NSW GOVERNMENT | Department of Primary Industries

Regulatory Impact Statement
Proposed Stock Medicines Regulation 2019

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Regulatory Impact Statement: Proposed Stock Medicines Regulation 2019

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More information

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Executive Summary

The Stock Medicines Regulation 2010 (the SM Regulation) is due for a staged repeal on 1 September 2019. Remaking this rule requires the preparation of a Regulatory Impact Statement (RIS) and a period of public consultation.

The SM Regulation is the main legislation that supports the *Stock Medicines Act 1989* No. 182 (the SM Act). The SM Act sets the foundation for strategic and coordinated management of the use of stock medicines used to treat livestock. This legislation is also guided by the *Agricultural and Veterinary Chemicals Act (NSW) 1994 No 53* and the Commonwealth *Agricultural and Veterinary Chemicals Code Act 1994*.

Stock medicines are drugs or medicines that are used to treat or prevent disease, injury and parasites or relieve pain and suffering in livestock. Effective use of stock medicines will maintain the health of humans and livestock, the productivity of livestock production, animal welfare conditions, and access to international markets.

In 2017-18, the value of livestock production that made use of stock medicines to maintain productivity was estimated at $2.3 billion for beef, $1.3 billion for wool, $0.97 billion for lamb and goat meat and $0.81 billion for poultry (NSW DPI, 2018).

Without government regulation, there is no strong incentive for the effective use of stock medicines which may result in a range of negative risks, such as:

- Human health – from unsafe levels of residue that could enter human food.
- Antimicrobial resistance – from inappropriate use of antimicrobials which has the potential to breed antibiotic resistant pathogens.
- International trade – from non-compliance with the residue tolerance limits of importing countries.
- Animal welfare – from inadequate or inappropriate use of stock medicines.

This RIS assesses three options against the 'base case' (i.e. to remake the existing regulation) referred to as Option 1. The three options are:

- Option 2: Make the proposed Stock Medicines Regulation
- Option 3: Self-regulation (allowing the SM Regulation to lapse)
- Option 4: Co-regulation (allowing the SM Regulation to lapse).

Making of the proposed Regulation (Option 2) under the SM Act is the preferred option, as it maintains the majority of powers of the existing regulation, modernises language and removes unnecessary regulation or red tape for provisions that are no longer required.

Additionally, the penalty notice (PIN) capacity will be removed from seven offences listed in Schedule 1 (while maintaining the offences in the Act). These changes reflect the difficulty of a compliance officer to decide if an offence is committed "knowingly" or "intentionally" – offences will instead be referred to court (see Table 3).

Options 3 and 4 are not preferred to either of the regulatory options, as they would increase the likely risks to consumers, businesses (i.e. livestock producers and veterinary practitioners) and the environment and increase costs to the NSW Government. Potential impacts include:

- unsafe levels of chemical residues in the human food chain
- harm to animals from incorrect use of stock medicine
- a reduction in the returns to livestock producers (i.e. quality of livestock carcass and quantity of exports)
- an increase in health care costs to the NSW Government.

1.About this Regulatory Impact Statement

1.1. Why is the Stock Medicines Regulation 2010 being remade?

The Stock Medicines Regulation 2010 (the SM Regulation) is due for staged repeal on 1 September 2019. A regulation that is due for staged repeal may be:

- allowed to lapse
- maintained and the staged repeal process postponed
- remade with or without amendments.

The staged repeal of the SM Regulation has been postponed on four occasions to allow for the making and implementing of the *Biosecurity Act 2015* and Biosecurity Regulation 2017 and also to allow further progress of some national reviews related to stock medicines.

1.2. Why has this RIS been prepared?

Section 5 of the *Subordinate Legislation Act 1989* (the SL Act) provides that before a regulation is made, a Regulatory Impact Statement (RIS) should be prepared in connection with the substantive matters to be dealt with by the regulation and public consultation undertaken.

1.3. What will this RIS consider?

Schedule 2 of the SL Act prescribes that a RIS must contain:

- a statement of the **objectives sought** to be achieved and the reasons for them
- an identification of the **alternative options** by which those objectives can be achieved (whether wholly or substantially)
- an assessment of the **costs and benefits of the proposed statutory rule**, including the costs and benefits relating to resource allocation, administration and compliance
- an assessment of the **costs and benefits of each alternative option** to the making of the statutory rule (including the option of not proceeding with any action), including the costs and benefits relating to resource allocation, administration and compliance
- an assessment as to which of the alternative options involves **the greatest net benefit or the least net cost** to the community
- a statement of the **consultation program** to be undertaken.

It is also a matter of practice that the NSW Treasury's seven principles of Better Regulation are applied when designing and developing a regulatory proposal. A description of these principles and their application may be found in the Guide to Better Regulation (see TPP19-01 https://www.treasury.nsw.gov.au/sites/default/files/2019-01/TPP19-01%20-%20Guide%20to%20Better%20Regulation.pdf).

