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Regulatory Impact Statement
Draft Stock Medicines Regulation 2024

June 2024

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Regulatory Impact Statement - Draft Stock Medicines Regulation 2024

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More information

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Table of Contents

List of Tables

Executive Summary

The Stock Medicines Regulation 2019 (the SM Regulation) is the main instrument used to support the *Stock Medicines Act 1989* (the SM Act). The SM Act sets the foundation for strategic and coordinated management of stock medicines used to treat livestock and other animals for the purposes of protecting the health and safety of humans, protecting the environment, safeguarding the health of stock and other animals and to maintain access to international markets. This legislation is also guided by the *Agricultural and Veterinary Chemicals Act (NSW) 1994 and* the Commonwealth *Agricultural and Veterinary Chemicals Code Act 1994*.

Stock medicines play a crucial role in improving productivity and boosting the gross value of production across various agricultural commodities in NSW. In 2022-23, the total gross value of livestock production that made use of stock medicines to maintain animal health and productivity was estimated at $8.41 billion ($3.4 billion for beef, $1.1 billion for wool, $1.42 billion for sheep and goat meat and $1.27 billion for poultry meat and eggs (NSW DPI, 2023)).

The SM Regulation is due for staged repeal on 1 September 2024. It is proposed to remake this regulation with a small number of minor improvements to existing provisions to adhere to current plain English drafting guidelines and to make the Regulation clearer. See Section 5 for an overview of regulatory provisions for the draft Stock Medicines Regulation 2024 (the draft Regulation).

Remaking the SM regulation requires the preparation of a Regulatory Impact Statement (RIS) and a period of public consultation.

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

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

Making the draft Regulation (Option 2) under the SM Act is the preferred option, as it generates the greatest net benefits to the community, businesses and government. Option 2 ensures responsible practices in the supply and use of stock food treated with stock medicines by improving transparency, compliance, animal welfare and public health protection relative to the base case (Option 1).

Government intervention in the oversight of stock medicines is essential to uphold regulations and standards governing their efficient usage, thereby safeguarding the well-being of the community and businesses. Without government regulation, there is no strong incentive for the safe and 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.

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

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

1. About this Regulatory Impact Statement

1.1 Why is the Stock Medicines Regulation 2019 being remade?

The Stock Medicines Regulation 2019 (the SM Regulation) is due for staged repeal on 1 September 2024 in accordance with the *Subordinate Legislation Act 1989* (SL Act). The remake of this regulation requires the preparation of a Regulatory Impact Statement (RIS) and public consultation. 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.

Through the staged repeal process, the NSW Government has reviewed the SM Regulation and identified that minor administrative amendments are recommended to clarify the some of the provisions. There is no substantive change to the content of the regulation as it is currently fit for purpose.

1.2 Why has this RIS been prepared?

Section 5 of the SL Act provides that before a regulation is made, a RIS should be prepared in connection with the substantive matters to be dealt with by the regulation. In this case, a RIS is required as the regulation includes penalty provisions even though no change is proposed to these provisions.

Substantive matters include an assessment of the impacts of the provisions under the draft Regulation and the alternative options.

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 draft 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 NSW Government Guide to Better Regulation (see TPP19-01).

Policy and economic analysis conducted for this RIS assessed that the draft Regulation does not affect competitive neutrality between governments and businesses or restrict competition.

1.4 Will the public have a say on the draft Stock Medicines Regulation 2024 and RIS?

Yes. The draft Regulation and RIS will be publicly exhibited for 29 days until 3 July 2024 at 11.59pm.

The draft Regulation and RIS are accessible at:

- The NSW DPI website: https://www.dpi.nsw.gov.au/agriculture/chemicals/animal-chemicals/stock-medicine
- The NSW Have your say website: https://www.nsw.gov.au/have-your-say/draft-stock-medicines-regulation-2024

Submissions can be posted to:

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

   Stock Medicines Regulation 2024

   Regulatory Policy & Economics, Strategy and Engagement

   NSW Department of Primary Industries

   Level 3/66 Harrington St – Foreshore House, The Rocks - Sydney NSW 2000

The closing date for submissions is 3 July 2024 at 11:59pm.

1.5 What will the government do with your submission?

NSW DPI will review all submissions that are received by the closing date and consider the issues raised.

The Minister for Agriculture 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 draft Regulation 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 want 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 *Government Information (Public Access) Act 2009.*

1.7 Who will be consulted on the draft regulation and RIS?

NSW DPI is seeking input from the community, businesses 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' Council of Australia
- RSPCA NSW
- Animal Medicines Australia
- Veterinary Manufacturers and Distributors' Association.

