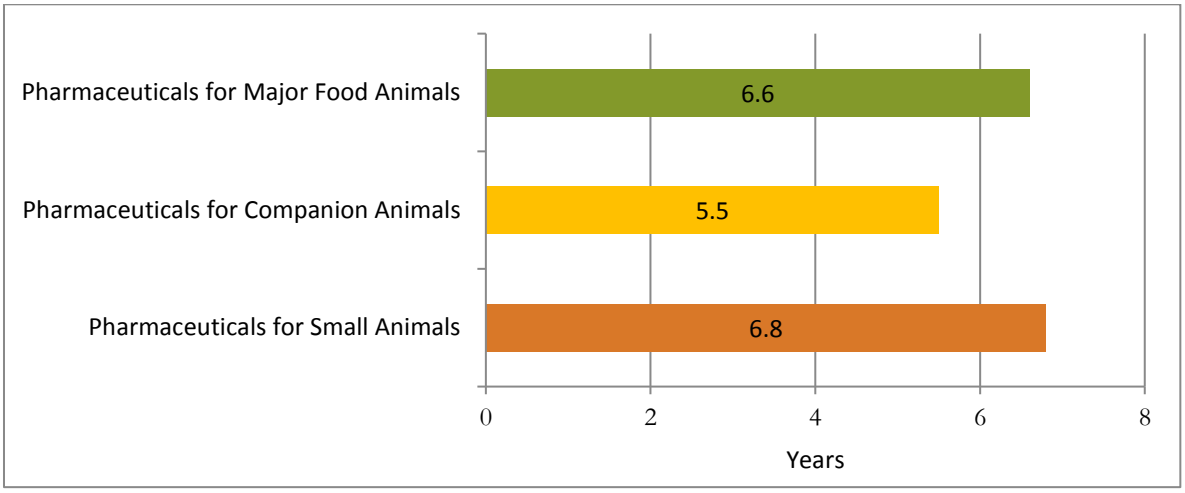
Factors causing an increase in expenditure on mandatory defensive R&D
Act 36 ▪ **Clinical trials** - Approval requirements for clinical trials and importation of trial material, requiring review by up to 3 Government Departments (2 in Agriculture and 1 in Health) with additional costs and long-time delays exceeding a year. - Requirements for conduct of new studies ▪ **Cost of additional clinical studies** - Residue studies for withdrawal period changes - Additional clinical trial requirements - Stability studies - Analytical costs relating to formulation changes ▪ **Cost of experts for:** - Preparation of expert reports for local clinical studies - Statistical analyses - Formulation changes ▪ **Cost of Public Private Partnership** - The SAAHA Public Private Partnership increased costs as submission fees were paid to the regulator as well as to the Project for evaluation by an External Technical Evaluator. ▪ **Change in requirements** - The long delays in registration require changes to new product claims during registration. - Extensive new regulatory requirements which continuously change - New guidelines - Unwillingness to accept international data without local studies ▪ **Additional resources are required to support** ongoing quality commitments necessary to maintain products on the market ▪ **Increased competitor pressure in vaccine market** ▪ **Timelines** - Extended time to market - Delayed registration timelines ▪ **Processes** - Inefficiency - There is no set benchmark against which evaluators carry out their reviews o Different evaluators have different requirements for dossiers o There is no peer review committee ▪ **Communication** - Poor response

7. TIME to gain registration for a major new product in SOUTH AFRICA

Please state the AVERAGE LENGTH OF TIME it takes you to gain registration for a major new product, from submission of the marketing authorisation dossier to first-market product approval.

Average time to gain registration for a major new pharmaceutical product under Act 101 ranged from 5.5 to just under 7 years for all three market segments. These are outlined in Figure 6.

Figure 6: Time to gain registration for a major new pharmaceutical product in South Africa (Act 101)

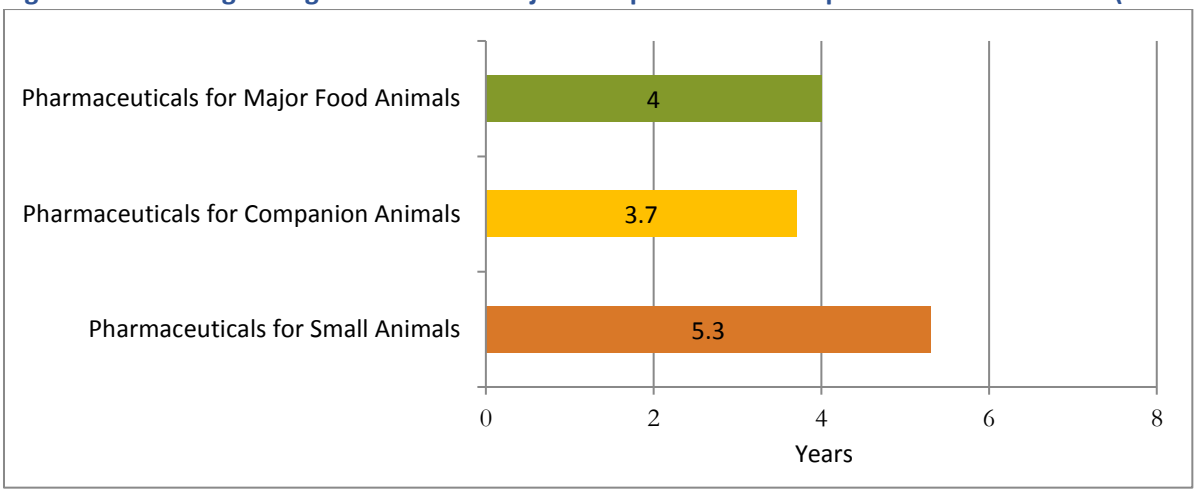


Two participants have only recently submitted Act 101 products and were unable to comment.

Although Act 101 covers biological products, all animal vaccines were registered under Act 36. No biological registration times were reported for Act 101.

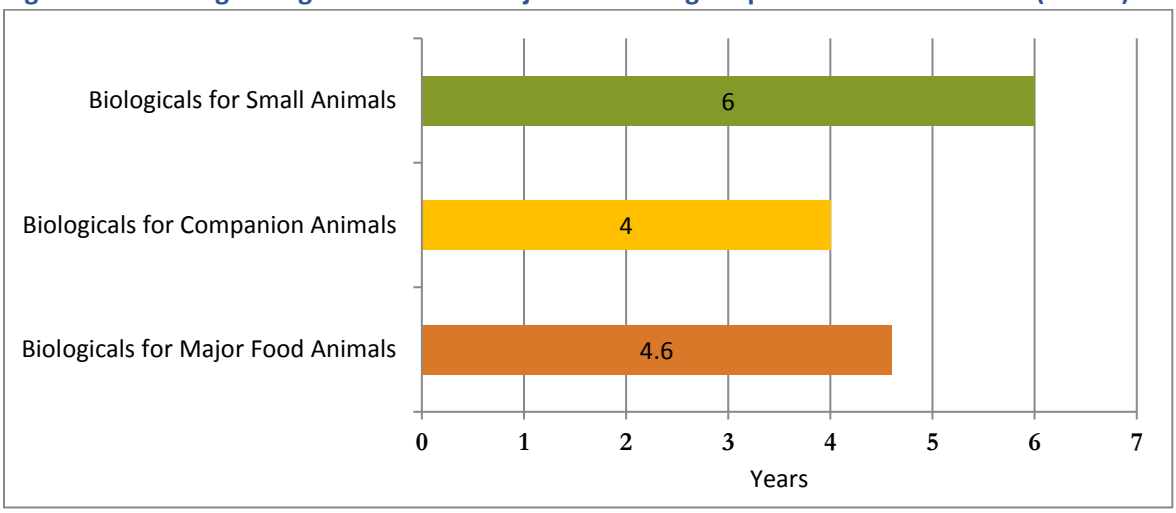
The average times to gain registration for a major new pharmaceutical product under Act 36 were considerably lower ranging from 3.7 to just over 5 years for all three product types (Figure 7).

Figure 7: Time to gain registration for a major new pharmaceutical product in South Africa (Act 36)



The average time for registration of a new Biological product ranged from 4-6 years (Figure 8). Since no biological times were reported for Act 101, no comparisons could be made.

Figure 8: Time to gain registration for a major new Biological product in South Africa (Act 36)

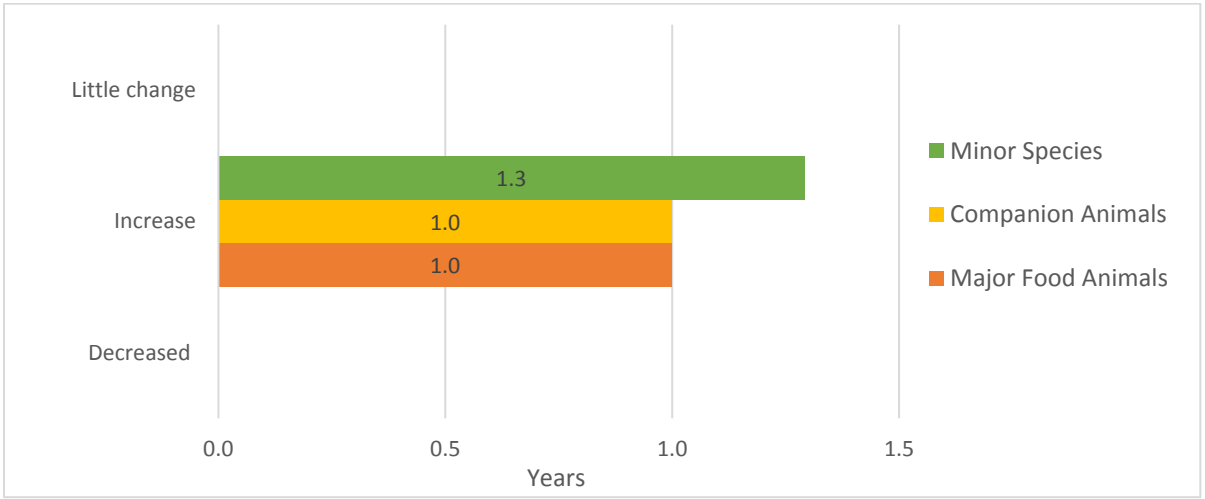


8. Impact of Regulations on TIME to develop a major new PHARMACEUTICAL product

Have REGULATORY FACTORS caused a change in the AVERAGE LENGTH OF TIME it takes you to develop a major new PHARMACEUTICAL product in South Africa (from initial research to final market authorisation), compared to 2015?

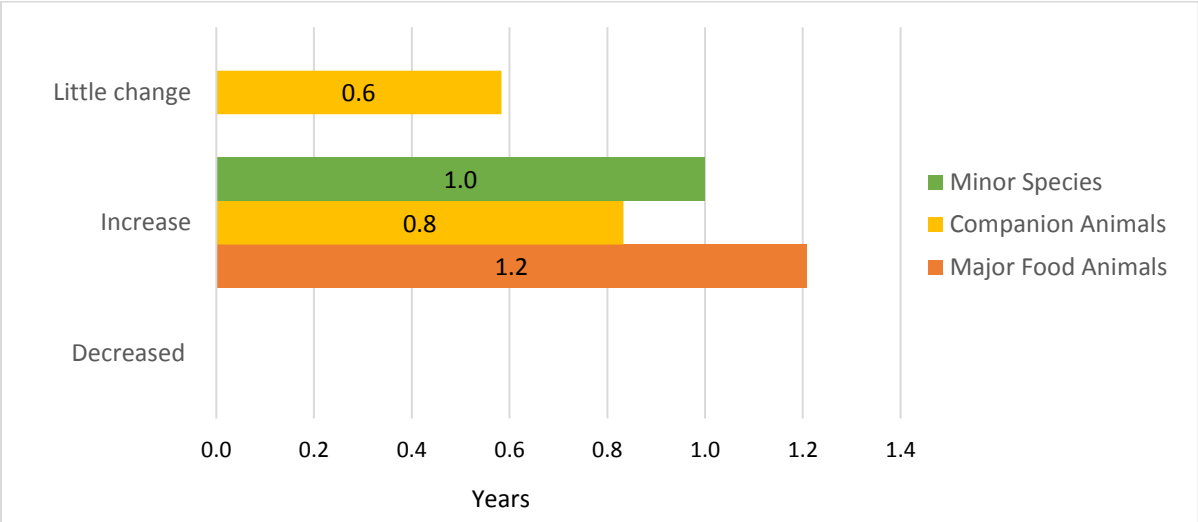
Respondents were unanimous in their estimation that regulatory factors in **Act 101** have caused an increase in time to develop a new pharmaceutical product citing an increase of 1 year for Companion Animals and Major Food Animals and 1.3 years for Minor Species (Figure 9).

Figure 9: Change in time to develop a major new pharmaceutical product in South Africa (Act 101)



Similar to the responses regarding Act 101, companies found that the regulatory factors in **Act 36** caused, on average, a 1-year increase in the time it takes to develop a major new Pharmaceutical product (Figure 10). The average increase for Major Food Animal products (1.2 years) was larger than for Companion Animal Products (0.8 years). For some companies, however, there was little change for the Companion Animal Segment.

Figure 10: Change in time to develop a major new pharmaceutical product in South Africa (Act 36)



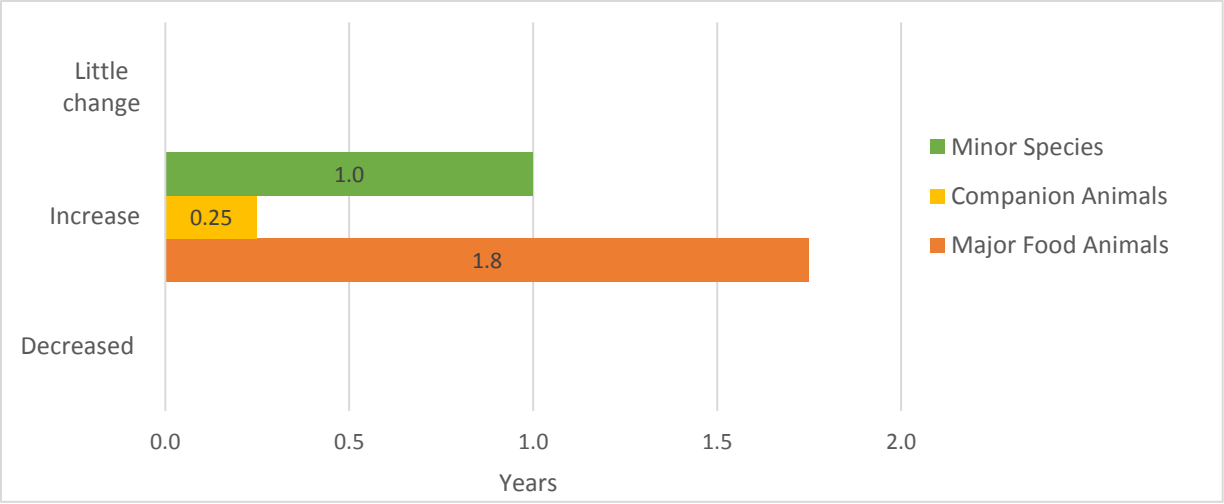
9. Impact of Regulations on TIME to develop a major new BIOLOGICAL product

Have REGULATORY FACTORS caused a change in the AVERAGE LENGTH OF TIME it takes you to develop a major new BIOLOGICAL product in South Africa (from initial research to final market authorisation), compared to 2015?