1.4. Will the public have a say on the proposed Stock Medicines Regulation 2019 and RIS?

Yes. The proposed Regulation and RIS will be publicly exhibited for a period of 28 days until Wednesday 10 July 2019.

The proposed Regulation and RIS are accessible at:

www.dpi.nsw.gov.au/biosecurity/discussion-papers

If you would like to have your say on the proposed changes to the Regulation and/or the RIS, please submit your feedback in one of these two ways:

1. By email to: biosecuritylegislation@dpi.nsw.gov.au
2. By post to:

   Biosecurity and Food Safety
   Policy, Legislation, Performance and Consultation
   NSW Department of Primary Industries Locked Bag 21
   ORANGE NSW 2800

The closing date for submissions is *Wednesday 10 July 2019 at 6:00pm*.

1.5. What will the government do with your submission?

NSW Department of Primary Industries (NSW DPI) will review all submissions that are received by the closing date and consider the issues raised.

The Minister for Agriculture and Western NSW is required to consider submissions and actions arising from the submissions. A copy of all submissions will be provided to the Legislation Review Committee of the NSW Parliament with the final version of the Regulation. The Committee will also be provided with a report on the outcomes of consultation detailing the issues raised in submissions and how these have been addressed.

The Regulation that is proposed may be amended following consideration of any issues or comments made in the submissions.

1.6. Will it be possible to make a confidential submission?

NSW DPI generally places submissions, or summaries of submissions received, on its website. Please advise us if you do not want your submission published or if you would like part of it to be kept confidential (e.g. your name). NSW DPI will respect your request, unless required by law to disclose this information, for example under the provisions of the NSW *Government Information (Public Access) Act 2009*.

1.7. Who else will be consulted on the proposed regulation and RIS?

NSW DPI is seeking input from the community, stakeholder groups and government agencies.

The following stakeholders were advised of the availability of the RIS and the draft Regulation:

- NSW Veterinary Practitioner's Board
- NSW Farmers' Association
- NSW Division of the Australian Veterinary Association
- Local Land Services
- NSW Food Authority
- NSW Ministry of Health
- NSW Department of Justice
- NSW Environment Protection Authority
- Australian Pesticides and Veterinary Medicines Authority
- Stock Feed Manufacturers' Association of New South Wales
- Animal Health Alliance
- Veterinary Manufacturers and Distributors' Association.

In addition, other states and territory governments have been advised.

1.8. Where are the proposed Stock Medicines Regulation 2019 and RIS advertised?

A notice of the proposed Regulation and RIS has been published in the NSW Government Gazette and in the following NSW newspapers:

- Sydney Morning Herald
- The Daily Telegraph
- The Land

A notice has also been placed on the following websites:

- Have your say www.nsw.gov.au/improving-nsw/have-your-say/
- Department of Primary Industries www.dpi.nsw.gov.au/biosecurity/discussion-papers

2.Key terms and definitions

Term	Definition
Agvet Code	The Commonwealth *Agricultural and Veterinary Chemicals Code Act 1994*.
Analyst	Person authorised to conduct analysis under the *Biosecurity Act 2015*.
Ectoparasites	A parasite, such as a flea, that lives on the outside of its host.
Major food producing species	Cattle, sheep, pigs, chickens, bees, ducks, farmed fish, farmed crustaceans and farmed molluscs, geese, goats and turkeys.
NSW DPI	New South Wales Department of Primary Industries.
Livestock/stock	The use of the term livestock in this document refers to terrestrial and aquatic animals species.
Off-label	Medication used in a manner not specified on the Australian Pesticides and Veterinary Medicines Authority (APVMA) approved packaging **label**, or insert.
Package	Anything in or by which any stock medicine is covered, enclosed, contained or packed.
Prescribe	The provision of a written instruction by a veterinary practitioner for the supply of a stock medicine (including stock food treated with a stock medicine).
Proposed Regulation	The proposed Stock Medicines Regulation 2019.
Provision	A component of a regulation or Act. Provisions may provide powers to persons or require a person to undertake a specific activity.
RIS	Regulatory Impact Statement.
SM Regulation	Stock Medicines Regulation 2010.
SL Act	*Subordinate Legislation Act 1989*.
Veterinary practitioner	A person who is registered under the *Veterinary Practice Act 2003* as a veterinary practitioner.
Withholding period	The minimum period which should elapse between the last administration of the stock medicine and: • the slaughter of an animal for human consumption to which stock medicine has been administered • the harvesting of wool, fibre, milk or eggs or the release of honey for human consumption from an animal to which the stock medicine has been administered.

3.The need for government intervention

3.1. About Stock Medicines

Background information

Stock medicines are drugs or medicines that are used to treat or prevent disease, injury and parasites or relieve pain and suffering in NSW livestock, in accordance with the *Agricultural and Veterinary Chemicals (New South Wales) Act 1994 No. 53* and the Commonwealth's *Agricultural and Veterinary Chemicals Code Act 1994 No. 47* (the Agvet Code).