In addition, the Commonwealth and other states and Territory governments have been advised.

1.8 How has the draft Stock Medicines Regulation 2024 and RIS been advertised?

A notice of the draft Regulation and RIS has been published in the NSW Government Gazette and in the following NSW newspapers *(effective from 12 June 2024)*:

- *Sydney Morning Herald*
- *The Daily Telegraph*

A notice has also been placed on the following websites:

- NSW DPI website: https://www.dpi.nsw.gov.au/agriculture/chemicals/animal-chemicals/stock-medicine
- Have your say: https://www.nsw.gov.au/have-your-say/draft-stock-medicines-regulation-2024

2. Key terms and definitions

Term	Definition
Agricultural and veterinary (agvet) chemicals	Products developed to protect crops, livestock and domestic animals; safeguard our environment from invasive weeds and pests; and meet consumer needs for things such as household insecticides and pool and spa chemicals.
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 animal 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).
Draft Regulation	The draft Stock Medicines Regulation 2024.
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 Act	*Stock Medicines Act 1989* No. 182.
SM Regulation	Stock Medicines Regulation 2019.
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 the Regulation

3.1. About the Stock Medicines Regulation 2019

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 *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.

Uses and benefit of Stock Medicines

A brief summary of the uses and benefits of effective use of stock medicines 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.

Table 1 The benefits of the effective use of stock medicines.

Uses include:	Benefits
Effective diagnosis and treatment of livestock to minimise the spread of infectious parasites and diseases to maintain herd health.	Herd health
Effective diagnosis and treatment of livestock with zoonotic diseases to minimise potential human exposure; the absence of residue in food products.	Human health
Treatment of livestock to relieve pain and suffering through prevention and treatment of parasites, disease and injuries.	Animal welfare
Improves animal health which is likely to increase animal growth rates, carcase value and returns to producers.	Productivity
Ensures that NSW livestock producers can maintain access to domestic and international markets.	Market access

Table 2 presents the gross value of production for relevant livestock commodities produced in NSW during the period 2022-2023. Among the listed commodities, beef cattle had the highest value at $3.4 billion, followed by sheepmeat at $1.4 billion and wool at $1.1 billion. Other significant contributors to the gross value of production include poultry at $0.92 billion, milk at $0.81 billion, eggs at $0.35 billion and pork at $0.25 billion (NSW DPI, 2023).

Table 2 Gross value of production for a range of NSW produced commodities, 2022-2023

Commodity	value ($billions)
Beef cattle	3.40
Sheepmeat	1.40
Wool	1.10
Poultry	0.92
Milk	0.81
Honey and Beeswax	0.05
Eggs	0.35
Pork	0.25
Goat meat	0.02
Aquaculture	0.11
Total	8.41

Source: NSW DPI (2023).

3.2. Identification of the need for the Regulation

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.

Figure 1 Risks associated with the unregulated use of stock medicines.

The impact of unregulated use of stock medicines could differ from the outcomes that are desired by the broader community, livestock industry groups, international trading partners and the NSW Government. Additionally, non-compliance in the use of stock medicines by one individual may impact the entire industry by imposing a negative externality on the compliant industry members, resulting in:

- the removal of affected products from Australian stores
- the 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 economies.

3.3. State and Australian government objectives

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent statutory authority of the Commonwealth responsible for the regulation and control of agricultural and veterinary chemicals in Australia up to the point of retail sale. The states and Territories are responsible for 'control-of-use' which means legislating and regulating the use of agricultural and veterinary chemicals in their respective jurisdictions. In New South Wales, NSW DPI regulates the use of veterinary chemicals, and the Environment Protection Authority (EPA) regulates the use of pesticides.

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

- the regulation of stock medicines continues after 1 September 2024
- stock medicines legislation continues to be aligned to national objectives
- the risks associated with non-regulated stock medicines are mitigated
- industry access to international markets is maintained.

The Australian Government will respond to a national policy review that will impact both NSW and other states and Territories' stock medicine legislation. The *Independent review of the pesticides and veterinary medicines regulatory system in Australia* has proposed that the Australian Government take responsibility for legislation and policy relating to a single national law for control of use of agricultural and veterinary chemicals. It also proposed that the states and Territories take responsibility for funding and delivery of regulation and enforcement of control of use of agvet chemicals in their respective jurisdictions, under a single national law administered by the Australian Government.

The NSW Government has sought consultation on the Australian Government Response to the independent review. NSW and other states and Territories have postponed their legislative amendments to ensure harmonisation with the Australian Government.