With respect to **Act 101**, respondents reported that this question was not applicable to their business.

However, regarding **Act 36**, companies found that there had been an increase in the time to develop a major new biological product ranging from 3 months (Companion Animals) to 1 year (Minor Species) to just under 2 years for Major Food Animals.

Figure 11: Time (years) to develop a major new biological product in South Africa (Act 36)



10. Impact of Regulations on TIME to develop a major new PESTICIDAL product

Have REGULATORY FACTORS caused a change in the AVERAGE LENGTH OF TIME it takes you to develop a major new PESTICIDAL product in South Africa (from initial research to final market authorisation), compared to 2015? Please make separate estimates for major livestock species, companion animals and minor species.

- **Pesticides are not regulated under Act 101** and are only registered under Act 36.
- **As pesticide registrations follow pharmaceutical registration requirements**, time frames reported are the same as those reported for pharmaceuticals under Act 36 (see below and Figure 10).

PESTICIDE PRODUCT	Increase in development time (years)
Major Food-Producing Animals	1.2
Companion Animals	1.8
Minor species	1.0

11. COST of developing a major new PHARMACEUTICAL product

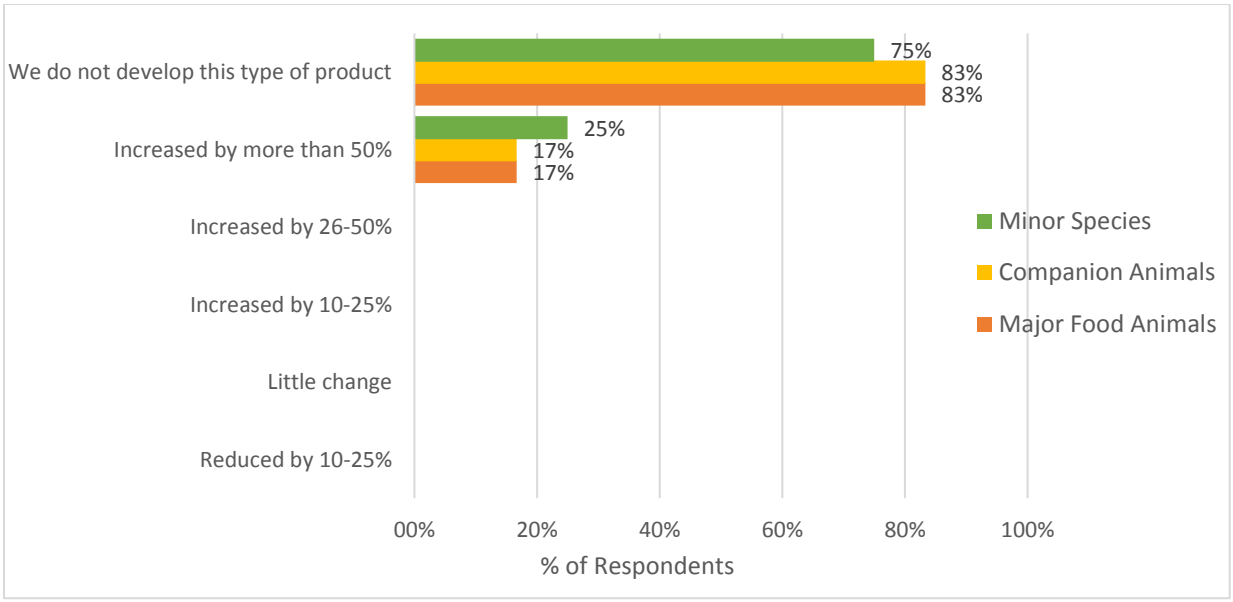
Thinking about the AVERAGE COST of developing a major new PHARMACEUTICAL product in South Africa (from initial research to final market authorisation) for all possible species and indications for that product, compared to 2015, have REGULATORY FACTORS caused this cost to change in real terms? Make separate estimates for major livestock species, companion animals, and minor species.

Act 101

Most companies reported that their businesses did not develop Act 101 pharmaceutical products.

Only 2 companies reported expenditure on product development for Act 101 pharmaceutical products for Food-Producing and Companion animals, and 3 companies for Minor Species. In these cases, expenditure on product development had increased by more than 50% over the period 2015 to 2019 as depicted in Figure 12.

Figure 12: Perceived change in COST to develop new pharmaceutical product (Act 101)



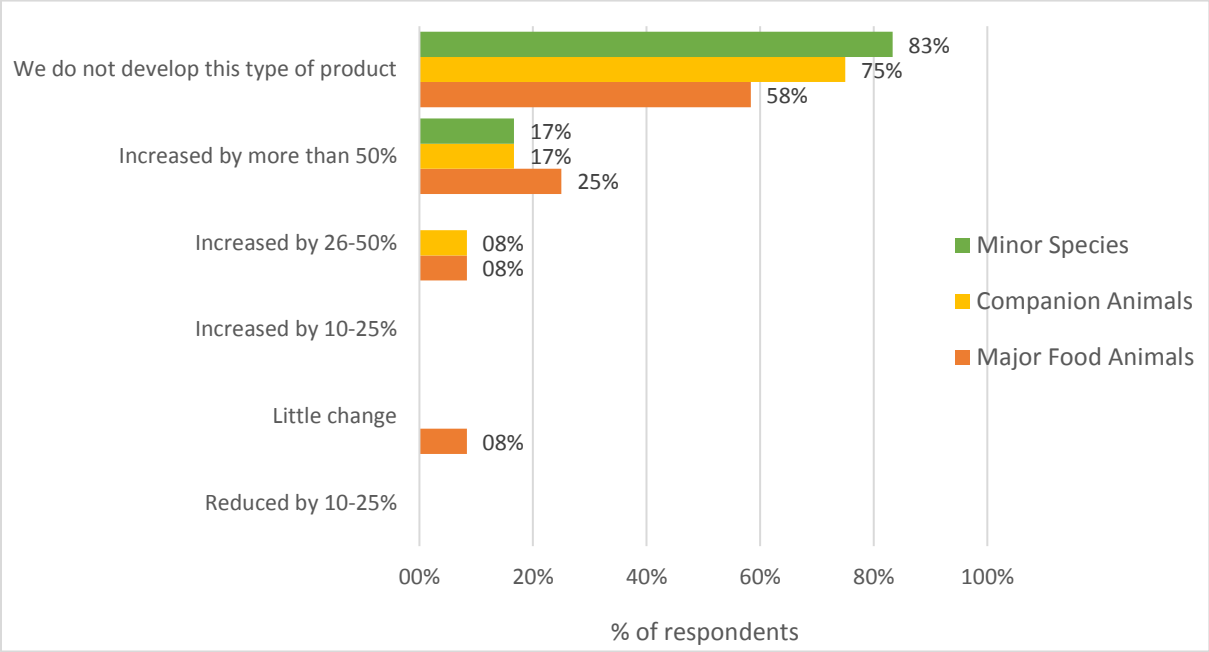
Act 36

As before, most companies reported that their businesses did not develop Act 36 pharmaceutical products.

However, 5 companies reported expenditure on product development for Act 36 pharmaceutical products for Food-Producing Animals, 3 for Companion Animals, and 2 companies for Minor Species.

The majority of companies reported that expenditure on product development had increased by more than 50% for all 3 product categories over the period 2015 to 2019. Some individual companies (8% of respondents) reported less increases (Figure 13).

Figure 13: Perceived change in COST to develop new pharmaceutical product (Act 36)



12. COST of developing a major new BIOLOGICAL product

Thinking about the AVERAGE COST of developing a major new BIOLOGICAL product in SOUTH AFRICA (from initial research to final market authorisation) for all possible species and indications for that product, compared to 2015, have REGULATORY FACTORS caused this cost to change in real terms? Make separate estimates for major livestock species, companion animals, and minor species.

For both Act 101 and Act 36, most companies do not develop biological products (Figures 14 and 15). For those that did, Act 101 caused only slight increases in development cost while Act 36 caused considerable increases, especially for Major Food Animals (Figure 15).

While certain biological products are registered under Act 101, animal vaccines are registered under Act 36.

Only 5 companies reported expenditure on product development for Act 36 biological products for Food-Producing Animals, 1 for Companion Animals, and 2 companies for Minor Species. On average, expenditure on product development had increased by more than 50% over the period 2015 to 2019.

Figure 14: Perceived change in COST to develop new biological product (Act 101)

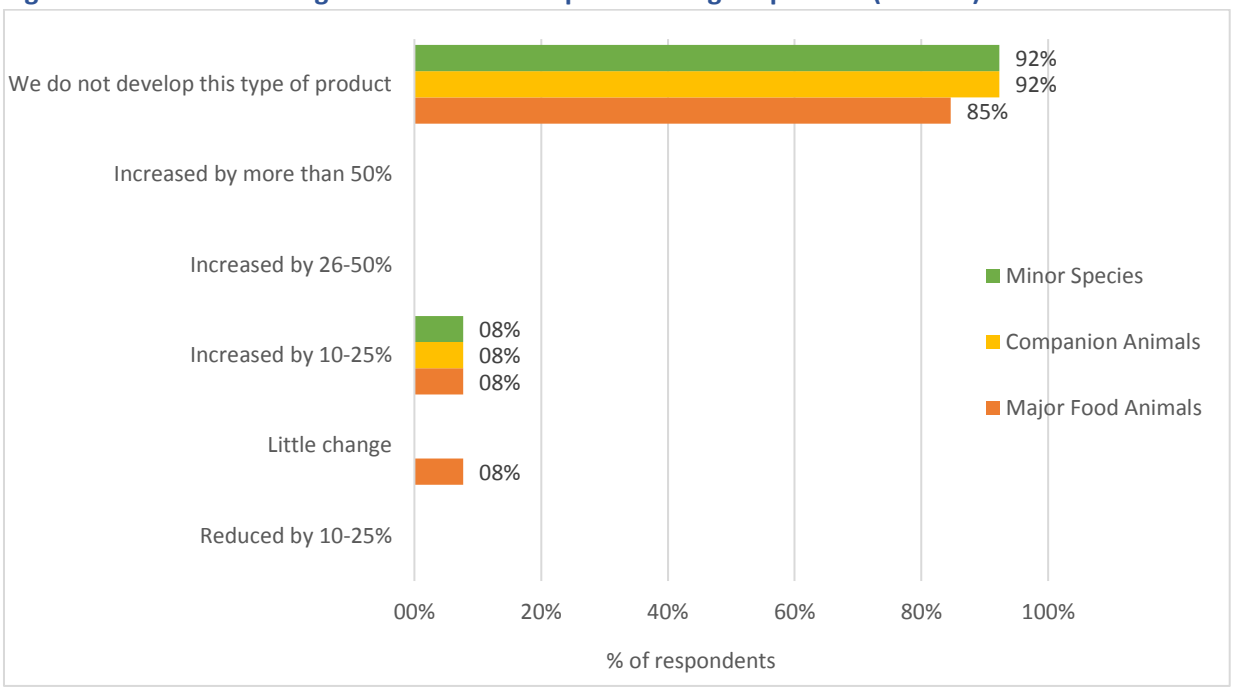
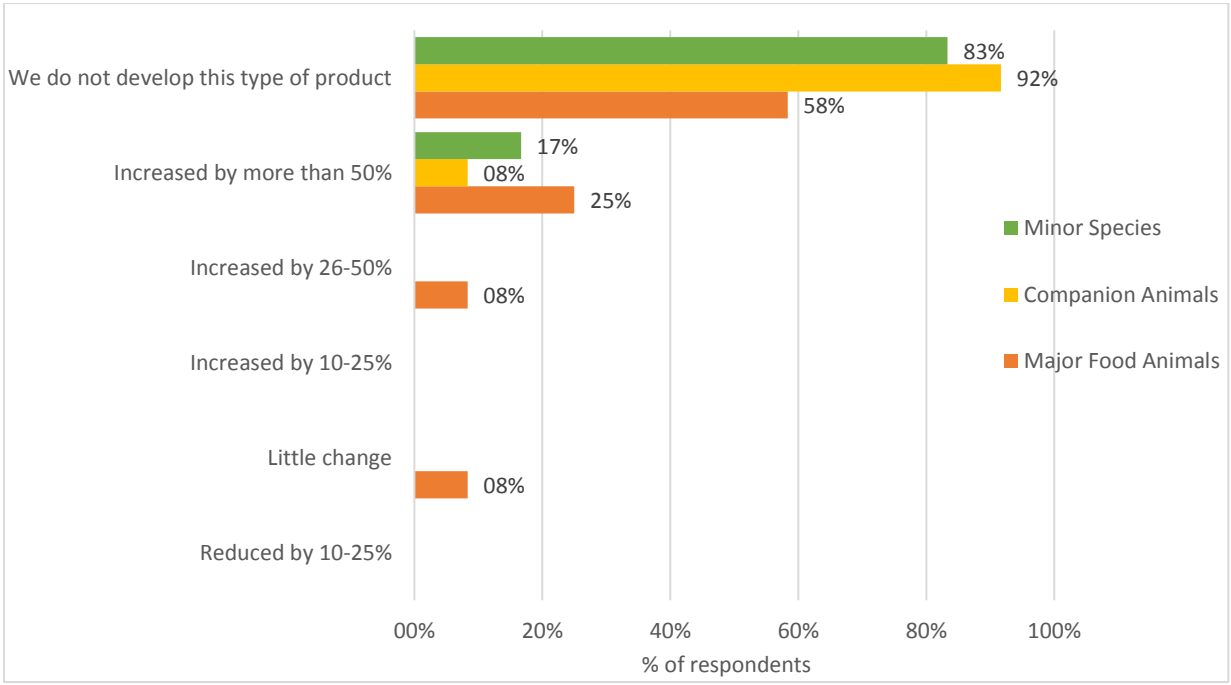


Figure 15: Perceived change in COST to develop new biological product (Act 36)



13. Data protection (market exclusivity) given by the different agencies in South Africa as an incentive

- Data protection and market exclusivity provisions are not currently part of the regulations in South Africa. Participants to the workshop uniformly agreed that this was not helpful to business.

- Legislation is needed to guarantee a period of data protection for innovator products.

- A 20-year patent protection is applied that starts at the time of submission. Delays in the registration process considerably erode the value of the patent time. In other jurisdictions (e.g. EU) a 5-year supplementary protection certificate can be requested to compensate for the delay to market due to the registration process.

- Data protection / data integrity is a major issue for South Africa. SAAHA has previously raised the matter with the regulatory authorities and will continue to do so.

Section C - COMMERCIALISATION OF EXISTING PRODUCT

1. Commercialisation factors for exploiting EXISTING PRODUCTS

Thinking about Government Regulations in South Africa, how would you assess the impact of each of the areas of regulation listed below on your ABILITY TO commercialise EXISTING PRODUCTS successfully?