Stock medicines have the same meaning as veterinary chemicals under the AgVet Code, except as modified by the SM Act where stock medicines:

1. also include a substance or mixture of substances that is prepared by a:
    - pharmacist in accordance with the instructions of a veterinary practitioner
    - veterinary practitioner in the course of the practice of his or her profession.
2. do not include a veterinary chemical product, that is:
    - represented as being suitable for, or is manufactured, supplied or used for, the external control of ectoparasites of stock; and
    - concentrated and requires dilution or mixing in water before use, unless it is prescribed by the regulations to be a low-risk veterinary chemical product.

Benefits of effective use

A summary of the benefits from the effective use of stock medicines on livestock is provided in Table 1. The value of these benefits to livestock producers is a proportion of their total value of production which is presented for a selected group of commodities in

Table 2.

The total value of exports for beef, wool and lamb was estimated at $1.4 billion, $0.87 billion and $0.75 billion respectively, in 2017-18; these values illustrate the significance of export markets to these industries especially when compared to the total value of production presented in

Table 2 (NSW DPI, 2018).

Table 1 Benefits of the effective use of stock medicines

Benefit	The use of stock medicines allows….
Herd health	The effective diagnosis and treatment of livestock to minimise the spread of infectious parasites and diseases to maintain herd health.
Human health	The effective diagnosis and treatment of livestock with zoonotic diseases to minimise potential human exposure; the absence of residue in food products.

Benefit	The use of stock medicines allows….
Animal welfare	The treatment of livestock to relieve pain and suffering through prevention and treatment of parasites, disease and injuries.
Productivity	Improves animal health which is likely to increase animal growth rates, carcase value and returns to producers.
Market access	Ensures that NSW livestock producers can maintain access to domestic and international markets.

Table 2 Gross value of production for a range of NSW produced commodities, 2017-18

Commodity	Value ($ billion)
Beef cattle	2.28
Wool	1.32
Sheep and goat meat	0.97
Poultry	0.81
Milk	0.64
Eggs	0.26
Fish	0.17
Pork	0.16
Aquaculture	0.07

Source: NSW DPI (2018).

3.2. Identification of the problem

The use of stock medicines may improve the productivity of livestock production and the welfare of livestock; however, without government intervention there is no strong incentive for the effective use of stock medicines.

Particularly, there is greater potential for incorrect use of stock medicines and a range of risks that are outlined in Figure 1.

The impact of unregulated use of stock medicines could differ from the outcomes that are desired by the broader community, livestock industry groups and the NSW Government. Additionally, non-compliance in the use of stock medicines by one individual may impact the entire industry (negative externality). This could include:

- removal of affected products from Australian stores
- closure of exports to international markets
- a reduction in the consumption of products, where animal welfare conditions or antimicrobial resistance considerations are insufficient

- a reduction in the income of agricultural producers with flow-on effects to regional communities.

Figure 1 Risks associated with the unregulated use of stock medicines

3.3. State and Commonwealth government objectives

A number of national policy reviews are underway that will impact on NSW Stock Medicine legislation in future. This includes the development of a national framework for harmonisation of veterinary chemical off-label use of S5, S6 and S7; and development of a national framework for veterinary prescribing and compounding.

The overarching objectives of remaking the SM Regulation are to ensure that:

- current stock medicines legislation continues to be aligned to national objectives
- stock medicines are regulated after the current regulation is repealed
- the risks associated with non-regulated stock medicines are mitigated
- industry access to international markets is maintained.

4.Legislative framework

This chapter outlines the role of the SM Regulation within the existing legislative framework. A summary of the proposed Regulation is provided in Chapter 5.

The *Stock Medicines Act 1989* No. 182 (the SM Act) is the primary legislation that sets the foundation for the strategic and coordinated management of the use of stock medicines to treat livestock. The SM Act is supported by the SM Regulation.

The SM Act and Regulation are supported by the:

- *Agricultural and Veterinary Chemicals (New South Wales) Act 1994 No. 53*
- Agricultural and Veterinary Chemicals (New South Wales) Regulation 2015

and the Code of Orders that apply to the use of stock medicines include:

- 1996-1 Chloramphenicol and Diethylstilboestrol
- 1998 Injectable steroids
- 2000-1 Revocation of HGP
- 2013 Hormone Growth Promotant Control
- 2018 Stock Medicines (Silirum vaccine control) Order 2018.

The Code of Orders provide prescriptive controls for the use of high risk stock medicines. For example, Chloramphenicol and diethylstilboesrol are prohibited from use in food producing animals as they both present serious human health risks.

Relevant Commonwealth legislation includes:

- *Agricultural and Veterinary Chemicals Code Act 1994* No. 47 (the Agvet Code Act)
- Agricultural and Veterinary Chemicals Code Regulations 1995.

The use of stock medicines, that require dilution to treat external parasites of livestock, are regulated under the *Pesticide Act 1999*, rather than the SM Act. For example, this includes the use of dips and sprays for the control of lice on sheep, ticks on cattle and fish parasites in aquaculture.