4. Legislative framework

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

The *Stock Medicines Act 1989* (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*
- 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 supply of substances scheduled under the Poisons Standard, including stock medicines, is regulated under the *Poisons and Therapeutic Goods Act 1966.*

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 present serious human health risks.

Relevant Commonwealth legislation includes:

- *Agricultural and Veterinary Chemicals Code Act 1994* (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

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 2019

The SM Regulation commenced on 1 September 2019 and was made under the SM Act. This Regulation replaced the Stock Medicines Regulation 2010, which was repealed on 1 September 2019 by section 10(2) of the *Subordinate Legislation Act 1989*. It assists with regulating the use of veterinary chemical products and medicines and unregistered substances used to treat animals, on all food producing animal species in New South Wales.

A summary of the provisions under the SM Regulation is provided below in Figure 2.

Figure 2 Summary of provisions under the Stock Medicines Act 1989/Regulation 2019

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:

- protecting the health and safety of human beings
- safeguarding the health and safety of stock and other animals
- protecting the environment
- ensuring that use of products today will not impair the prospects of future generations
- furthering trade and commerce between Australia and places outside Australia, and the present and future economic viability and competitiveness of primary industries

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 Act and SM Regulation.

5. The draft Stock Medicines Regulation 2024

The draft Regulation has been prepared by the 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 medicines. The review also identified a small number of minor improvements to clarify 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).

The overarching objective of the draft SM Regulation is to maintain and improve the management of stock medicines used to treat livestock and other animals by

- defining major food producing species
- clarifying the requirements for a person to supply stock food to another person
- clarifying the records to be kept by veterinary practitioners
- clarifying advertising requirements and penalty notice offences.

Table 3 Overview of regulatory provisions for the draft Stock Medicines Regulation 2024

Provision group	Regulatory provisions of the Stock Medicines Regulation 2019	Transition of existing provisions to the draft Regulation 2024	
		As is	With minor amendments
Major food producing species (Section 4)	**Clause 5** Lists the additional species that are considered 'major food producing species' for the purpose of s3(1) of the SM Act.		Renumbered to Section 4 as is.
Supply of stock food that has	**Clause 4** Prescribes the information that must be provided when supplying another person with		Renumbered to Section 5

Provision group	Regulatory provisions of the Stock Medicines Regulation 2019	Transition of existing provisions to the draft Regulation 2024	
		As is	With minor amendments
been treated with stock medicine—the Act, s 65(2)(b) (Section 5)	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 written specifications of the withholding period.		Without changing the intent of the provision, amended to move the penalty provision to sit under subsection (1) so that it is clear the penalty applies to the substantive obligation in (1).
Records to be kept by veterinary practitioners (Section 6)	**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.	✓	
Advertising (Section 7)	**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 Section 7 applies to (2) conditions for the advertisement of stock medicines detailed in subsection 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.		Addition of (1)(b) to refer to the *Medicines, Poisons and Therapeutic Goods Act 2022*.
Penalty notice offences (Clause 8)	Schedule 1 Each offence specified in Schedule 1 is an offence for which a penalty notice may be issued, and the amount payable under the penalty notice.		Renumbered to Section 8 as is.

Provision group	Regulatory provisions of the Stock Medicines Regulation 2019	Transition of existing provisions to the draft Regulation 2024	
		As is	With minor amendments
Savings (Clause 9)	**Section 8** Any act, matter or thing immediately before the repeal of the Stock Medicines Regulation 2019 has effect in both Regulations.	✓	Renumbered to Section 9 as is.

6. Identification of options

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

- considers a range of viable 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 the community, businesses and government.

6.1. Options to be assessed

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

The options assessed against the base case (Option 1) include:

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

These are the only options considered feasible to assess in this RIS.

The details of the draft Regulation (Option 2) that would be made under the SM Act would replace existing measures on 1 September 2024. If no further actions are taken by the NSW Government, the SM Regulation would lapse on 1 September 2024 and no new regulation would be made in its place. Two other options may be assessed in this case: self-regulation (Option 3) and co-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 and manage the monitoring and compliance of codes. The NSW Government would have no role under this option.

- **Option 4: Co-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 Sections of a machinery nature

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

Machinery sections in the draft Regulation include:

- Section 1 – Name of the Regulation
- Section 2 – Commencement date of the Regulation
- Section 3 – Definitions.

The above matters are of a machinery nature and so do not require further assessment in the RIS. That is, remaking these provisions will result in no substantial policy change.