Act 101

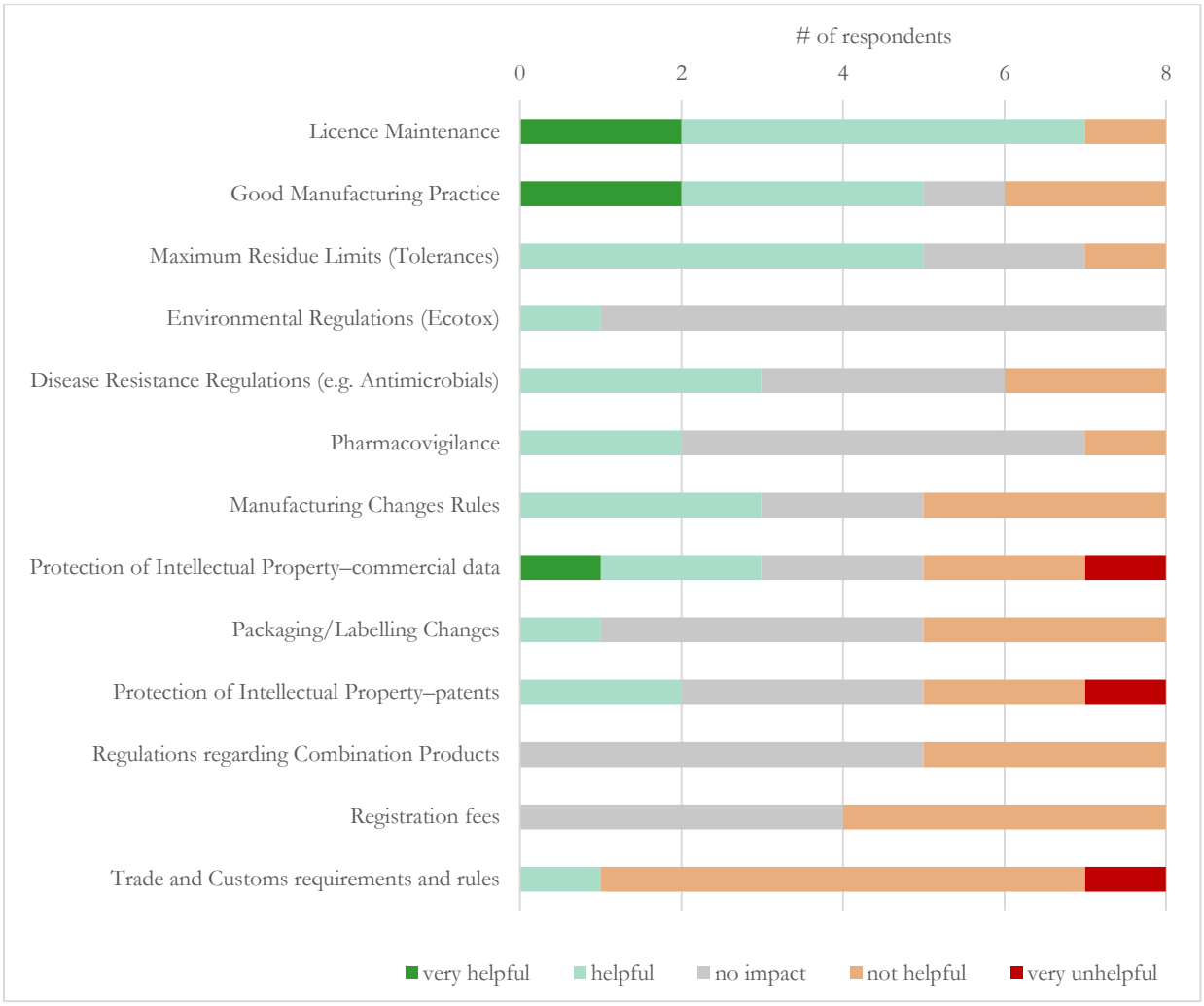
Companies were asked to rank the impact of Act 101 regulations helpfulness in exploiting existing products. **Eight** companies answered this question, and the results are shown in Figure 16 with the options listed in order of helpfulness.

The most helpful factors were Licence Maintenance and Good Manufacturing Practices, and to a lesser extent Maximum Residue Levels (see additional comments on MRLs below).

Many of the options received an overall neutral or balanced response, including Environmental Regulations (Ecotox), Disease Resistance Regulations (e.g. Antimicrobials), Pharmacovigilance and Manufacturing Changes Rules (e.g. marketing authorisation variations).

The least helpful area was seen as the Trade and Customs requirements and rules, but also regarded as overall unhelpful were Protection of Intellectual Property–patents, Regulations regarding Combination Products and Registration fees.

Figure 16: Influence of Act 101 regulations on existing product (listed in order of helpfulness)



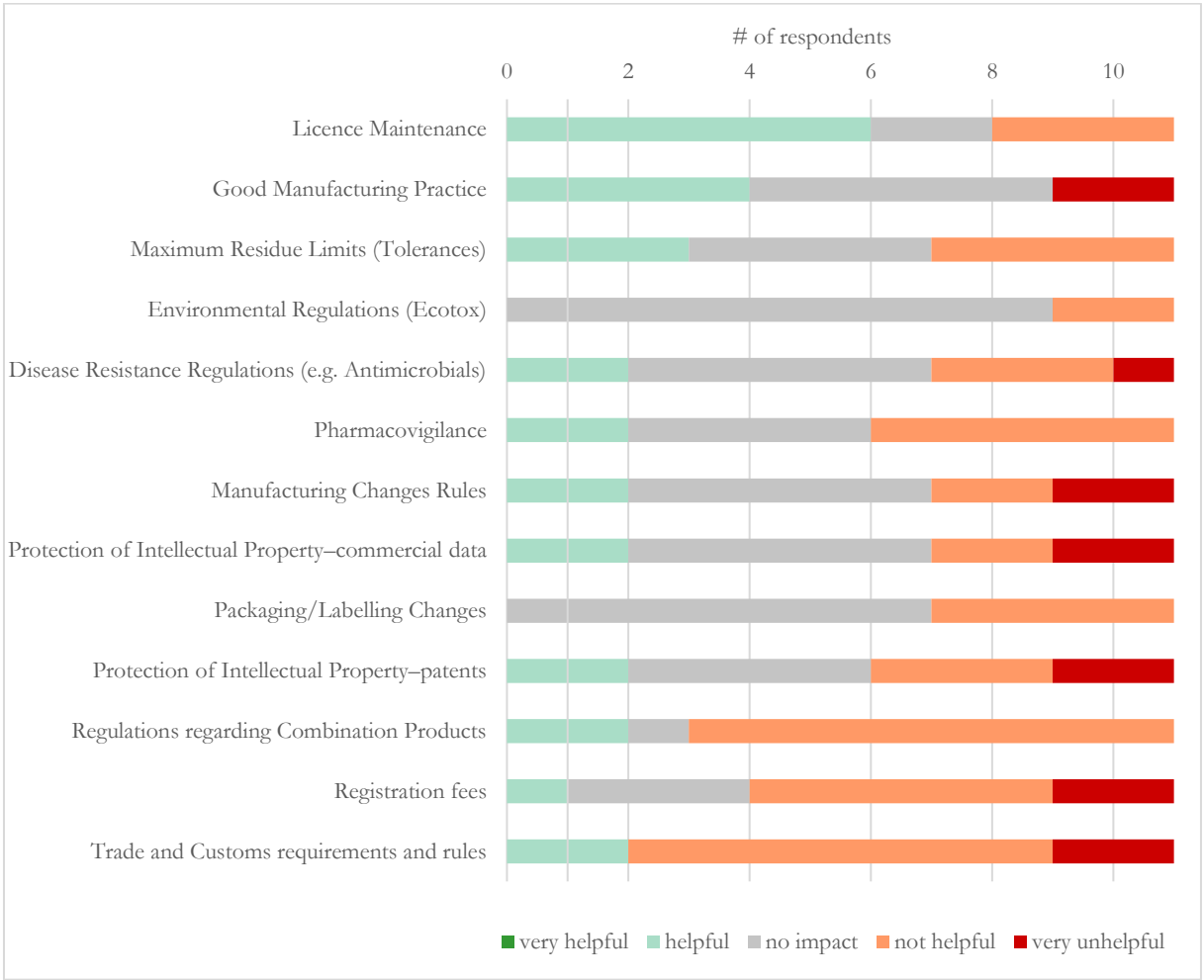
Act 36

Companies were asked to rank the impact of Act 36 regulations helpfulness in exploiting existing products. **Eleven** companies answered this question, and the results are shown in Figure 17 with the options listed in order of helpfulness.

The order of helpfulness is exactly as that found for Act 101, but under Act 36 there is a high level of dissatisfaction, with a greater number of 'not helpful' and 'very unhelpful' scores and no 'very helpful' scores.

One company also reported that the animal Health Dept. barriers - Section 20/21 permits were very unhelpful.

Figure 17: Influence of Act 36 regulations on existing product (listed in order of helpfulness)



Maximum residue levels (Act 101 and Act 36)

- Maximum residue levels were either considered to have no impact or to be helpful to the exploitation of existing products. MRLs are controlled through the Department of Health and are essentially based on the Codex and JECFA international standards.

- Difficulties are experienced when MRLs have not yet been aligned to international changes or have not been defined for species present in South Africa. This can lead to significant time delays with the conduct of clinical trials and the approval of registrations.

2. The effects of Regulation on business

Do government regulations in South Africa have any of the following effects on your business?

The participants were presented with a list of 10 potential business impacts and were asked to rank them from 1 for 'most important' to 12 for 'least important'. The total scores for each of the 10 options were collated to produce the overall outcomes presented in Figures 18 and 19, with the options listed in order of impact (from most negative impact to least impact).

Act 101

Eight companies answered this question, and the results are shown in Figure 18 and the overall ranking, from most important impact to least impact, is shown listed below.

Ranking of importance of impact on business

1. Create significant uncertainty
2. Create disproportionate costs for maintaining/extending marketing authorisations
3. Increase the cost of production
4. Remove profitable products from the market
5. Divert financial resources away from the development of new, innovative products
6. Divert management time
7. Increase the cost of distribution and marketing
8. Restrict the extension of existing technologies to additional species/indications
9. Limit the use of innovative marketing methods
10. Fail to protect intellectual property (patents & commercial data) adequately

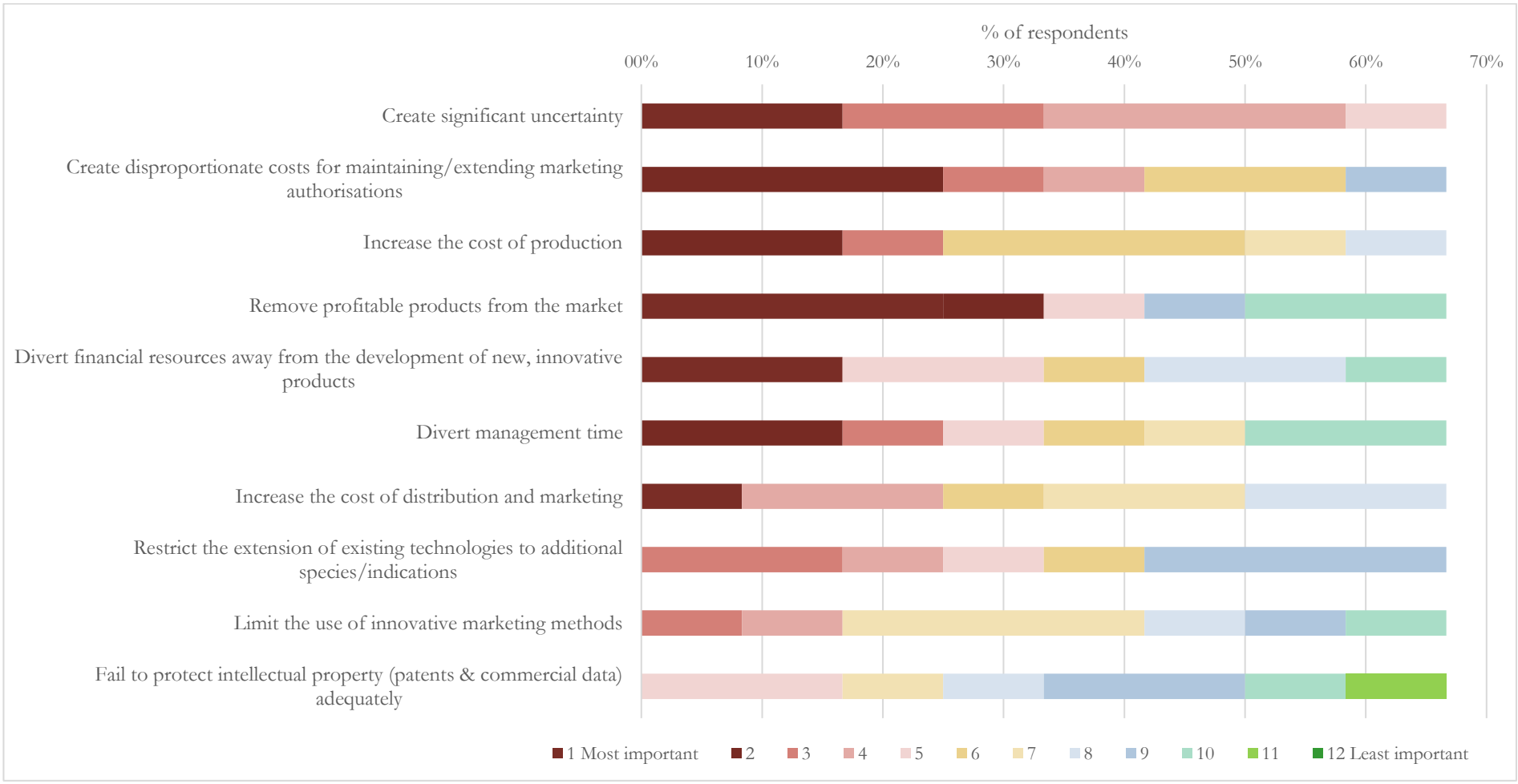
Currently there is a large degree of uncertainty created by the regulatory environment in South Africa and this has a major negative impact on business. The current evolution of the regulatory framework is also negatively impacting business by increasing the costs for maintaining and extending marketing authorisations.

Although ranked 10th on the list, in the workshop discussion participants considered that **uncertainty regarding protection of intellectual property had major impact on business**, particularly in terms of investment when registering new Animal Health products under both Act 101 and Act 36.

