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Introduction to the South African legal system and perspective from a non-EU country

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cost EUROPEAN COOPERATION IN SCIENCE & TECHNOLOGY

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South Africa

Partner member to EU COST Action

Legal framework within which medicinal plants can be administered to animals

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Faculty of Veterinary Science, University of Pretoria, South Africa


ONDERSTEPOORT VETERINÊRE AKADEMIESE HOSPITAAL
ONDERSTEPOORT VETERINARY ACADEMIC HOSPITAL

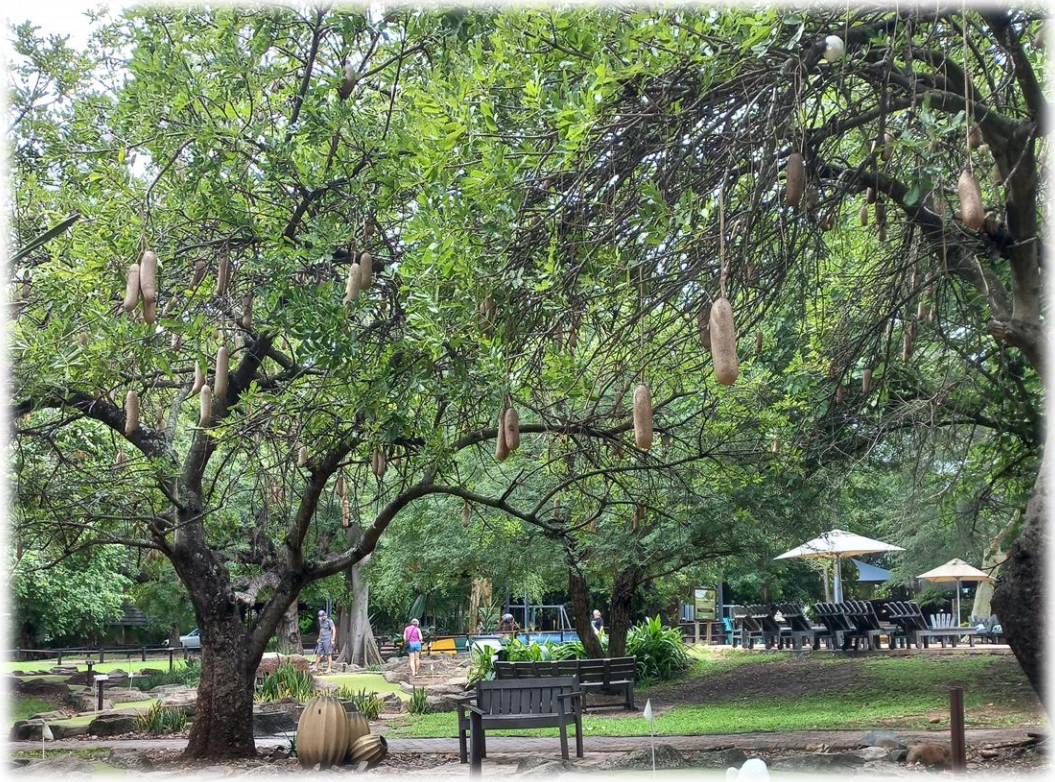
ONE HEALTH

SA: Plant diversity

- Plants as sources of novel therapeutic compounds
  SA floristic diversity: 24-30 000 spp.

- Plant extracts and compounds useful in human and animal health

Cape Floristic region
~9 000 vascular plant spp.



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SA: Cultural diversity

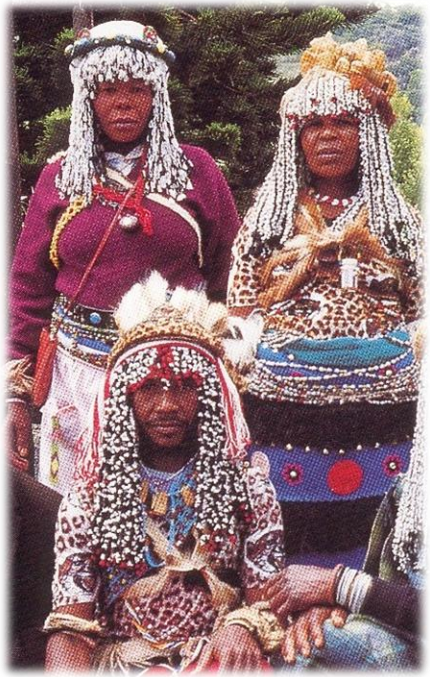

Photo: van Wyk et al., 1997

SA: 3 000 plants used in traditional medicine

350 species most commonly used/traded

- ± 200 000 indigenous healers, consulted by 2/3 of SA population
- Acute shortage of Western medical doctors, health clinics (also rural veterinary clinics)
- TMPs have essential role in primary health care (humans and animals)