7. Assessment of impacts

In this assessment the impacts, benefits and costs of propositions under Options 2 through 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 Stock Medicine Regulation 2019 without amendments.

7.1.1. Overview of the base case (Option 1)

Under the base case, the existing regulatory provisions under the SM Regulation would be remade, as is, with no amendments, on 1 September 2024.

A description of the provisions under the base case and the draft Regulation are provided in Table 3 of Section 5 above.

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 management of stock medicine. A list of the expected protections and the impacted parties is provided in Table 4.

Table 4 Impact of the draft Stock Medicines Regulation 2024 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 (Section 4)	Prescribes the information that must be provided when supplying another person with stock food that has been treated with stock medicine. This includes:	✓	✓	✓		

Provision group	Impact: Under the base case (Option 1)	Who is impacted?				
		Business	Consumer	Community	Government	Environment
	1. conditions that a supplier of stock food treated with stock medicines must comply with 2. written specifications of the withholding period.					
Major food producing species (Section 5)	For the purposes of the definition of major food producing species in section 3 (1) of the Act, the following types of stock are prescribed: bees, ducks, farmed fish, farmed crustaceans and farmed molluscs, geese, goats, turkeys.	✓	✓	✓	✓	
Records to be kept by veterinary practitioners (Section 6)	The records required by the Act, section 39E must be retained by the veterinary practitioner for at least 2 years after the date of the prescription, supply or use of the stock medicine.	✓			✓	✓
Advertising (Section 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, pharmacists or wholesalers** of stock medicines and ensure that this information is not available to the **community**.	✓		✓		
Savings Section (8)	Any act, matter or thing that, immediately before the repeal of the Stock Medicines Regulation 2019, had effect under that Regulation continues to have effect under this Regulation.	✓	✓	✓	✓	
Schedule 1 Penalty notice offences	Lists each offence specified in this Schedule is an offence for which a penalty notice may be issued, and the amount payable under any such penalty notice is the amount specified in this Schedule for the offence.	✓	✓	✓	✓	

7.2. Option 2: Make the draft *Stock Medicine Regulation 2024*

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

Under the draft Regulation, all regulatory provisions of the SM Regulation would continue with minor amendments as shown in Table 3 Section 5 above.

The only amendment required to be reviewed in this RIS is section 5 which imposes a penalty of 50 penalty units and as a result does not fit any of the criteria for exemption under Schedule 3 of the SL Act.

The section 5 amendment in the draft Regulation modernises the current legislation relative to the base case (Option 1) by clearly defining penalty points to enhance compliance. This proposed minor amendment provides operational efficiency benefits to NSW Government and key industry bodies using the regulation. The intent of the SM Regulation is unchanged.

Overall, since Option 2 provides operational efficiency benefits, the draft Regulation is preferred to remaking the SM Regulation as is (base case).

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

Under Option 3, self-regulation would be implemented on 1 September 2024 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 its place.

Furthermore, relevant organisations from the NSW veterinary medicine industry, the farming industries and stock feed industry would need to 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 and the community.

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

Table 5 shows that relative to the base case, Option 3 would impose significant risks and costs on the community, businesses and government agencies.

A summary of the key impacts is 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.

Table 5 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 **(Section 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 **(Section 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 **(Section 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.

Provision group	Impact	Benefits	Costs
Taking of samples (Section 8)	• **Inspectors** of stock medicine samples would not have to adhere to conditions when collecting and storing samples. This would increase the likelihood of unauthorised access to samples and risk that samples are contaminated.	• **Inspectors** would not need to adhere to specific requirements about the collection and keeping of samples.	• There may be a reduction in the quality and accuracy of tests that are completed from samples, if the samples were not collected and stored correctly.
Penalty notices (Section 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 to lapse)

Under Option 4, co-regulation would be implemented on 1 September 2024 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 the community, businesses and government under this option will be similar to those outlined in Option 3 (see Table 5).

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 the community, businesses and government (as detailed in section 7.3.1).

If government and interested parties can 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, businesses 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 or remake the SM Regulation or the draft SM Regulation (Option 2).

7.5 Summary Case for Option 2

In conclusion, making the draft Regulation (Option 2) under the SM Act is the preferred option, as it modernises the current legislation relative to the base case (Option 1) by clearly defining penalty points to enhance compliance. Option 2 also maintains the powers of the existing regulation with subsequent positive impacts on the community, business and government.

Options 3 and 4 are not preferred to the base case, or the draft Regulation, as they would reduce powers to manage stock medicines and increase the risk of negative impacts and costs in NSW.

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