Act 36

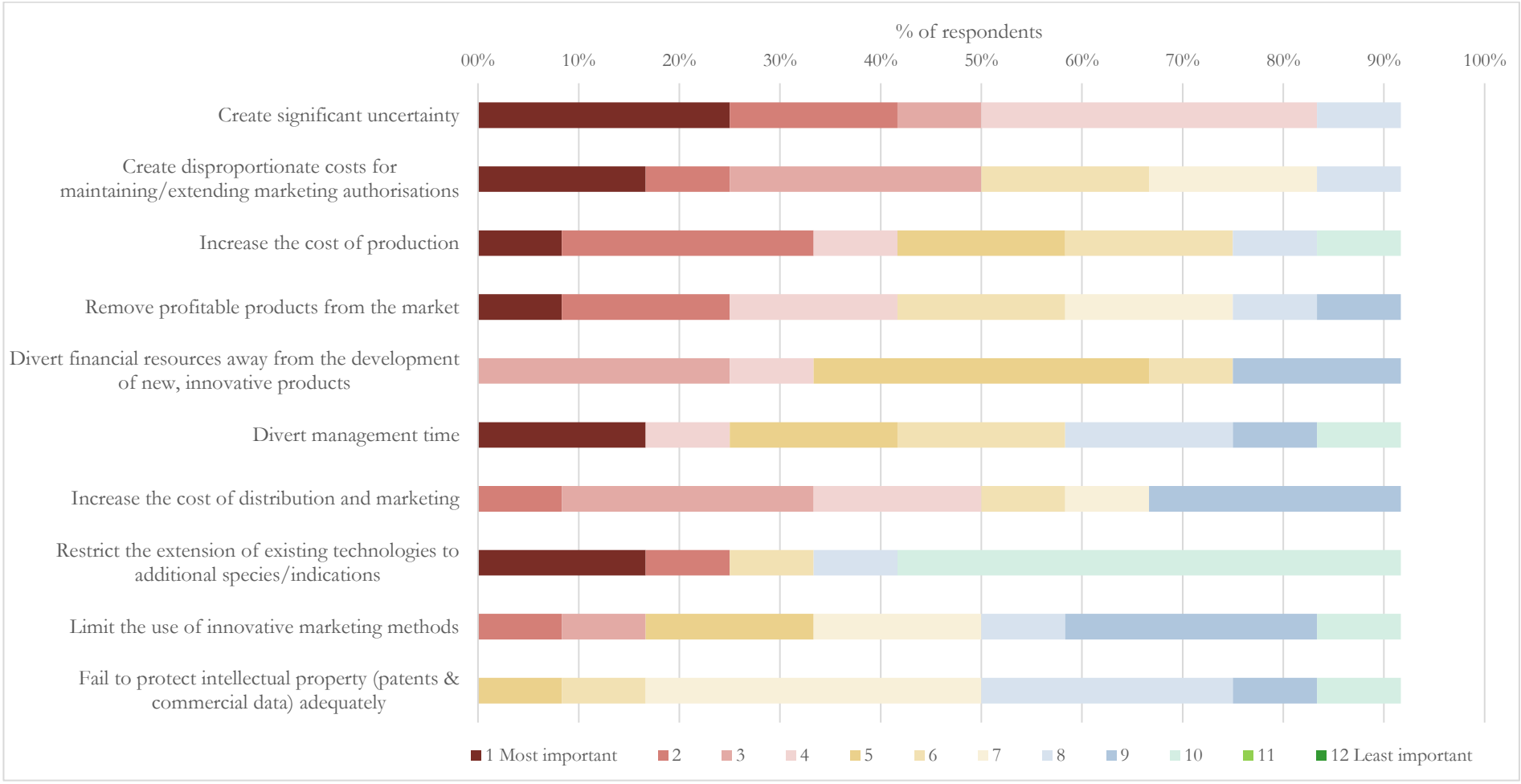
Companies were asked to rank the impact of Act 36 on the same 10 business parameters. **Eleven** companies answered this question, and the results are shown in Figure 19 with the options listed in order of impact (from most negative impact to least impact). The order of helpfulness is exactly as that found for Act 101.

Figure 18: Ranking of the most helpful areas of regulation for business (Act 101)[2]



[2] Please rank from 1 for 'most important' to 12 for 'least important'. In the workshop, please agree a final ranking by consensus

Figure 19: Ranking of the most helpful areas of regulation for business (Act 36)[3]



[3] Please rank from 1 for 'most important' to 12 for 'least important'. In the workshop, please agree a final ranking by consensus

3. Lost product development opportunity due to illegal compounding

Illegal compounding of veterinary products has been identified as a concern. Please estimate the number of products that you have not pursued development and approval for because of potential competition and lost sales as a result of illegal compounding.

Illegal compounding of veterinary medicinal products has had an impact on the commercialisation of new products. The next three sections detail the impact of lost product development opportunities due to illegal compounding. From basic numbers (27) of products not pursued for development (Table 8) to products currently losing sales (Table 9) and, finally, some range of numbers detailing the impact in terms of estimated lost sales (Table 10), the total impact is presented.

Table 8: Products not pursued for development and approval sales as a result of competition from illegal compounding

Product category	Number
Pharmaceutical	13
In-feed medication	5
Pesticides	3
Biologicals	5
Other (Pet food)	1
Total	**27**

4. Number of products losing sales due to illegal compounding

Please estimate the number of your approved products that are currently losing sales due to illegally compounded drugs that compete with your products.

Table 9: Estimated number of products losing sales due to illegally compounded competitor products

Product category	Number
Pharmaceutical	23
In-feed medication	8
Pesticides	3
Biologicals	14
Other	1
Total	**49**

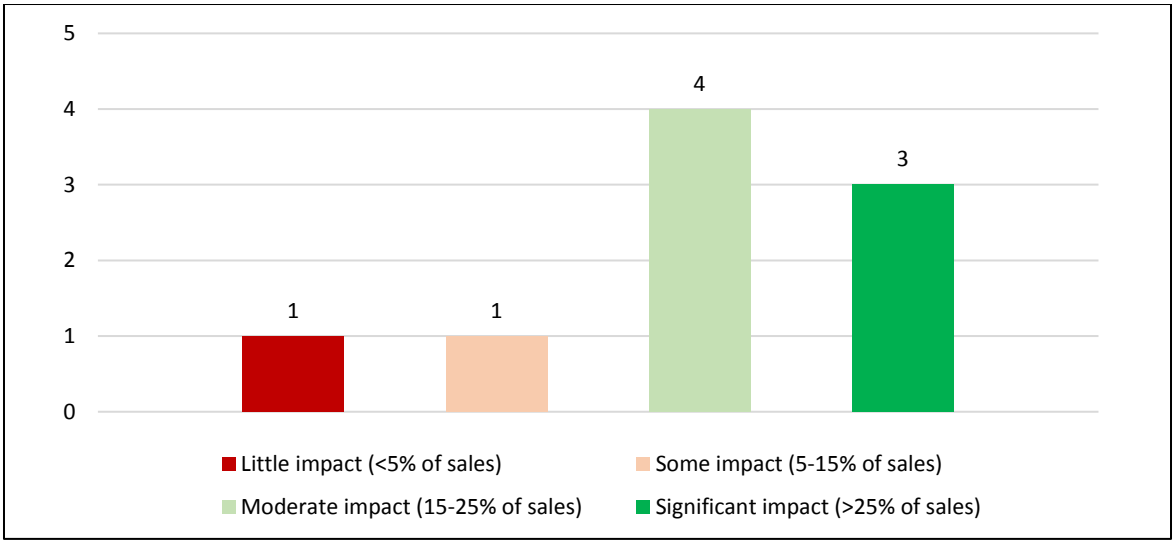
5. Quantified impact of lost product sales due to illegal compounding

For those products that are affected by illegal compounding, please give quantitative information on the impact of illegally compounded medicines on your business in terms of estimated reduction in total potential sales.

Table 10: Range of impact on lost sales

Little impact (<5% of sales)	1
Some impact (5-15% of sales)	1
Moderate impact (15-25% of sales)	4
Significant impact (>25% of sales)	3

Figure 20: Impact of illegal compounding sales



All companies that responded on the impact of illegally compounded medicines on their business reported some impact on their sales, with most companies reporting moderate to significant impact (15 – 25% of sales or >25% of sales).

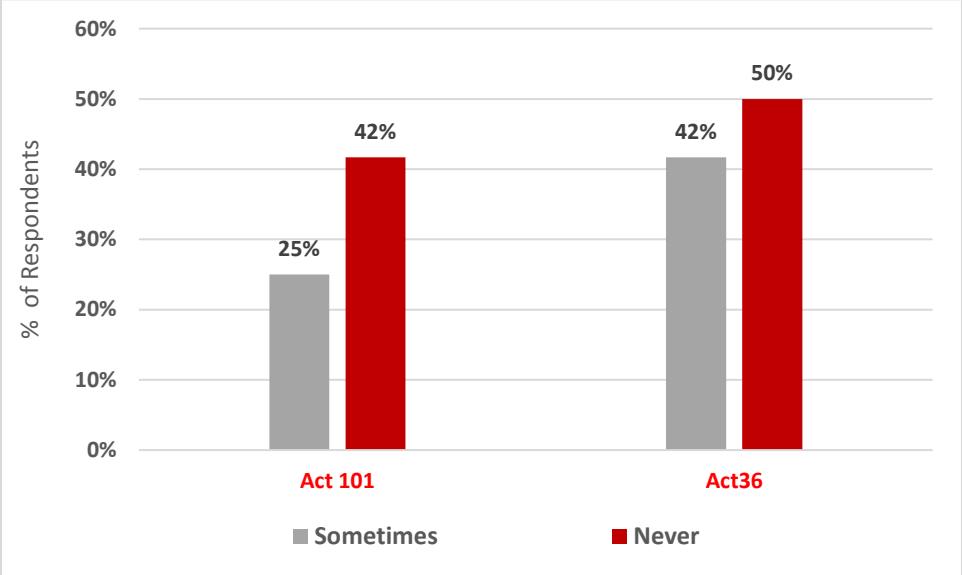
Section D - REGULATORY PREDICTABILITY & QUALITY

1. Predictability of regulatory procedures in South Africa

(a) Does the regulatory procedure in South Africa as currently managed provide you with the regulatory predictability that you need and the regulatory quality you expect? (b) If not, please tell us what the top issues are and what might be done about them (your proposed solutions moving forward).

The companies' viewpoints regarding regulatory predictability were fairly negative. Respondents were particularly negative about the regulatory predictability of Act 36 with half responding 'Never' and 42% with 'Sometimes'. No respondent gave an answer of 'Always' or 'Mostly' for either regulation act.

Figure 21: Regulatory predictability under Act 101 and Act 36



2. Main issues and potential solutions to lack of regulatory predictability

Act 101

1. Timelines
   - There is no predictability in terms of timelines
   - Timelines are unclear from time of new submission to marketing authorisation
   - Although established, timelines for responses are not adhered to
   - Products that were 'close to registration' two years ago are still not registered
2. Communication
   - Communication regarding progress is limited
   - Response times are slow
   - Telephone calls are not answered, and emails are not responded to
   - Anticipated response cannot be predicted
3. Lack of resourcing
   - The Veterinary Unit requires more human resources
4. There is lack of accountability for regulator officials

5. Guidelines
   - Guidelines are outdated and sometimes impractical
   - Closer alignment and implementation of VICH guidelines
   - Some guidelines discussed in 2017 have had no further feedback since then
6. Wildlife-specific drugs have impractical guidelines that make no sense
   - e.g. companion guidelines are applied
7. Poor record keeping
   - Poor management of submissions and queries received
   - Applications and amendments are lost, and cannot be traced
8. Processes
   - There is high documentation demand for products which are already registered in other countries
9. Evaluations are inconsistent

Act 36

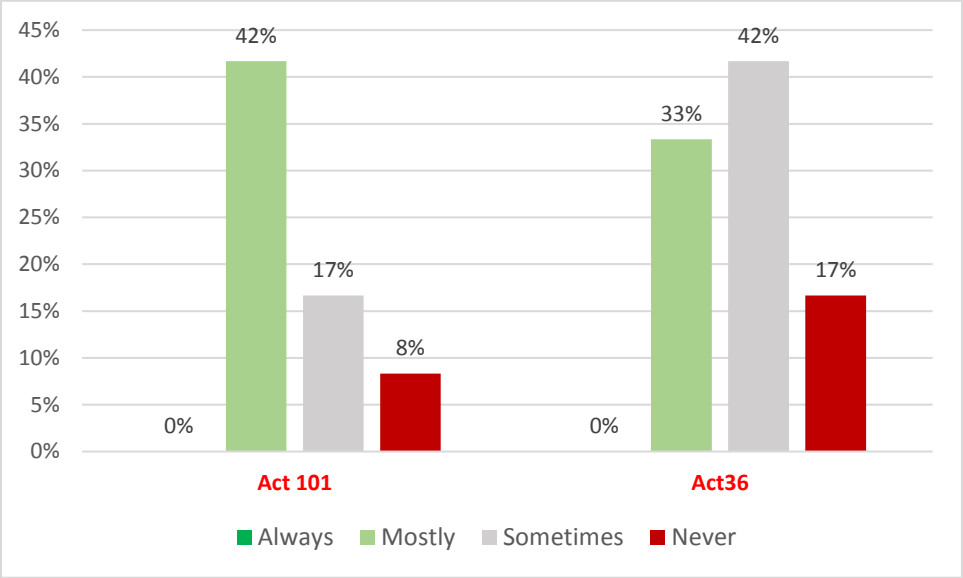
1. Timelines
   - There is no predictability in terms of timelines
   - Although established through a Ministerial Task Team, timelines for responses are not respected
   - Queries do not receive attention until the applicant makes a fuss
   - Research and development is costly and time-consuming, and the registration process should not cause excessive further delays
2. Communication
   - Lack of trust
   - Lack of decision making
   - Poor to no communication
   - Inboxes are always full, and officials cannot be reached by phone
3. Inconsistent quality requirements and review
   - Goal posts move back and forth
   - Requirements change from one evaluator to the next and some evaluators are more stringent than others (e.g. Dossier evaluations are prone to 'luck of the draw', which is an unfair practice)
   - One company reports products of similar quality standard; 1 is registered without additional information requirements, another has a 3-page recommendation letter and a third received a 14-page recommendation letter.
   - The two internal Technical Advisors are not united and do not necessarily agree on Act 36 registration requirements and regulations.
   - New internal Technical Advisor appointments are not adequately trained, with resultant gaps in understanding of product development and registration. This adds to registration delays and unnecessary and unrelated information requests.
4. Lack of resourcing
5. Accountability
   - Lack of personal accountability on part of evaluators
6. Processes
   - High documentation demand for products that are already registered in other countries
   - Re-evaluation of dossiers that have already been approved by other regulatory authorities is time-consuming. Other authorities should be recognised
   - Officials should consider that vaccines for production animals are important for food security
   - Registration procedures should be effective without being time-intensive
   - Peer review is essential so that there is benchmarking of regulatory requirements
   - Lack of decision-making

3. Quality of regulatory procedures in South Africa

(a) Does the regulatory procedure in South Africa as currently managed provide you with the regulatory quality that you need and the regulatory quality you expect? (b) If not, please tell us what the top issues are and what might be done about them (your proposed solutions moving forward).

In contrast with the results for regulatory predictability, companies were more optimistic about regulatory quality for Act 101 and Act 36 as shown in Figure 22 below. Act 101 was perceived by 42% of the respondents showing it 'Mostly' delivered on quality expectations and Act 36 with 33% of respondents.