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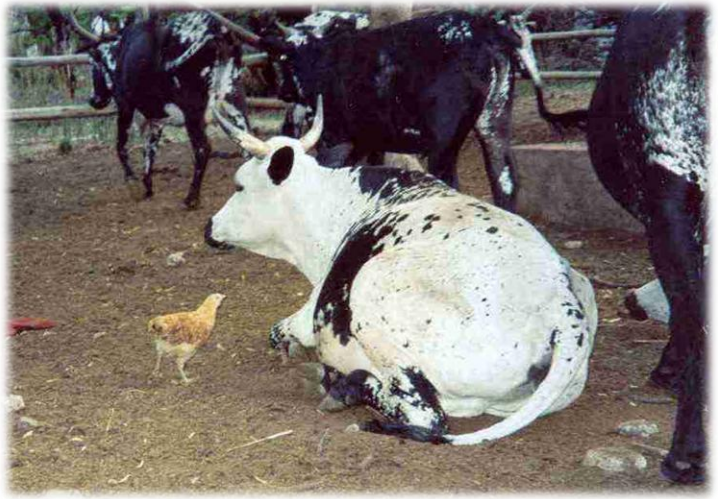
Ethnoveterinary medicine (EVM) in South Africa

- EVM: rural livestock keepers – access to orthodox remedies limited
- Diseases NB economic impact on livestock: loss of animals, decreased output (milk, meat)
- Cattle, goats and sheep: often non-specific indications
- For common ailments (coughs, wounds, skin disease) = possible alternative or complement to Western medicine
- EVM complex system of management



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Rural livestock keepers

- Plants used to treat livestock and poultry
- SA: rich cultural diversity and plant diversity
- Animals sources of wealth and livelihood
- When animal sick or dies – loss of transport, aid to farming, dairy products, meat, other products (wool, hair = extra income or clothing)
- Owners of livestock generally treat animals with own medicinal plant knowledge rather than consulting traditional healers

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Photos: Anderson Munengwa

South Africa: growing interest in plants for animal health

- Antimicrobial resistance
- Parasite resistance
- Sustainable livestock and poultry production
- Consumer preferences
- Chemical residues in environment / animal products
- Companion animal healthcare

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What about the legal aspects for veterinarians?

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South African legal system – brief introduction

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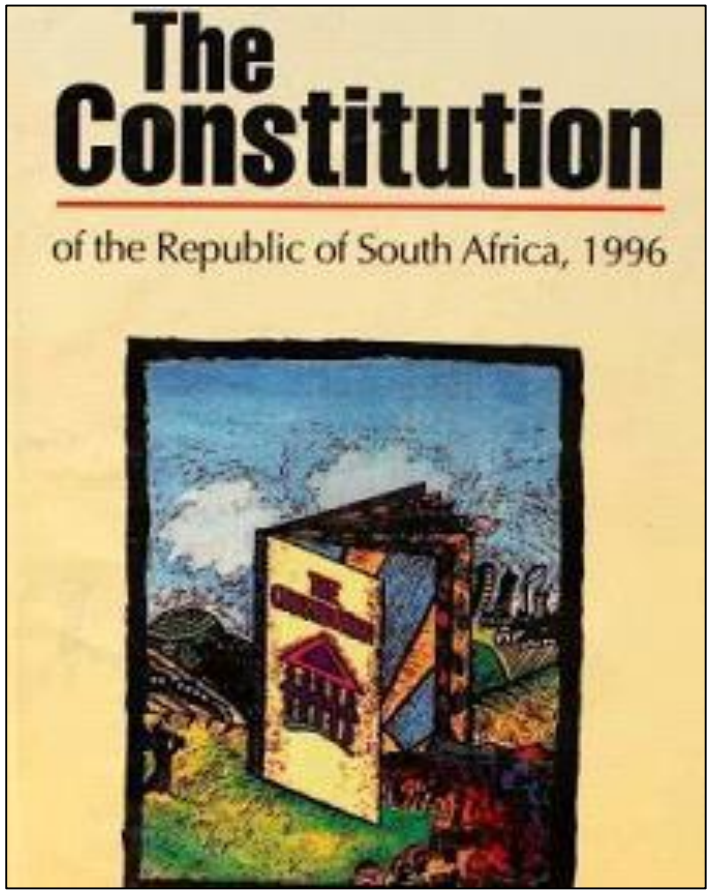
South African legal system – brief introduction