4.1 Stock Medicines Act 1989 No. 182

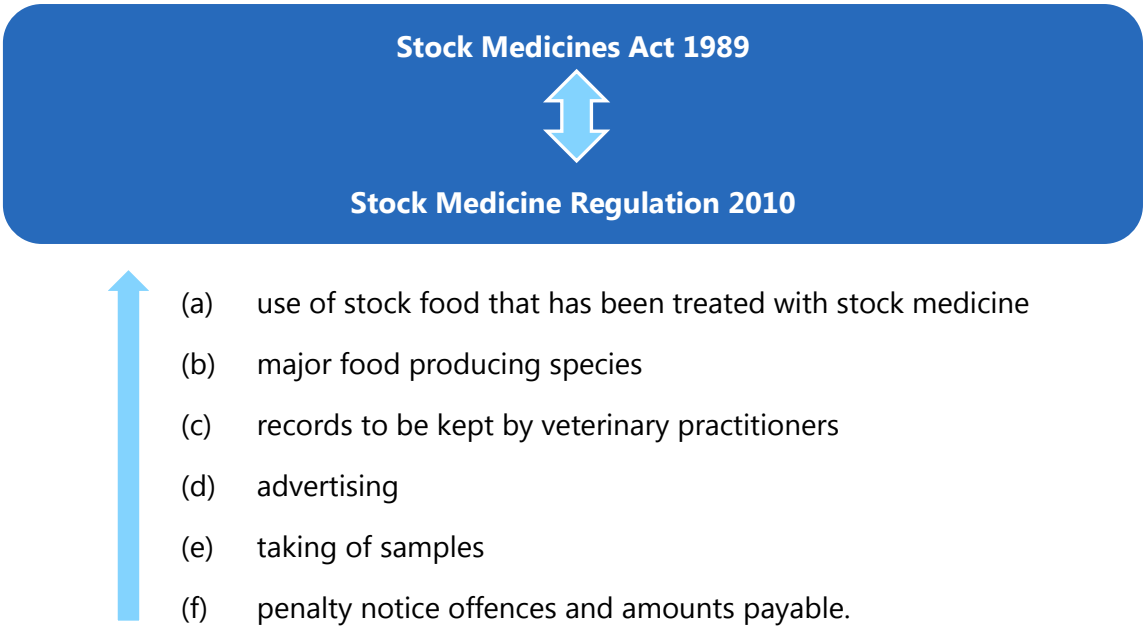
The SM Act commenced on 1 July 1990 and provides the legal framework for the NSW Government to:

- **protect human health** to ensure that illegal or unsuitable levels of chemical residues, from stock medicines, do not enter the human food chain.
- **facilitate international trade** to make sure that livestock and animal products comply with the residue tolerance of international trading partners.
- **protect animal welfare** to allow for the availability of treatments to relieve the suffering of livestock (from diseases, parasites, injuries and pain) and ensure that medicines are applied appropriately.

4.2 Stock Medicines Regulation 2010

The SM Regulation commenced on 1 September 2010 and was made under the SM Act. It assists with regulating the use of veterinary chemical products and medicines on all food producing animal species in New South Wales.

A summary of the provisions under the SM Regulation 2010 is provided in below.



4.3 The Commonwealth Legislation

The key Commonwealth legislation includes the:

- *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code Act)
- Agricultural and Veterinary Chemicals Code Regulation 1995.

The Agvet Code Act is about agricultural chemicals and veterinary medicines for the purposes of:

- enhancing the quality of agricultural production
- protecting the environment
- safeguarding the health of stock and other animals.

The Agricultural and Veterinary Chemicals Code Regulations 1995 support the Agvet Code Act to regulate the import, manufacture, registration and labelling of veterinary chemical products for all food producing animal species in Australia.

The Agvet Code also provides for the importation, manufacture, registration, labelling and permits for off-label use; up to the point of distribution, of agricultural and veterinary chemicals in Australia. Control of use is legislated by the state and territory governments and in NSW is regulated by the SM Regulation.

5. The proposed Stock Medicines Regulation 2019

The proposed Regulation has been drafted by Parliamentary Counsel's Office and informed by internal review of the SM Regulation. This review found that all existing regulatory provisions would be required for continued management of stock medicine. The review also identified a small number of minor improvements to existing provisions.

A summary of provisions in the existing SM Regulation and the proposed amendments is provided in Table 3. The table also states whether a regulatory provision represents the:

- transition of an existing regulatory arrangement, or
- repeal of existing regulatory arrangements (deleted).

Table 3 Overview of regulatory provisions for the proposed Regulation 2019

Provision group	Regulatory provisions of the Stock Medicines Regulation 2010	Transition of existing provisions to the proposed Regulation 2019		
		As is	With amendments	Deleted
Use of stock food that has been treated with stock medicines (SM)	**Clause 4** Prescribes the information that must be provided when supplying another person with stock food that has been treated with stock medicine. This includes: (1) conditions that a supplier of stock food treated with stock medicines must comply with (2) written specifications of the withholding period.	✓ With minor amendments, without changing the intent of the provision.		
Major food producing species	**Clause 5** Lists the additional species that are considered 'major food producing species' for the purpose of S3c1 of the SM Act.	✓ Clause 5 is excluded from assessment in the RIS, as it is machinery in nature. That is, it reasonable practice for implementing the SM Regulation.		