Figure 22: Regulatory quality under Act 101 and Act 36



The top issues

Act 101

1. Administrative errors are problematic
   - Misspelling
   - Inattention to detail (e.g. an Active Pharmaceutical Ingredient manufacturer is recorded as a Finished product manufacturer)
2. An electronic tracking system that is accessible by the applicant
3. Improved communication

Act 36

1. No set timelines for regulatory feedback
2. Excessively long approval times
3. Unpredictable assessments
   - Requirements and focus of review inconsistent
   - Information that is supplied is missed during the assessment process

4. Main issues and potential solutions to lack of regulatory quality

Act 101

1. Timelines
   - A stop-clock system should be implemented
   - Strict timelines should be adhered to
   - Details of timelines and actions taken to date would assist
   - Standardise practices and criteria that will positively impact on predictability of evaluation timelines
2. Communication
   - Mandatory and improved consultation with industry was identified numerous times
3. Lack of resourcing
   - The Veterinary Unit in particular requires more human resources
4. Accountability
   - Establish service level agreements that will be maintained by the regulator in terms of queries, submissions, communication received
   - Providing details of who is dealing with a submission would be of value
   - Accountability for errors and inattention to detail
5. Guidelines
   - Regular review of guidelines would be of benefit
   - More detailed review of VICH guidelines
   - Mandatory consultation with industry before publishing guidelines
6. Poor record keeping
   - Improve documentation practice and systems at the regulator
   - Tracking / traceability of queries and submissions
7. Processes
   - Human pharmaceutical processes and templates that are reviewer friendly (eg eCTD and e-submission) could be of value where feasible
   - Reduce documentation requirements for reliance and recognition routes
8. Evaluation consistency
   - Establish standard evaluation practices and criteria
   - Training
   - Peer review

Act 36

1. Timelines
   - Adhere to Ministerial Task Team timelines
   - Research and development is costly and time-consuming, and the registration process should not cause excessive further delays
2. Communication
   - Clear mailboxes or increase their size
   - Allocate an official to respond to queries
3. Inconsistent quality requirements and review
   - Harmonise review requirements for External Technical Evaluators
     - Establish standard evaluation practices and criteria
     - Training
     - Peer review
   - Set regulatory requirements, with no moving goal posts.
   - Peer review so that regulatory requirements can be benchmarked
   - Training of the applicant and regulator on interpretation of guidelines has been lacking
4. Accountability

- Evaluators should be personally accountable

5. Processes
   - Other authorities should be recognised, and Mutual Recognition procedures established
   - Registration procedures should be effective without being time-intensive
   - Evaluators should apply good science and common sense
   - Standardise practices and criteria that will positively impact on predictability of evaluation timelines
   - Reduce documentation requirements
     - An electronic tracking system that is accessible by the applicant
     - Improved application format
6. Increased capacity

5. Procedures for registering NEW products

Consider the current process for approving new products. To what extent does the process meet the following criteria?

Act 101
Eight companies answered this question and the results are shown in Figure 23.

The overall picture is relatively balanced with a tendency towards 'sometimes' and 'mostly', a few instances where individual companies believed the criterium was 'never' met, and a few more instances where several companies felt the criterium was 'always' met.

The criteria that received the most positive outlook were "Final approval of new products is based on the expert assessment of safety, quality, and efficacy" and "based on best available science".

Figure 23: Current process for approval of new products (Act 101)

Act 36

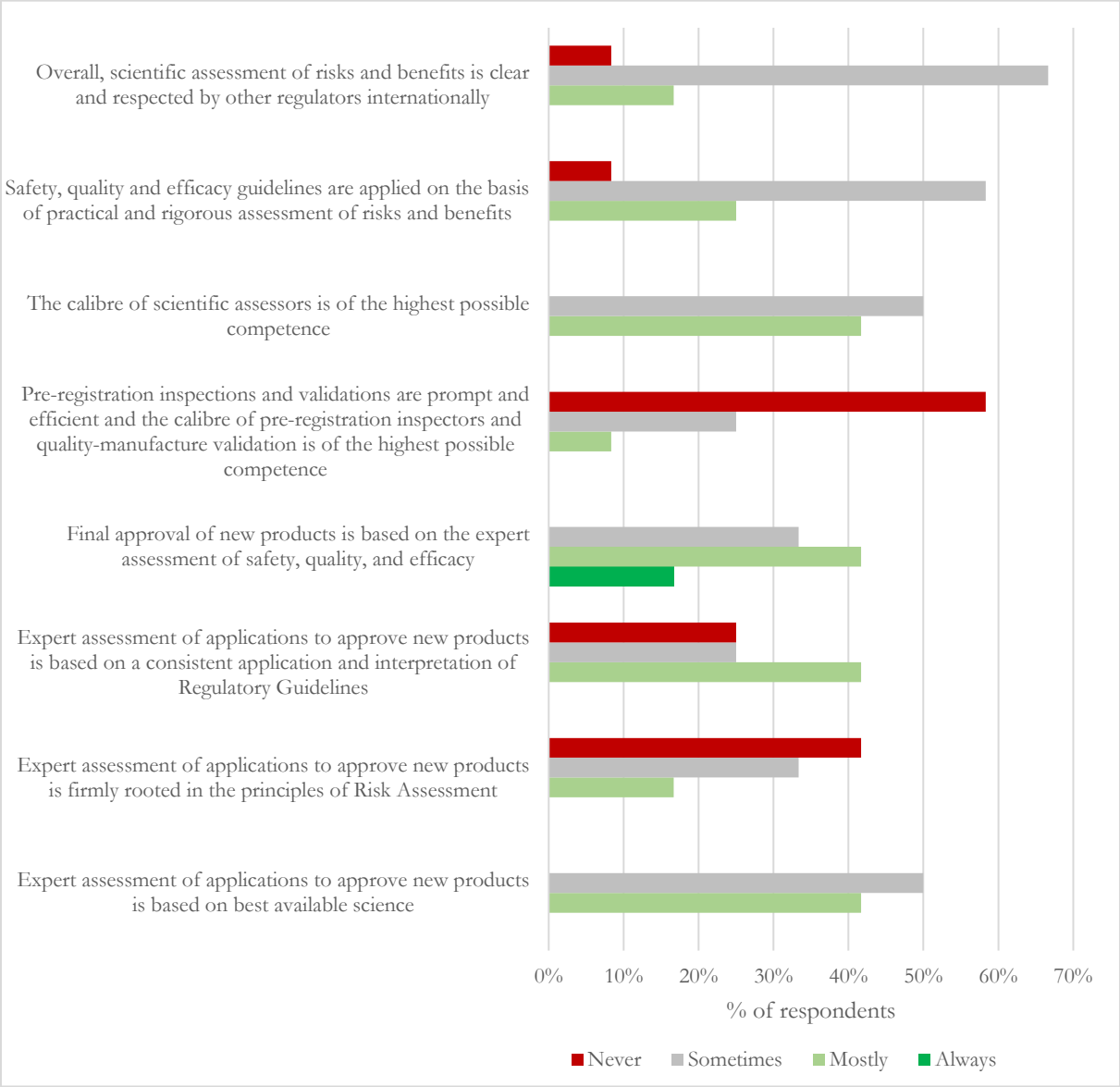
Eleven companies answered this question and the results are shown in Figure 24.

The overall picture is slightly less positive than with Act 101, with a greater tendency towards 'sometimes' and less tendency towards 'mostly'. There are more instances where several companies believed the criterium was 'never' met, and a few more instances where several companies felt the criterium was 'always' met.

As with Act 101, the criteria that received the most positive outlook were "Final approval of new products is based on the expert assessment of safety, quality, and efficacy" and "based on best available science".

The 2 criteria that companies felt was 'never' the most were "Pre-registration inspections and validations are prompt and efficient and the calibre of pre-registration inspectors and quality-manufacture validation is of the highest possible competence" and the assessment is "firmly rooted in the principles of Risk Assessment".

Figure 24: Current process for approval of new products (Act 36)



6. Procedures for maintaining EXISTING products on the market

Consider the current process for maintaining existing products on the market. To what extent does the process meet the following criteria?

The participating companies were asked to consider to what extent the current process for maintaining existing products on the market meets the 4 criteria below, and the outcome is shown in Figure 25 (Act 101) and Figure 26 (Act 36).

1. New tests or reviews are based only on a rigorous science-based analysis of pharmacovigilance data OR relevant advances in knowledge of risks based on best available science
2. Assessment is based on best available science and risk assessment
3. A clear and transparent division exists between risk assessment and risk management decisions
4. The CVP does not apply overly-bureaucratic requirements for minutiae

Figure 25: Process for maintaining existing products (Act 101)

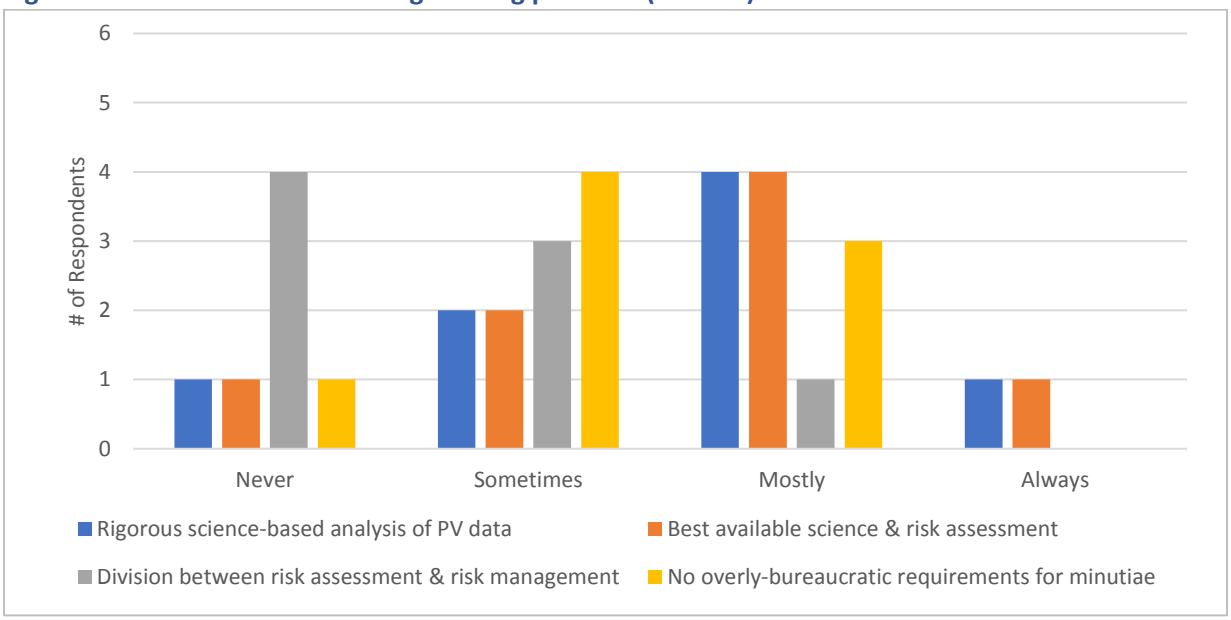
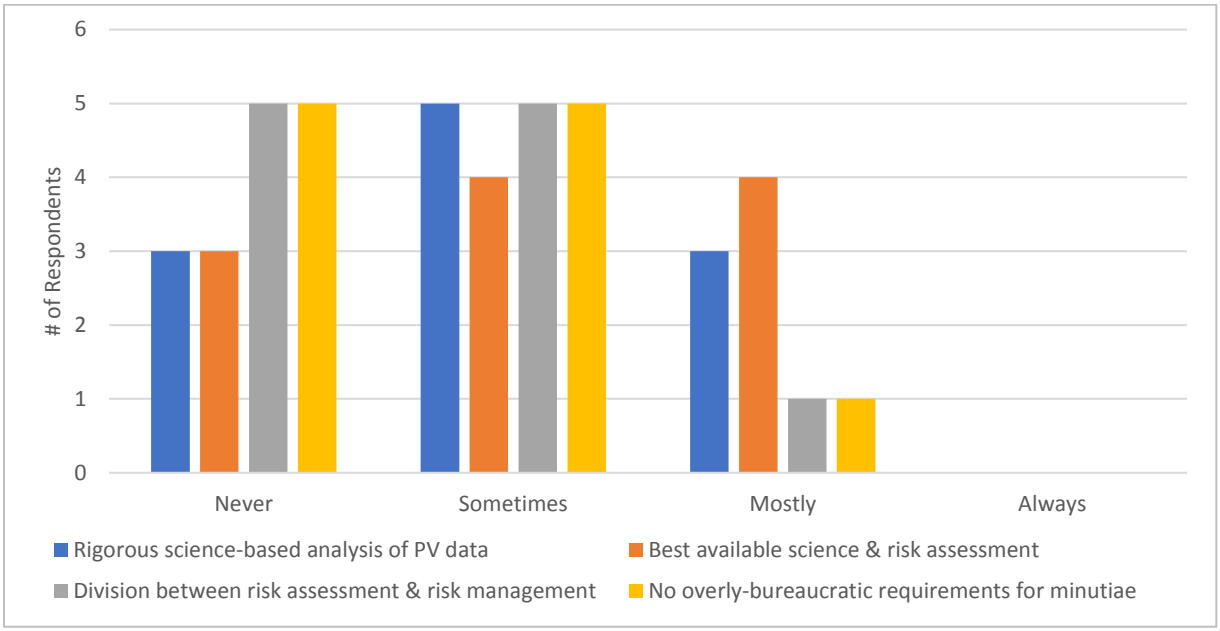


Figure 26: Process for maintaining existing products (Act 36)



7. Scientific basis of the current regulatory procedures for registering new products.

Consider the scientific basis of the current regulatory procedures for registering new products. To what extent does the process meet the following criteria?

The participating companies were asked to consider to what extent the current process for maintaining existing products on the market meets the 6 criteria below, and the outcome is shown in Figure 27 (Act 101 - eight companies responded to this question) and Figure 28 (Act 36 - eleven companies responded to this question).

- The calibre of scientific assessors is of the highest possible competence
- Safety, quality and efficacy guidelines are applied on the basis of practical and rigorous assessment of risks and benefits
- Overall, scientific assessment of risks and benefits is clear and respected by other regulators internationally
- The regulatory authorities deal with pre-submission stages helpfully and promptly
- The regulatory authorities deal with submission helpfully and promptly
- The regulatory authorities deal with further interactions promptly

For Act 101 the companies were generally more positive towards the first 3 criteria, concerning the scientific assessment, than towards the last 3 criteria, which asked about promptness of service. For Act 36 the most common response was 'sometimes' to all the options except the first; 6 of the 11 the companies believed that 'the calibre of scientific assessors is of the highest possible competence'.