Constitution = supreme law (highest law) of the country



All legislation is measured and interpreted against the Constitution

- Applies to all people and institutions within the borders
- Any law or act in conflict with Constitution not allowed
- Interpretation of statute and common law must be within the framework of the Constitution
- Bill of Rights (s7-S39)
    - No right is all-inclusive, all rights have limitations

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Legislative, executive, judicial

- **Legislative**: creation of law – pass new laws, change existing ones
  - Function lies with Parliament (or provincial or local authorities)
  - Laws formulated by State (executive) passed by legislative body (Parliament)
- **Executive**: President is Head of State (government)
- **Judiciary**: Independent judicial authority
  - Administers justice through courts
  - Develops law through judicial precedent

- Separation of powers
- Rule of law

Sources of South African Law

- **Legislation** (statutory law) / statutes / acts of parliament / by-laws (municipalities) / Constitution
- **Court decisions** (judicial precedent system – verdict lower courts bound by upper court decisions – legal principle, same facts)
- **Common law** (Roman-Dutch, influenced by English law)
- **African indigenous law and customary law**
- **Persuasive influence**: other legal systems, books, expert opinions

Law continually developing

The South African Veterinary Council (SAVC): savc.org.za

- Statutory controlling body that functions independently
- Composition laid down in the Veterinary and Para-Veterinary Professions Act

- Ethical rules
- Monitors professional practice and delictual (civil) standards or statutory (criminal) transgressions
- Protects the interests of the public
- Mediates disputes between professionals

SAVC
SOUTH AFRICAN VETERINARY COUNCIL

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Veterinary legislation

- Veterinary and Para-Veterinary Professions Act
- Regulations

- Rules Relating to the Practising of Veterinary Profession
- [Incorporates NB aspects of Medicines Act which also controls veterinary medicines]

- Code of Conduct and Practice for Veterinarians

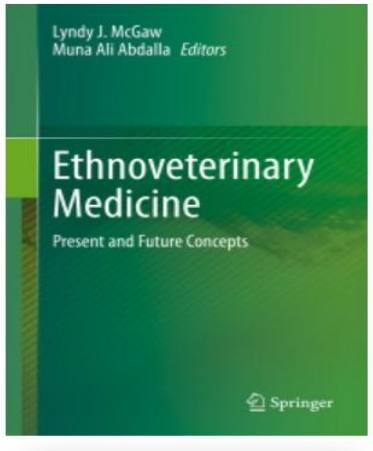
Medicine (Rule 10 (1))

Veterinary professional … administers / … prescribes … satisfy himself ….. justified …benefits and risks ….
the animal to which it is administered and
the person by whom it is administered = duty to take into consideration interests of client - residues

Inform client: effect, precautionary measures, withdrawal period

VME 310 Ethnoveterinary medicine

1. Students will have an awareness of the use of plants in animal healthcare
2. The basis for potential efficacy and toxicity of ethnoveterinary medicine will be understood
3. Potential interactions of plant-based ethnoveterinary remedies with orthodox medicines will be understood
4. Students will be sensitized to the use of indigenous knowledge and complementary medicine in animal health



Use of complementary medicines / EVM in livestock production and veterinary practice in South Africa

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Stock Remedies Act 36

Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act 36 of 1947

To provide … for the registration of fertilizers, farm feeds, agricultural remedies, stock remedies, …

- **Department of Agriculture**
- Many non-scheduled, over-the-counter herbal supplements and remedies are registered as stock remedies or pet food supplements under Act 36 of 1947

  Application process ensures they meet specific **quality and labelling** standards

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Medicines Act 101

Medicines and Related Substances Act 101 of 1965

To provide for the registration of medicines and related substances intended for human and for animal use…

- **SAHPRA** (SA Health Products Regulatory Authority)

SAHPRA evaluates the **safety, efficacy and quality** of products before approval

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Definitions

i) The definition of a **complementary medicine (CM)** is provided as:
“Complementary medicine” means any substance or mixture of substances that—

(a) originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by Council, and

(b) is used or purporting to be suitable for use or manufactured or sold for use—

(i) in maintaining, complementing, or assisting the innate healing power or physical or mental state, or

(ii) to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state, of a **human being or animal**, and

(c) is used—

(i) as a health supplement, or

(ii) in accordance with those disciplines as determined by Council, or

(d) is declared by the Minister, on recommendation by the Council, by notice in the Gazette to be a complementary medicine.