Provision group	Regulatory provisions of the Stock Medicines Regulation 2010	Transition of existing provisions to the proposed Regulation 2019		
		As is	With amendments	Deleted
Records to be kept by veterinary practitioners	**Clause 6** Extensive records are required and must be retained by the veterinary practitioner for at least 2 years from the date of prescription, use or supply.	✓ This includes: (1) List of detail required to be recorded by the veterinary practitioner (2) Records must be retained by the veterinary practitioner for at least 2 years.		
Advertising	**Clause 7** Conditions for the advertising of stock medicines that are listed in Schedule three, four or eight of the *Poisons and Therapeutic Goods Act 1966*. This includes: (1) clarification of the stock medicines that Clause 7 applies to (2) conditions for the advertisement of stock medicines detailed in subclause 1. These stock medicines must only be advertised in a journal whose circulation limited, or in a document distributed exclusively, to veterinary practitioners, pharmacists or wholesalers of stock medicines.	✓ c7(1)		
			✓ c7(2) Amendments to clarify: • the advertising activities that are not permitted for stock medicines (i.e. the making of claims, statements or representations relating to the use of, or the dissemination of information concerning a stock medicine or its uses) • that the same restrictions apply for advertising activities using electronic communication • that electronic communication intended for distribution exclusively to, veterinary practitioners, pharmacists or wholesalers of stock medicines are not	

Provision group	Regulatory provisions of the Stock Medicines Regulation 2010	Transition of existing provisions to the proposed Regulation 2019		
		As is	With amendments	Deleted
			subject to the restriction under this clause.	
Taking of samples	**Clause 8** Conditions that inspectors must follow when taking and storing samples. **(1)** Permissions to deliver a sample to analysts with evidence of a chain of custody. **(2)** Conditions under which a package must be safe guarded when in the inspectors possession.			✓ Deleted because the content of the clause is now covered under the *Biosecurity Act 2015*.
Penalty notices	**Clause 9** States that each offence arising under a provision specified in Column 1 of Schedule 1 is prescribed as a penalty notice offence and the penalty amounts for each offence.	✓		
	Schedule 1 Specifies the location and details of all offences and penalty amounts payable by offenders — individuals and corporations under the SM Act.	All provisions except: • Section 37(1) • Section 38(1) • Section 39(1) • Section 40A(1) • Section 40A(2) • Section 40B(1) • Section 54(2) • Clause 4(1). Clause 37(1) and 38(1) are penalties for offences under the SM Act whereby a person has knowingly possessed or used unregistered stock		✓ Deleted as: • Section 37(1), 38(1), 39(1), 40A(1), 40A(2), 40B(1) and Clause 4(1) are deleted penalty notices (while still maintaining the offences in the Act). These changes reflect the difficulty of a compliance officer to decide if an offence is committed "knowingly" or "intentionally" – offences will instead be referred to court.

Provision group	Regulatory provisions of the Stock Medicines Regulation 2010	Transition of existing provisions to the proposed Regulation 2019		
		As is	With amendments	Deleted
		medicines on stock without authorisation from a veterinary practitioner. Section 39(1) is a penalty for offences under the SM Act whereby a person knowingly has used registered stock medicines contrary to the instructions. Clause 4, Section 40A(1) - (2) and 40B(1) are penalties for offences under the SM Act or the Regulation whereby a person has knowingly supplied stock food or sold stock that have been treated with stock medicines, or stock products from treated animals without communicating information of these treatments. An offence can only be established if it can be proved that a person was aware of their actions.		• Section 54(2) supports provisions in the SM Act that have been repealed/deleted and so are no longer required.
Savings	**Clause 10** Any act, matter or thing immediately before the repeal of the Stock Medicines Regulation 2010 has effect in both Regulations.	✓ Clause 10 is excluded from assessment in the RIS, as it is machinery in nature.		

6.Identification of options

In accordance with the SL Act and the NSW Government Guide to Better Regulation, this assessment:

- considers a range of feasible options
- identifies and assesses the impacts of government action for each option relative to a base case
- considers the costs and benefits of each option relative to the base case
- identifies a preferred option that provides the greatest benefit to stakeholders (i.e. the community and environment).

6.1. Options to be assessed

The Stock Medicine Regulation 2010 contains the current regulatory provisions and under the base case (Option 1) these provisions would be remade with no change.

Three options will be assessed against the base case:

- Option 2: Make the proposed Regulation
- Option 3: Self-regulation (allowing the SM Regulation to lapse)
- Option 4: Quasi regulation (allowing the SM Regulation to lapse).

These are the only options considered feasible in this RIS.

The details of the proposed Regulation (Option 2) which would be made under the SM Act are provided in **Table 3**. This regulation would replace existing measures on 1 September 2019.