Figure 27: Scientific basis of the regulatory procedures for registering new products (Act 101)

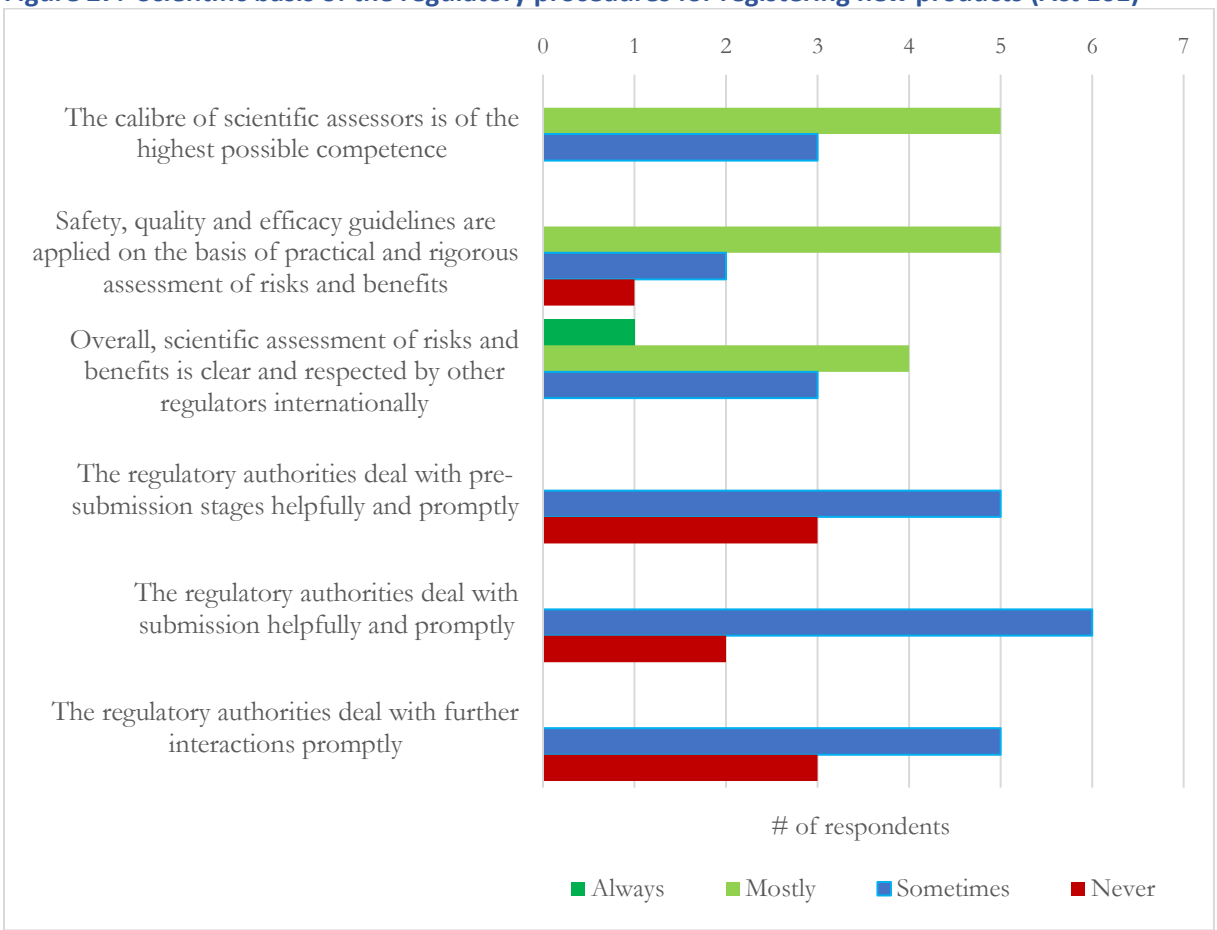
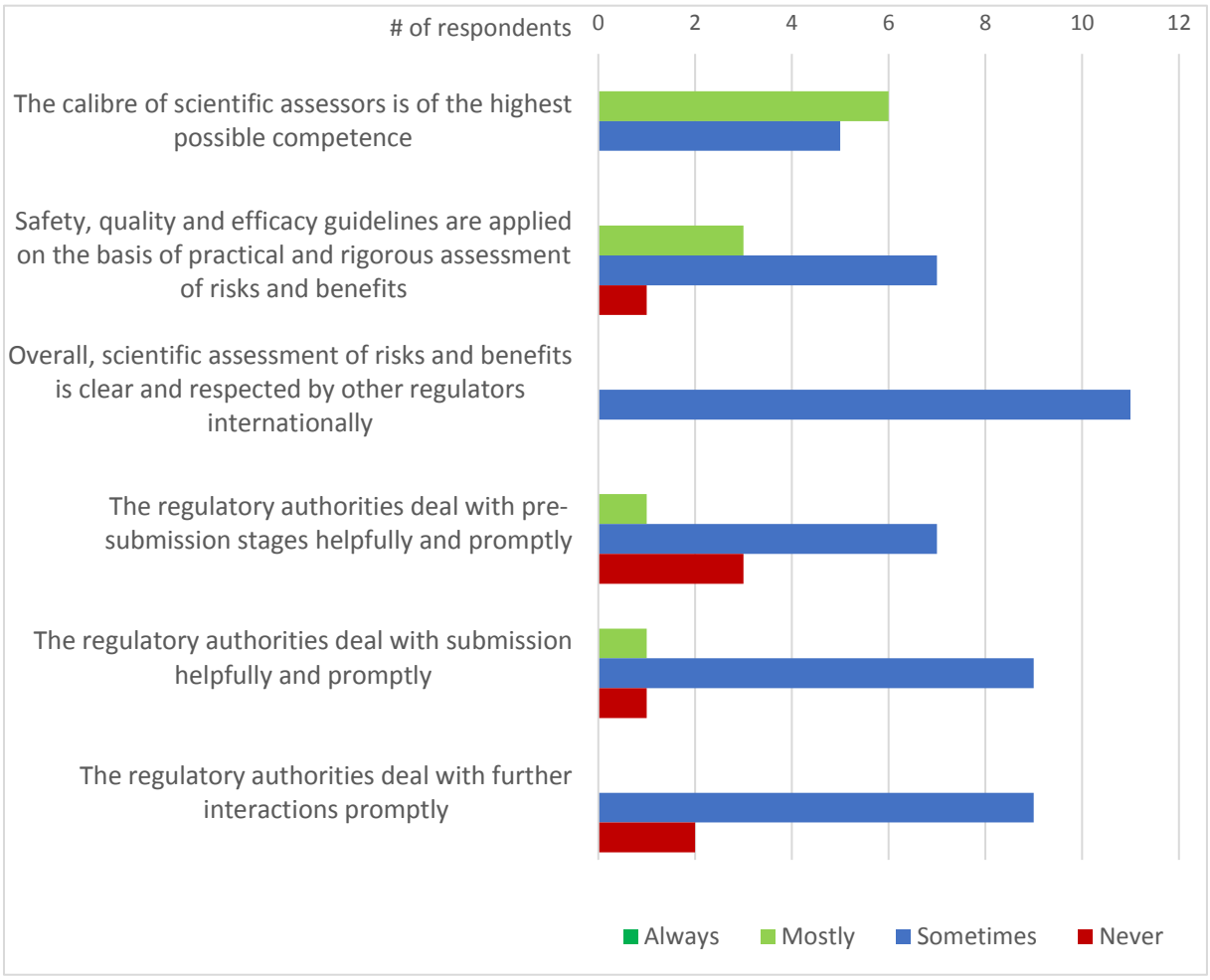


Figure 28: Maintenance of existing products (Act 36)



Section E - REGULATORY TRENDS

1. Recent beneficial changes to the regulatory frameworks in South Africa

What beneficial changes have occurred in regulatory frameworks SINCE 2015?

Act 101

1. Adoption of new guidelines
   - Harmonisation with EU guidelines
   - In particular, the EMA variations guideline
2. New regulatory authority
   - SAHPRA promises to be more effective than the former Medicines Control Council
   - The Department of Health strike is over
3. Harmonisation and mutual recognition
   - Steps towards harmonisation with other regulatory authorities, although the process has been very slow
4. Process
   - Paperless (electronic) submissions
     - More efficient
     - Environmentally friendly
     - More secure
   - Acceptance of the Reliance model for companion animal products
     - The model is a risk assessment-based model
     - More efficient in terms of registration approval time frames
   - Although not a regulatory requirement for veterinary medicines, CTD format is accepted
     - Template is reviewer-friendly
   - Veterinary medicines are being channelled for the most part exclusively through the Veterinary Medicines Unit
     - This facilitates the registration process as there is better understanding of the unique requirements and administration of veterinary medicines
5. Backlog
   - Pharmaceutical and analytical backlog being attended to
6. Communication
   - There has been more consultation on regulatory practices and policies with Animal Health stakeholders

Act 36

1. Guidelines
   - Alignment with some international guidelines.
   - Adoption of some guidelines that were drafted by SAAHA
2. The DAFF-SAAHA Stock Remedy Registration Project (a Public-Private Partnership with the Department of Agriculture)
3. The GMP guideline is close to completion and acceptance
   - The Inspectorate is performing gap analyses with local South African companies in order to assist them with GMP certification
   - This will assist companies to comply with GMP requirements for other African countries, thereby facilitating export
4. Autogenous vaccines guideline has been accepted by Act 36
   - Will assist to regulate these vaccines
   - Will have impact on the illegal manufacture of unregistered compounded vaccines

2. Expected changes that have NOT occurred in South Africa regulatory frameworks

What expected changes have NOT occurred in regulatory frameworks SINCE 2015 in spite of promises of change?

Act 101

1. New regulatory authority
   - Not all processes are clear with formation of SAHPRA (e.g. Inspectorate)
2. Veterinary Products Policy Task Team (VPPTT)
   - A multi-agency working group that was intended to implement VICH guidelines has not met for 2 years
3. Timeframes
   - The registration and variation backlog has not been cleared
   - Registration timelines have not decreased as promised to 12 months for new submissions and 3-6 months for major Type II variations and additional clinical claims
4. Guidelines
   - Approval of new guideline for the registration of Minor Use and Minor Species
   - Many guidelines still under review and not yet published or adopted, with no further feedback
5. Capacity
6. Policies
   - Mutual recognition
   - Pharmacovigilance
   - Minor Use / Minor Species (MUMS) guideline

Act 36

1. Ministerial Task Team recommendations
   - These have not been adopted per the recommendations for improvements on the regulatory system of Agricultural and Stock Remedies interim report dated 02 September 2011.
2. Timeframes
3. The DAFF-SAAHA Stock Remedy Registration Project (a PPP with the Department of Agriculture)
   - Participants noted that, while the Project was rigorously controlled by SAAHA, a lack of buy-in from the regulatory authority resulted in delays being augmented
   - While most companies agreed that they have seen benefit from the Project, one company considered the PPP to be a waste of companies' resources, and another noted that results were not yet satisfactory
   - Although the PPP was intended to reduce an extensive registration backlog, the Department treated it as a project to improve dossier quality. Dossiers were not therefore fast-tracked and the backlog was not treated with urgency.
   - Project evaluations were more comprehensive, and requirements were applied retrospectively, thereby increasing the length of time to approval
4. Revised guidelines adopted in 2017 were retrospectively implemented on dossiers that had already been in the system prior to 2017.

3. Problematic changes to the South Africa regulatory frameworks

What regulatory changes SINCE 2015 have given you the most problems and why?

Act 101

1. New regulatory authority
   - Conversion of the regulator from the MCC to SAHPRA (from a Government entity to a self-funding institution)
   - Relocation of the regulatory authority to new premises
     - Resulted in no assistance, review or communication for an extended period
     - There was no access to previously submitted variations and dossiers
   - Protest action at the Department of Health
     - Officials were not available for a number of months
     - Applicants were unable to deliver submissions, collect communications, or meet officials
2. Clinical trial requirements
   - Multi-agency requirements lead to stringent application requirements and major time delays in obtaining trial approvals
   - Agency involvement sometimes exceeds their mandate
   - Application requirements are tedious and impractical
   - Feedback has been lacking on submitted applications, thereby delaying dossier submission
3. Guidelines
   - New guidelines implemented before consensus agreement
   - New guidelines made applicable while ignoring projects already in development
4. Process
   - Resubmissions are required on a regular basis, resulting in duplication of work and effort
   - The SCORE document is time-consuming
   - Registration transfers for new legal entities are not addressed in totality
     - Some were addressed as 'business as usual' and were approved
     - Others were included in the backlog and are pending registration

Act 36

1. Process
   - No transparency
   - Inconsistent
   - No sense of urgency
     - Excessive delays in registration
   - Companies are not treated equally
2. Guidelines
   - Changes to guidelines
   - Excessive new regulatory criteria
3. Guidelines
   - Envisaged GMP requirements may prove challenging but will be necessary
   - Guidelines are not enforced consistently
4. Regulator applying a non-risk-based interpretation of new guidelines (overly bureaucratic requirements are applied for minutiae) to applications that were submitted years prior to the new guidelines being adopted
   - This has led to a discord between the company experts who compiled the original dossiers, and the assessment years later to a set of rules that personnel had not even been trained in
5. The DAFF-SAAHA Stock Remedy Registration Project (a Public-Private Partnership with the Department of Agriculture)
   - One company reported that the PPP had been particularly problematic for them
   - SAAHA PPP and the promise of clearing the backlog and fast-tracking of registrations has not happened.

- Global principals were made promises that companies could not keep.
- Additional cost implications did not translate into registrations
- PPP evaluations are more stringent

6. Significant increase in Stock Remedy tariffs but no reciprocal improvement in service delivery

4. Business decisions influenced by regulations

Have regulations played a major role in influencing you to take any of the following major decisions over the last five years?

The participants were asked whether regulations had played a major role in influencing major business decisions over the last five years. Ten paired (e.g. increase or decrease) options were presented, and the average score attributed to these options by the participants are shown in Figure 29 (Act 101) and Figure 30 (Act 36). The top 5 decisions where regulations did and did not play a role are summarised in Table 11. The Figures also highlight the business decisions frequently not done.

Table 11 identifies the most common business decisions taken (from the options provided). It is also apparent from this data that regulations can influence a decision in either direction. For example, for both Act 101 and Act 36, the most common decisions were to increase product range and to reduce product range in South Africa. It is also evident that for common decisions (such as increasing or decreasing a product range) regulations frequently play a role but are also quite likely not to play a role in the decision. Thus the impact of regulations can have a varied effect and depends upon the precise nature of the products or the business situation of the company.

Table 11: The top 5 decisions where regulations did and did not play a role

Top 5 where regulations played a role	Top 5 where regulations played no role
Act 101	
1. Increase product range in South Africa	1. Increase product range in South Africa
2. Reduce product range in South Africa	2. Invest in production outside South Africa
3. Invest in production outside South Africa	3. Increase (geographic) market focus in South Africa
4. Invest in production inside South Africa	4. = Reduce product range in South Africa = Switch R&D budgets to labs outside South Africa = Locate R&D Facilities outside South Africa = Locate R&D Facilities inside South Africa
5. Restrict (geographic) market focus in South Africa	
Act 36	
1. Increase product range in South Africa	1. Increase (geographic) market focus in South Africa
2. Reduce product range in South Africa	2. Increase product range in South Africa
3. Locate R&D Facilities outside South Africa	3. Invest in production inside South Africa
4. Invest in production outside South Africa	4. = Invest in production outside South Africa = Reduce product range in South Africa = Switch R&D budgets to labs inside South Africa = Locate R&D Facilities inside South Africa
5. Locate R&D Facilities inside South Africa	

The following observations were made during the workshop:

- The veterinary sector is becoming over-regulated, and it is becoming less viable to pursue new products.
- The dual registration system with registrations under the Departments of Health and Agriculture is problematic, and makes it difficult for companies to make decisions, particularly as there is no clarity on how this matter will be resolved.
- The One-Health approach will increase synergy and food security will become problematic.
- Alignment with VICH will be of value. Companies could make commercial decisions regarding viability for the South Africa market.