If no further actions are taken by the NSW Government, the SM Regulation would lapse on 1 September 2019 and no new regulation would be made in its place. Two options may be assessed in this case: self-regulation (Option 3) and quasi regulation (Option 4).

- **Option 3: Self-regulation** — under this option the SM Regulation would lapse and the NSW branch of the Australian Veterinary Association and livestock industry bodies would collaborate to develop a voluntary code of conduct for the use of stock medicines.

  These groups would implement the rules; managing the monitoring and compliance of codes. The NSW Government would have no role under this option.

- **Option 4: Quasi Regulation** — under this option the SM Regulation would lapse and the NSW branch of the Australian Veterinary Association and livestock industry bodies would collaborate with the NSW Government to develop a code of practice.

  These groups would formulate rules and codes of conduct for the use of stock medicines, and the NSW Government would provide legislative backing to enable the enforcement of arrangements.

6.2. Machinery clauses

The proposed Regulation would make a number of regulatory provisions of a machinery nature. Generally speaking, machinery clauses are those which could broadly be described as relating to 'process' rather than a substantive policy matter.

Machinery clauses in the proposed Regulation include:

- Clause 1 – Name of the Regulation
- Clause 2 – Commencement date of the Regulation
- Clause 3 – Definitions
- Clause 5 – Major food producing species (definition)
- Clause 8 – Savings
- Historical notes.

Matters of a machinery nature do not require a RIS. This RIS does not consider these provisions in detail however comment on these provisions may be included in submissions and will be considered.

7.Assessment of impacts

In this assessment, the impacts, benefits and costs under Options 2 through Option 4 are compared with those from the base case (Option 1). The direct and indirect impacts of each option have also been considered. Direct impacts are the immediate impacts on stakeholders, whereas indirect impacts are those affecting a third party.

7.1. Base Case (Option 1): Remake the SM Regulation without amendments

7.1.1. Overview of the base case

Under the base case the existing regulatory provisions under the SM Regulation would be remade, as is, with no amendments, on 1 September 2019.

A description of the provisions under the base case and the proposed Regulation are provided in Table 3 of Chapter 5.

7.1.2. Identification of impacts under the base case (Option 1)

Under Option 1, the existing powers of the SM Regulation would continue to support the effective use of stock medicines in NSW. A list of the provisions and the impacted parties — i.e. businesses, consumers, community, government or the environment — is provided in **Table 4**.

Table 4 Impact of the SM Regulation under the base case (Option 1)

Provision group	Impact: Under the base case (Option 1)	Who is impacted?				
		Business	Consumer	Community	Government	Environment
Use of stock food that has been treated with stock medicines (Clause 4)	**A person** supplying stock food is required to provide information and make records of food that is treated with stock medicines, to ensure buyers are aware and to maintain written documents of stock medicines use (including details of withholding periods).	✓	✓	✓		
Records to be kept by veterinary practitioners (Clause 6)	**Veterinary practitioners** must keep records as detailed under the SM Regulation and store these records for at least 2 years.	✓	✓	✓	✓	
Advertising (Clause 7)	The location that stock medicines (listed in Sch 3,4,8 of the Poisons and Therapeutic Goods Act) may be advertised is restricted to a journal or documents that are distributed exclusively to **veterinary practitioners,**	✓		✓		

Provision group	Impact: Under the base case (Option 1)	Who is impacted?				
		Business	Consumer	Community	Government	Environment
	pharmacists or wholesalers of stock medicines and ensure that this information is not available to the **community**.					
Taking of samples **(Clause 8)**	**Inspectors** must collect and store samples in a manner that is defined under the SM Regulation and ensure that samples of stock medicines are not released to the **community or environment**.			✓	✓	✓
Penalty notices **(Clause 9)**	Allocates penalty notices and amounts payable for offences under the SM Act. This will allow **authorised officers** to issue penalty amounts for prescribed offences; and encourage **individuals and corporations** to use stock medicines appropriately. For example, under 39C (3) of the Act, if a veterinary practitioner prescribes or supplies an unregistered stock medicine that is not a registered human pharmaceutical and has not been compounded by a veterinary practitioner or a pharmacist, a fine can be given rather than having to prosecute through a court.	✓	✓		✓	

7.2. Option 2: Make the proposed Stock Medicines Regulation 2019

Under Option 2, the proposed Regulation would be made under the SM Act. The proposed Regulation seeks to support implementation of the SM Act, which prescribes management rules for stock medicines.

Under the proposed Regulation, all regulatory provisions of the SM Regulation would continue with the exception of:

- **Clause 7(2) – Advertising** would be amended.
- **Clause 8 – Taking of samples** would be deleted.
- **Section 37(1), 38(1), 39(1), 40A(1), 40A(2) and 40B(1) of Schedule 1 – Penalty notices** would be deleted.
- **Section 54(2) – Schedule 1 Penalty notice** deleted; as is no longer required.
- **Clause 4(1) – Schedule 1 Penalty notice** would be deleted.

A summary of the proposed amendments are provided in Table 3 of Chapter 5.

7.2.1 Impacts, benefits and costs under Option 2

A summary of the impacts, costs and benefits from the amended provisions is provided below in Table 5. It shows that Option 2:

- reduces red tape for provisions that are no longer required under the SM Act
- provides greater clarity regarding existing provisions
- removes penalty notices from some offences that are no longer deemed appropriate.

This option would maintain most of the current provisions that are provided under the base case with the exception of select penalty notices. Changes to penalty notices are likely to increase the administrative costs to the government and cost to guilty offenders.

While the removal of these penalty notices in the proposed Regulation is likely to increase costs, the changes reflect the difficulty of a compliance officer to decide if an offence is committed "knowingly" or "intentionally". The offences will remain in the Act, and alleged offences will instead be referred to court. This will benefit primary producers, allowing them the opportunity to provide further evidence to a judge in court in relation to an alleged offence, rather than being issued a fine. For these reasons, Option 2 — the proposed Regulation — is preferred to remaking the SM Regulation (base case).

Table 5 Impact, benefits and costs of the provisions under Option 2 (the proposed Regulation) relative to the base case

Provision group	Proposed amendments	Impact	Benefits	Costs
Clause 7 **Advertising**	Amended	• Clarify the advertising activities that are not permitted for stock medicines. • Clarify that the restrictions also apply to electronic communication. • Clarify the types of communication that are exempted from the restriction under the clause.	• Incentivise appropriate advertising activities. This would minimise the likelihood of risks on the community. • Allow electronic communication exclusively to veterinary practitioners, pharmacists or wholesalers of stock medicines.	Nil
Clause 8 Taking of samples	Deleted	Remove duplication as the clause is now included under the *Biosecurity Act 2015*.	A reduction in unnecessary regulation or red tape.	Nil
Schedule 1 **Section 37(1), 38(1), 39(1), 40A(1), 40A(2), 40B(1), Clause 4(1) – Penalty notices**	Deleted	Penalty notice offences and amounts for section 37(1), 38(1), 39(1), 40A(1), 40A(2), 40B(1) and clause 4(1) would cease to exist. However, offences under section 37(1), 38(1), 39(1) 40A(1), 40A(2), 40B(1) and clause 4(1) would continue to exist under the SM Act or Regulation and would require prosecution in court.	Provide offenders with a greater opportunity to provide further evidence in court relating to if they knew or did not know they had committed the relevant offence.	Potentially increase administrative costs for government and to offenders found guilty; as these offences would be prosecuted in court. However, this is expected to have a small impact as there has not been a significant number of these offences in recent years (DPI, unpublished data).
Schedule 1, Section 54(2) – Penalty notices	Deleted	Individuals and businesses are no longer required to pay for penalties for an offence that no longer exists in the SM Act.	A reduction in unnecessary regulation or red tape.	Nil

7.3. Option 3: Self-regulation (allowing the SM Regulation to lapse)

Under Option 3, self-regulation would be implemented on 1 September 2019 when the SM Regulation would lapse. This means that the regulatory provisions detailed in the base case (section 7.1) would cease to exist and no new regulation would be made in their place.

Furthermore, relevant organisations from the NSW veterinary medicine industry, the farming industries and stock feed industry would formulate a voluntary code of conduct to provide clarity relating to the provisions of the SM Act. This group would also be responsible for the monitoring and enforcement of these rules and the NSW Government would have no role.

The SM Act would remain in place and would continue to describe the use of stock medicines with the objectives of protecting human health, facilitating international trade and protecting the welfare of animals.

7.3.1 Impacts, benefits and costs under Option 3

Lapse of the SM Regulation and implementing self-regulation would have a range of impacts, benefits and costs for NSW businesses, government, consumers and the community, and the environment.

Table 6 shows that relative to the base case; Option 3 would impose significant risks and costs on consumers, the community, businesses and the government.

A summary of the key impacts are listed below:

Consumers and the community

Potential increase in the:

- risk of physical and psychological harm to humans from the consumption of food contaminated with chemical residues from stock medicines
- harm to animals from incorrect use of stock medicine.

Businesses

A potential reduction in the:

- value of livestock carcases and returns to production
- quantity of NSW livestock exports and revenues if the international trade standards for chemical residues are not met.

Governments

A potential increase in health care costs to the NSW Government that is ultimately an economic burden on the community.

For these reasons, Option 3 — Self-Regulation — is not preferred to remaking the SM Regulation (base case) or Option 2 to make the proposed Regulation.