Figure 29: Influence of regulations on business decision-making (Act 101)

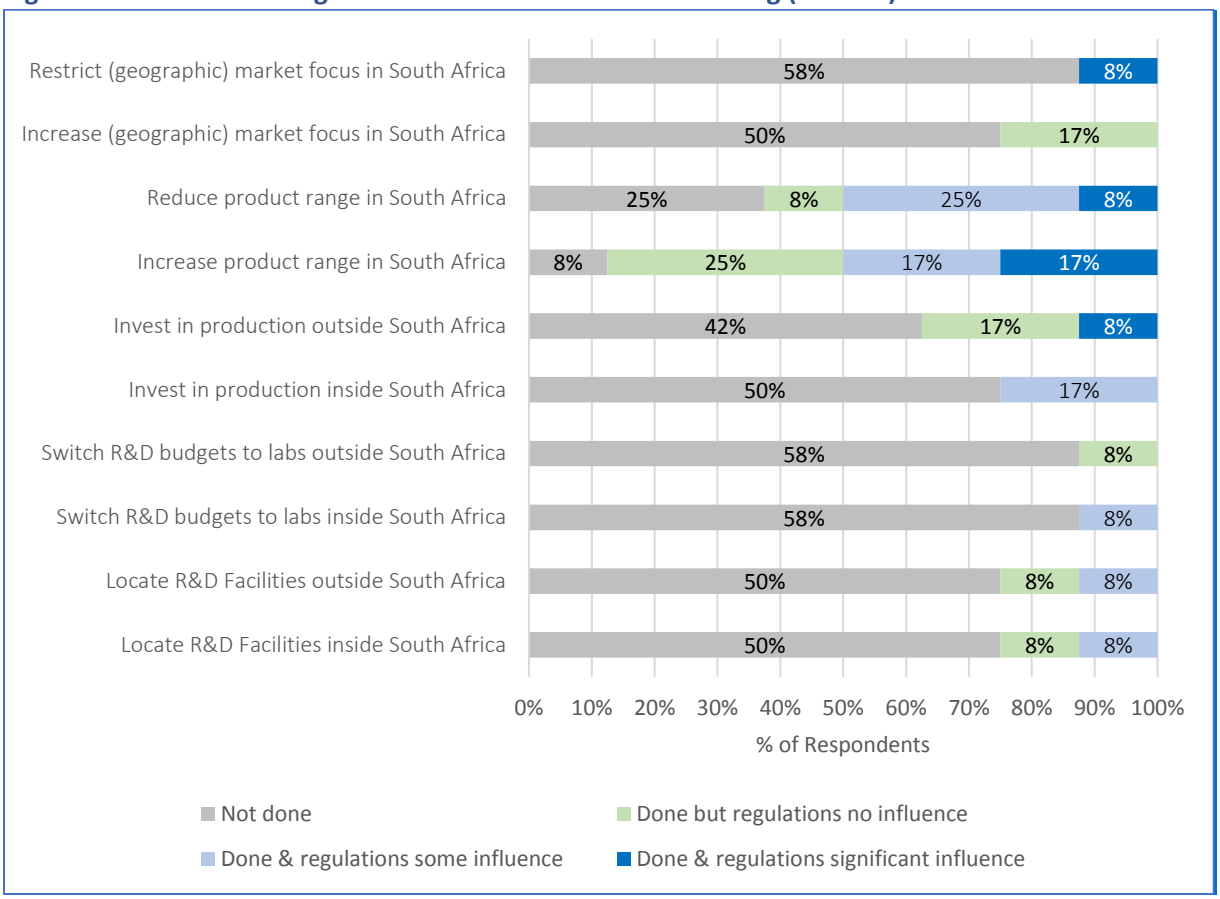
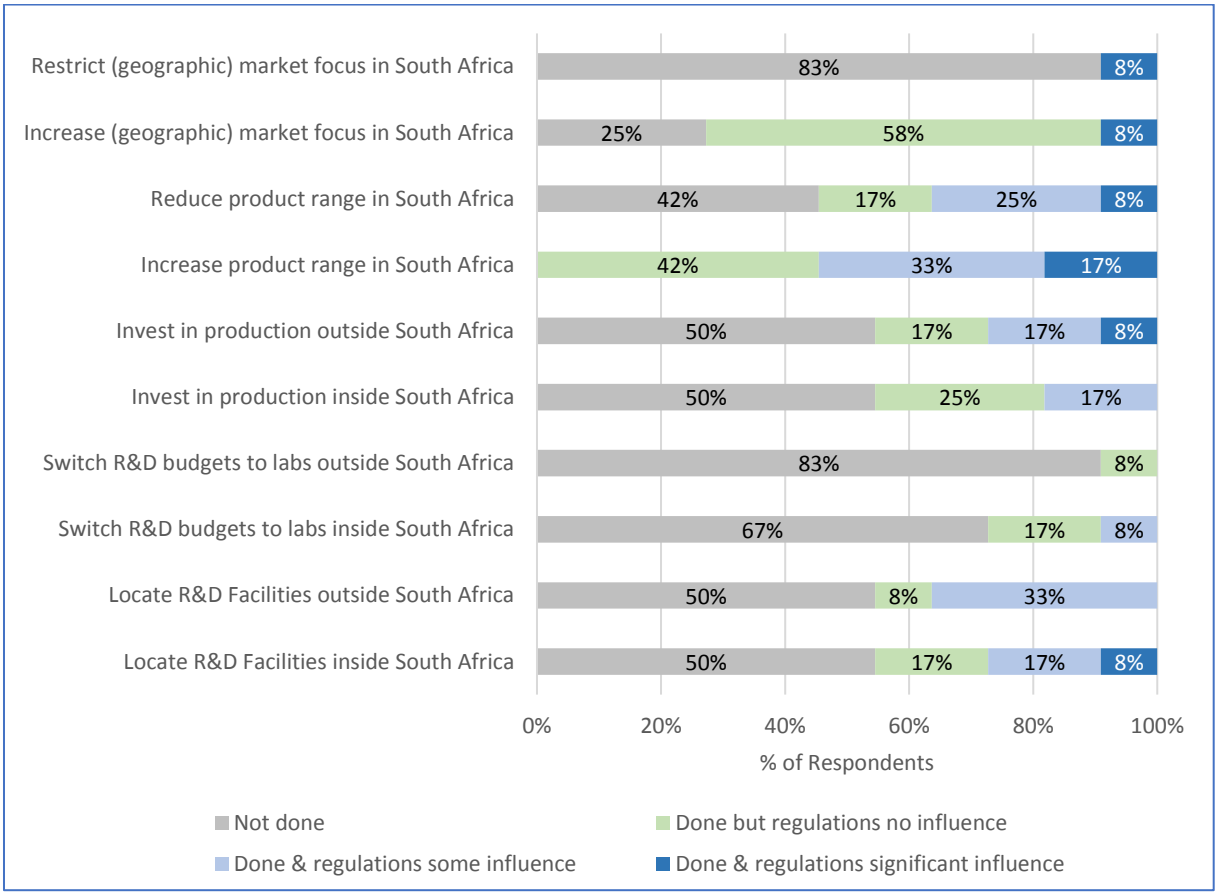


Figure 30: Influence of regulations on business decision-making (Act 36)



Section F - HOPES AND EXPECTATIONS FOR THE NEXT 5 YEARS

1. Changes in regulatory approach and their impact on the future

The following trends or changes in regulatory approach have been taking place recently and may well have an impact in future. What impacts do you expect these changes to have on your business in the next 5 years?

The participants were presented with 8 current trends or changes in regulatory approach and asked to rank them on a scale from very helpful to very unhelpful.

Nine companies answered this question for **Act 101** and twelve companies for **Act 36**. The results are presented, ranked in order of helpfulness, in Figure 31 and Figure 32 respectively. The order of the ranking of the 8 options is identical for both Acts, and the scoring is quite similar but with an overall more positive outlook regarding Act 101.

There was almost unanimous agreement that 4 of the eight options were very helpful or helpful:

- Electronic submission tailored to animal health (67% very helpful)
- Moves towards a common technical document (56% very helpful)
- Moving from a zero-risk approach to a benefit:risk assessment (44% very helpful)
- Acceptance of JECFA agreements for residues of non-contentious molecules (22% very helpful)

The remaining 4 options were also generally seen as helpful or very helpful, with the exception of one company, which regarded the trends as not helpful or very unhelpful.

Figure 31: Trends in regulatory approach (Act 101)

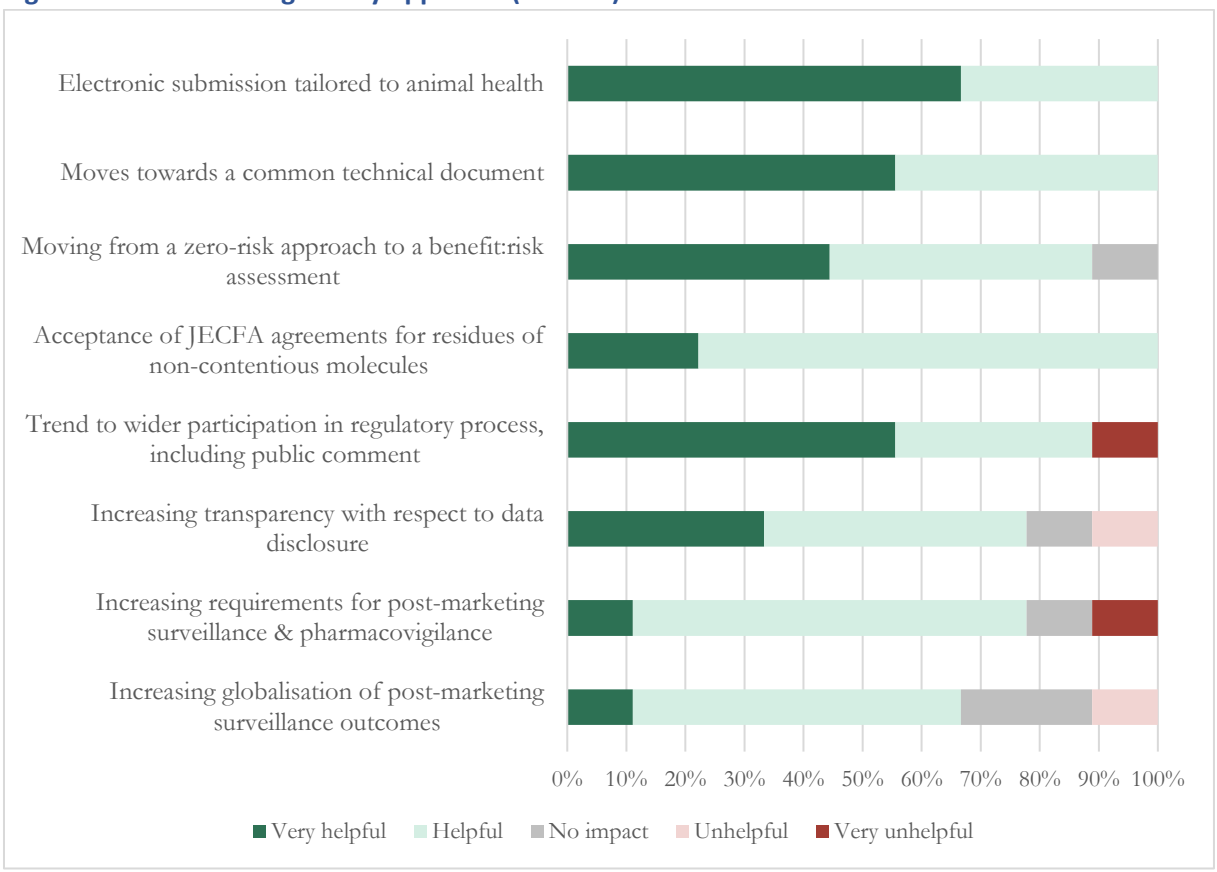
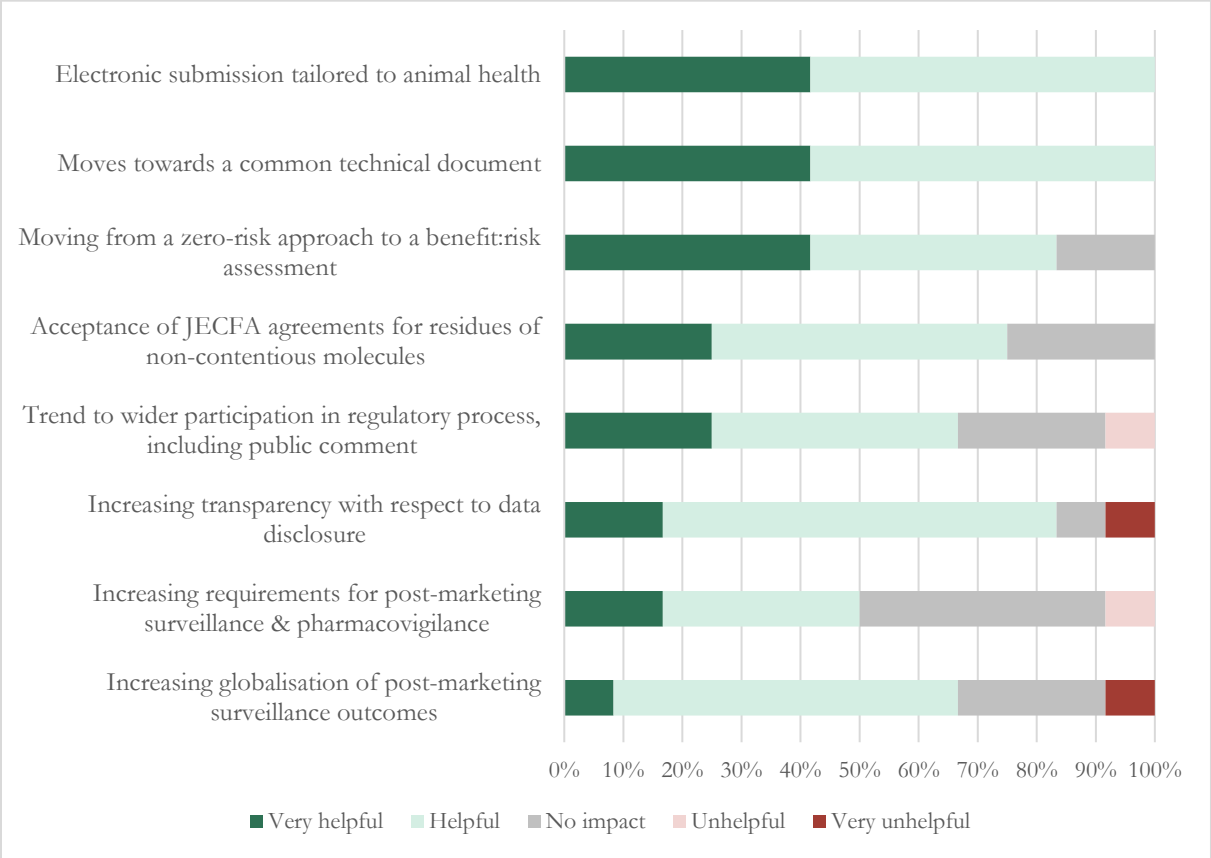