Table 6 Impact, benefits and costs of the provisions under Option 3 – Self-Regulation relative to the base case

Provision group	Impact	Benefits	Costs
Use of stock food that has been treated with stock medicine **(Clause 4)**	• Persons or **businesses** would not be required to provide detailed information or records of stock food that have been treated with stock medicines. • **Governments** would have no power to manage individuals and corporations' actions when these groups provide incorrect or insufficient information regarding stock foods treated with stock medicines.	• **Individuals** and **corporations** would not have to adhere to the regulation which may have a potential to reduce their costs of production and increase profits.	• A potential increase in the risk of illegal or unsuitable levels of chemical residues from stock medicines entering the human food chain, resulting in adverse impacts on human health. This could cause physical and psychological harm to **consumers** that have consumed foods. • A potential increase in health care costs to the **government** that is an economic burden on the community. • A reduction in the quantity of NSW livestock exports and revenues if the international trade standards for residues are not met (affecting **businesses**).
Records to be kept by veterinary practitioners **(Clause 6)**	• **Veterinary practitioners** would not be required to keep records for stock medicines.	• This change would reduce administration costs for **veterinary practitioners**.	• Potential for reduced traceability with the occurrence of an event that negatively impacts **consumers** and or the **welfare of livestock**. These provisions ensure that **governments** and **veterinarians** have transparency on how stock medicines have been used.
Advertising **(Clause 7)**	• **Individuals** and **corporations** would be able advertise stock medicines in any location and for any purpose.	• **Individuals** and **corporations** would have increased access to information on stock medicines and what they may be used for.	• Increase the potential risk of harm to **livestock** from increased availability of information on the use of stock medicines that should not be available to corporations or the general public. This could result in an increased pressure imposed on veterinary practitioners by the public to prescribe inappropriate or ineffective stock medicines.
Taking of	• **Inspectors** of stock medicine samples would not have to	• **Inspectors** would not need to adhere to specific requirements	• There may be a reduction in the quality and accuracy of tests that are completed from samples, if the

Provision group	Impact	Benefits	Costs
samples **(Clause 8)**	adhere to conditions when collecting and storing samples. This would increase the likelihood of unauthorised access to samples and risk that samples are contaminated.	about the collection and keeping of samples.	samples were not collected and stored correctly.
Penalty notices **(Clause 9 & Schedule 1)**	• Removal of penalty notice offences and amounts for offences, may result in the: a) increased likelihood of illegal or unsuitable behaviours b) the government would have to prosecute offenders through court.	• Removes potential for immediate penalties that **individuals and corporations** would have to pay if they commit offences.	• Increases the costs to **government** as it would have to prosecute offences through court. • Overall, this may significantly increase the costs to **offenders**, due to court fees and non-specified fine amounts. • With a reduced incentive for compliance with provisions there is an increased likelihood that **consumers** and livestock (i.e. animal welfare) would be negatively impacted.

7.4. Option 4: Co-regulation (allowing the SM Regulation)

Under Option 4, co-regulation would be implemented on the 1 September 2019 when the SM Regulation would lapse. This means that regulatory provisions in the base case (section 7.1) would cease to exist and no new regulation would be made in their place.

Furthermore, relevant organisations from the NSW veterinary medicine industry, the farming industries and stock feed industry could collaborate with the NSW Government to develop industry codes of conduct.

The NSW Government could provide the following legislative endorsement and support to enforce codes.

- Delegate enforcement powers to the key enforcement agencies.
- Require compliance of voluntary codes of conduct with NSW Government standards.
- Detail conditions where standards can be overridden by **industry bodies** and conditions under which this may occur.
- Prescribe codes and standards as either voluntary or mandatory (Australian Government 2007).

7.4.1 Impacts, benefits and costs under Option 4

When the SM Regulation lapses, it is likely that the impacts, benefits and costs to NSW businesses, consumers, government, the community and the environment under this option will be similar to those outlined in Option 3 (see Table 6).

However, with the formulation and implementation of a code of conduct, the magnitude and likely risks resulting from stock medicines use will depend on the:

- strength of industry incentives to comply with the arrangements
- strength of legislative support that the government may extend to minimise risks
- delay in establishing and implementing the codes of conduct.

In the interim where the use of stock medicines is self-regulated, there are likely to be a significant number of risks and costs to consumers, businesses and the government (as detailed in section 7.3.1).

If government and interested parties are able to agree and implement suitable codes of conduct; and risk creators are sufficiently incentivised to meet these requirements risk will be minimised. However, this will require a strong cohesiveness between groups involved in this process.

Furthermore, the industry groups and the NSW government would also have to incur additional costs to establish codes and another supporting legislation.

For these reasons, Option 4 — Co-Regulation — is not preferred to either the base case to remake the SM Regulation or the proposed SM Regulation (Option 2).

7.6 Summary Case for the preferred option

In conclusion, making the proposed Regulation (Option 2) under the SM Act is the preferred option, as it maintains the powers of the existing regulation (under the base case) and reduces red tape for provisions that are no longer required.

Option 2 modernises the current legislation relative to the base case (Option 1) by removing any redundant provisions. Options 3 and 4 are not preferred to the base case, or the proposed Regulation, as they would reduce powers to manage stock medicines and increase likelihood risk of negative impacts and costs in NSW.

References

NSW DPI (2018) *Performance, Data and Insights,* Department of Industry, November.

Australian Government (2007), Best Practice Regulation Handbook, viewed March 2019 <http://regulationbodyofknowledge.org/wp-content/uploads/2013/03/AustralianGovernment_Best_Practice_Regulation.pdf> Canberra.