Figure 32: Trends in regulatory approach (Act 36)



2. Impact of ability to use international data on ability to innovate

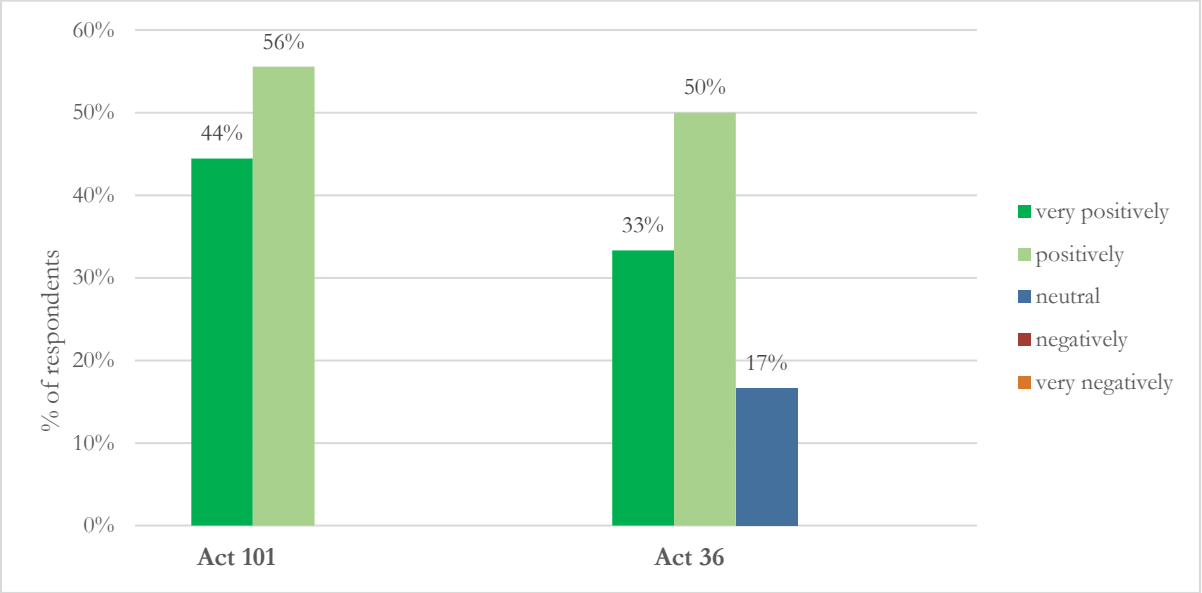
Does the ability to use international data in the SOUTH AFRICAN review process impact your ability to innovate?

Nine companies answered this question for Act 101 and twelve companies for Act 36. The results are shown in Figure 33.

Act 101
The participants were unanimous in their view that the ability to use international data in the South African review process has a positive or very positive impact on the ability to innovate.
T
Act 36
The large majority (83%) of participants agreed that the ability to use international data in the South African review process has a positive or very positive impact on the ability to innovate.

None of the companies viewed this negatively.

Figure 33: Impact of use of international data on ability to innovate



3. Desired changes

What changes do you still want to see and why?

Act 101

Communication

- Better communication
- Accessibility of officials
- More face-to-face meetings to enable companies to better track their submissions and facilitate registration
- Consolidated feedback from all departments on dossier submissions / amendment reviews will improve efficiency and permit industry to bring new products to market faster

Transparency

- Greater transparency

Process

- Implement promised changes and get them working properly
- Efficient, reliable and predictable registration process that would allow for better planning by companies
- Predictable outcomes based on data submitted
- Personal accountability for evaluators
- Reliance process fully implemented

Timeframes

- Shorter timelines
- Meeting target deadlines

Guidelines

- Publication of MUMS guideline

Act 36

Vaccines

- South African requirements for veterinary biologicals should be aligned to international requirements (e.g. USDA)
- Companies have problems with USDA dossiers for vaccines, which tend to be lighter on detail than is required by Act 36.
- Stronger, independent Act 36 for Veterinary Biologicals, independent of Act 101
- Tighter control on compounded vaccines

Process

- Introduce a transparent regulatory process with clear timelines
- Increase regulatory capacity through knowledge transfer
- Personal accountability for evaluators
- Regulator should not try to regulate outside of their scope
- Standardise agreed acceptance criteria for Stock Remedies based on risk category (i.e. pesticides, products for oral use, injectable products, biological products, complimentary products)
- More efficacy and dedication meeting target deadlines

Communication

- Website improvements with information available
    - Government websites should list all relevant information concerning the authorisation of veterinary medicinal products for transparency and predictability, and should also house a list of authorised products
- Improved communication channels
- Accessibility of officials
- More engagement with the Animal Stakeholders across a broader scope, e.g. the Department of Animal Health (Act 35) should be included in Liaison meetings

Mutual recognition

- International collaboration with other regulators
- Harmonisation of regulatory requirements within Africa (at least)

Timeframes

- Shorter timelines

Predictability

- Predictable outcomes based on data submitted
- More consistency

Guidelines

- Adoption of EMA guidelines
    - Implementation could result in reduced times for approvals of variations and submissions

Section G - REGULATORY COOPERATION AND SPECIAL PRODUCT CATEGORIES

1. Regulatory trend for regional regulatory cooperation

(a) Does your regulatory authority engage in any forms of regulatory cooperation, such as joint reviews or parallel assessment, with another regulatory authority? (b) If yes, how do joint reviews or parallel assessment between USA and another country impact your ability to innovate?

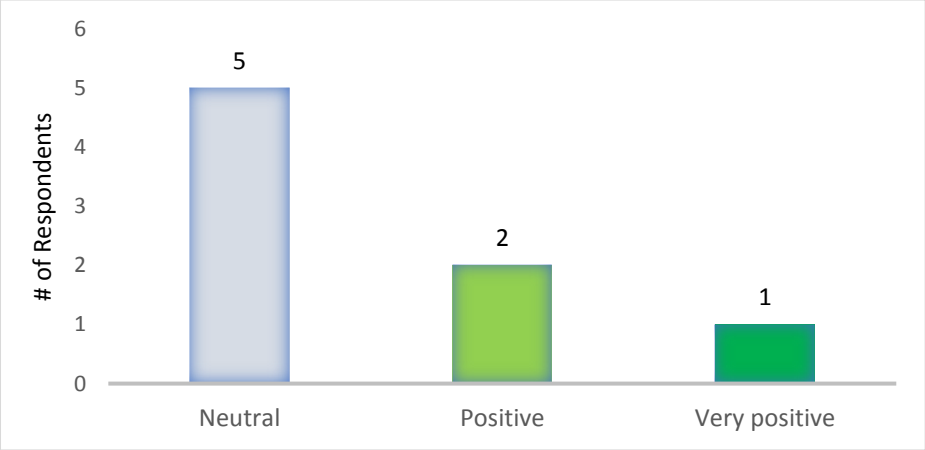
Act 101
SAHPRA engages in regulatory cooperation with several aligned authorities, including the EU, USA, Australia, Canada, Sweden, but there is little cooperation within the sub-Saharan region.

Generic products that are registered and listed under certain authorities with whom the regulator is aligned (EU, USA, Australia, Canada, Sweden) [mostly generics of antibiotics and NSAIDs].

Where regulatory alignment takes place it has either no impact or a (very)positive impact (Figure 34).

Act 36
There is no alignment for registrations held under Act 36.

Figure 34: Impact of regulatory cooperation on ability to innovate (Act 101)



Many companies manage regulatory functions for sub-Saharan Africa from South Africa. Regulatory cooperation, harmonisation and mutual recognition are important for developing and growing business into Africa.

2. Special product categories exempt from full data requirements

In South Africa do "special categories" of product exist, such as "minor species", or "generic" for which there is an exemption from certain data requirements (e.g. registration can be obtained with an abbreviated or abridged data dossier)?

In South Africa "special categories" of product exempt from full data requirements do exist for both Act 101 and Act 36.

Act 101

- Generic products that are registered and listed under certain authorities with whom the regulator is aligned (Europe, USA, Australia, Canada, Sweden) [Mostly generics of antibiotics and NSAIDs]
- Products where bioequivalence is established
- Minor Use / Minor Species (mostly game)

Act 36

- Minor Use / Minor Species
  - Pigeons, cage birds and fish remedies are considered to be Minor Species
- A system exists where 'daughter' and 'parallel' registrations are approved as an administrative process, provided that no changes are made to the daughter or parallel compared to the 'mother' product (i.e. identical dossiers in all respects, including production)
- Some exemptions are permitted on motivation by the applicant

5. Key Trends

South Africa's **dual registration system** for Veterinary Medicines with Human Medicines under Act 101/1965 and Stock Remedies under Act 36/1947 impacts business decision-making and complicates registration and product control. Measures to encourage **one act** have so far been unsuccessful. Harmonisation of requirements is seen to be a first step to rectifying the problem until such time as legislative changes can be considered. It is very difficult to harmonise into other regions when the local authorities themselves are not united in their requirements.

The newly formed **South African Health Products Regulatory Authority** (SAHPRA) is an entity of the National Department of Health, responsible for Human and Veterinary Medicine registration. **Veterinary Medicines** comprise medicines such as antibiotics, analgesics and anaesthetics. Approximately 10% of animal health products are registered under Act 101/1965 by SAHPRA, with the balance being **Stock Remedies** registered under Act 36/1947 by the Department of Agriculture, Land Reform and Rural Development.

Act 36/1947	Department of Agriculture	Stock Remedies	90% of products
Act 101/1965	SAHPRA, Department of Health	Veterinary Medicines (e.g. antibiotics, analgesics and anaesthetics)	10% of products

SAHPRA assumed the role of the former Medicines Control Council and is constituted as an independent entity reporting to the Minister of Health. The formation of SAHPRA was widely seen to be a positive step that is expected to bring about positive regulatory changes.

Regulatory predictability and certainty is lacking for veterinary registrations under both authorities. The need for **clear and timely communication** was raised in numerous discussions.

Data Protection for new molecules and new claims is lacking in South Africa.

Defensive R&D expenditure has increased significantly in recent years, diverting time, resources and focus from other development projects.

Regulatory timeframes have increased, and backlogs are encountered with both regulatory authorities.

Respondents highlighted delays encountered with **transfer of licence holders**. Some companies were forced to suspend business operations pending regulatory approval with no reliable timeframes for approval.

The emphasis on **more stringent data requirements for Stock Remedies**, while welcomed as being necessary to meet current global scientific standards, should be applied in a considered, scientific and risk-based manner. A retrospective evaluation of historical dossiers in the backlog according to current data requirements increased the **regulatory burden and documentation demand** for companies.

Stock remedy registration **guidelines are not applied consistently** by evaluators and are open to interpretation. Some respondents believe that **Stock Remedy applicants** are not **treated equally**.

The **multi-agency** approach to **clinical trial protocol and permit approval** is demanding and time-consuming, while increasing time for protocol approval. **Communication and responses** on protocol

applications are limited. While multiple agencies working together on protocol approvals is of benefit for veterinary products, the manner in which this process is conducted is considered to exceed regulatory authority mandates.

Regional regulatory harmonisation in sub-Saharan Africa is essential. The small volumes of product currently sold in the region compared to global sales necessitate a common label and dossier for sales of products to be viable. The region shows great potential for development and sales if current barriers to registration can be overcome.

Mutual recognition with other regulatory authorities would be of value to reduce documentation burden, and to speed up approval, particularly when taking into account the lack of **resources** within the South African authorities.

Illegal compounding, particularly of autogenous vaccines and compounding of veterinary products where an innovator product exists, requires additional controls and oversight. A review of relevant legislation should assure the rights of innovators where data protection and patents are in place. While the need for compounding is acknowledged in veterinary medicine, it should not permit a breach of the rights of innovator companies or be used to commercialise products that should rightly undergo a full registration review.

A review of **Maximum Residue Limits** is needed for Veterinary Medicines and Stock Remedies, particularly for new molecules, and for alignment with international MRL changes.

A regional **pharmacovigilance and a global post-marketing surveillance system** would be welcomed.

Data requirements for Stock Remedy biological and parasiticide products should be risk-based and based on current scientific requirements. A pharmaceutical dossier one size fits all approach has proven to be difficult to meet.

6. Conclusions and recommendations

- The **dual registration system** for Veterinary Medicines and Stock Remedies must be resolved. It is essential for the Ministers of Health and Agriculture to commit to a common process that would result in **one act for veterinary products.**
- Respondents look forward to changes to be implemented by the new **SAHPRA** and are positive that veterinary registration will be strengthened through the process.
- **Regulatory predictability and certainty** are a priority. Clear and reliable timeframes are required, with **reliable processes and systems.**
- Measures are required to ensure **Data Protection and Integrity**, as well as **Patent protection** for innovator products.
- **Defensive R&D expenditure** is expected to be significant for the foreseeable future. A **risk-based** approach to R&D requirements would be of value in reducing unnecessary research and costs, particularly for known molecules and species.
- Applications for **transfer of licence holders** should be prioritised as these approvals have commercial impact.
- The **data requirements for Stock Remedies** should be reviewed in discussion with External Technical Evaluators and the industry. Data requirements should focus on current global scientific standards and be risk-based.
- Consistent **evaluation guidelines** are required for External Technical Evaluators.
- The system for **clinical trial protocol and permit approval** should be reviewed and changes implemented to expedite approvals.
- **Regional regulatory harmonisation in sub-Saharan Africa** is critically important for growth of this market. **Common dossier formats**, **common labels** and **mutual recognition** should be encouraged.
- The **compounding legislation** should be reviewed for gaps and to ensure that the rights of innovators are addressed.
- **Illegal compounding** should be stringently addressed by regulatory authorities with offenders being prosecuted. A transparent process is required.
- **Maximum Residue Limits** for Veterinary Medicines and Stock Remedies require review.
- The implementation of a regional **pharmacovigilance and post-marketing surveillance system** should be encouraged.
- **Data requirements for Stock Remedy biological and parasiticide products** should be applicable to the type of product.

Acknowledgements

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Glossary of Abbreviations

Act 101	Medicines and Related Substances Control Act
Act 36	Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, Act 36 of 1947
APVMA	Australian Pesticides and Veterinary Medicines Association
CTD, eCTD	Common Technical Document, Electronic Common Technical Document
DAFF	Department of Agriculture, Forestry & Fisheries
FAO	Food & Agricultural Organisation (USA)
GMP	Good Manufacturing Practices
IP	Intellectual Property
JECFA	Joint FAO/WHO Expert Committee for Food & Agriculture (
MRL	Maximum Residue Levels
NSAID	Nonsteroidal Anti-Inflammatory Drugs
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PPP	Public Private Partnership
R&D	Research & Development
SAAHA	South Africa Animal Health Association
SAHPRA	South African Health Products Regulatory Authority
USDA	United States Department of Agriculture
VICH	Veterinary International Conference on Harmonization
VPPTT	Veterinary Products Policy Task Team
WHO	World Health Organisation

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This report and reports on the other markets included in the benchmarking survey are available at: HealthforAnimals.org/GBS2020

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