Act 101: General Regulations

9. (1) Medicines shall be classified into categories as follows:

(a) Category A = Medicines which are intended for use in humans and which are, without manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine;

(b) Category B = Medicines intended for use in humans and animals which cannot normally be administered without further manipulation;

(c) Category C = Medicines intended for **veterinary use** which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine; and

(d) Category D = **Complementary medicines** intended for use in humans and **animals** which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine

Regulations 2013:

Complementary medicines must adhere to same standards as conventional medicines

Until registered – *disclaimer:*
"This medicine has not been evaluated by SAHPRA and is not intended to diagnose, treat, cure or prevent any disease"

Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972)

- **The South African regulatory system does not prevent use of herbal medicines, but heavily regulates residues in food products**

- **Absence of established MRLs and withdrawal periods** for most herbal remedies implies that detectable residues could be viewed as non-compliance. Lack of comprehensive research on safe usage and residues.

- **Maximum Residue Limits (MRLs):** If substance is not listed with specific MRL, the default regulation for domestic food is that no residue above 0.05 mg/kg is permitted (considered equivalent to zero). Implies that many traditional herbal medicines are subject to a zero-residue tolerance in edible animal products.
- **Withdrawal Periods:** Registered conventional veterinary medicines must have a specified withdrawal period to ensure residues deplete to safe levels before products (meat, milk, eggs) enter food chain. As most traditional herbal remedies are not formally registered, they have no scientifically established withdrawal periods - risk of residues if treated animals used for food.
- **National Chemical Residue Control Programme (NCRCP):** SA has a national monitoring program to test for residues in animal products, especially for export markets like EU. Tests for banned substances and authorised veterinary medicines to ensure compliance with food safety regulations.

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South African Health Products Regulatory Authority

www.sahpra.org.za

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COMPLEMENTARY MEDICINES COMMUNICATION TO INDUSTRY

Search:

Document Number	Title	Categories	Date Updated	Version	Units	File Type	Link
	Communication to industry – SAHPRA Statement on Regulation of Category D Medicines	Communication to industry	02/06/2023	1	Complementary Medicines	pdf	Download

"medicinal purpose" . . . . . .

[Definition of "medicinal purpose" deleted by s. 1 (e) of Act No. 94 of 1991.]

"medicine"—

(*a*) means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—

(i) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or

(ii) restoring, correcting or modifying any somatic or psychic or organic function in humans; and

(*b*) includes any veterinary medicine;

[Definition of "medicine" substituted by s. 1 (d) of Act No. 17 of 1979, by s. 1 (i) of Act No. 72 of 2008 and by s. 1 (g) of Act No. 14 of 2015.]

"Minister" means the Minister of Health;

[Definition of "Minister" substituted by s. 1 (d) of Act No. 20 of 1981, by s. 1 (f) of Act No. 94 of 1991 and by s. 1 (g) of Act No. 90 of 1997.]

"nurse" means a person registered as such under the Nursing Act, 1978 (Act No. 50 of 1978);

[Definition of "nurse" inserted by s. 1 (g) of Act No. 94 of 1991.]

COMMUNICATION TO STAKEHOLDERS

Issue No.: PEM04-2023/24

2 June 2023

SAHPRA Statement on Regulation of Category D Medicines

In response to the Supreme Court of Appeal (SCA) judgment on 11 April 2022 regarding the Alliance of Natural Health Products (ANHP), the Minister of Health recently released, for public comment, draft amendments to the General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) on 24 March 2023.

The draft amendments align with the SCA and High Court judgments, which stated that only substances classified as "medicines" or "scheduled substances" as defined in section 1 of the Medicines Act should be subject to regulation and included in the scope of Category D medicines. Considering these judgments and the draft regulation amendments, SAHPRA initiated the relevant revision of its technical guidelines. These will be made available for a period of public comment.

This revision will primarily involve Guideline 7.02 (The roadmap and transitional process for the regulation of Category D medicines) and the proposed adjustments to the risk levels applied to Category D medicines. Guideline 7.02 will also clarify which products or substances will or will no longer be subject to regulation. All other technical guidelines related to Category D medicines will be aligned with Guideline 7.02 as revised, where relevant.

SAHPRA, will engage the industry stakeholders in line with its normal operation on the technical amendments of the revised Guideline 7.02 once it has been published for comment. The date of this engagement will be communicated accordingly.

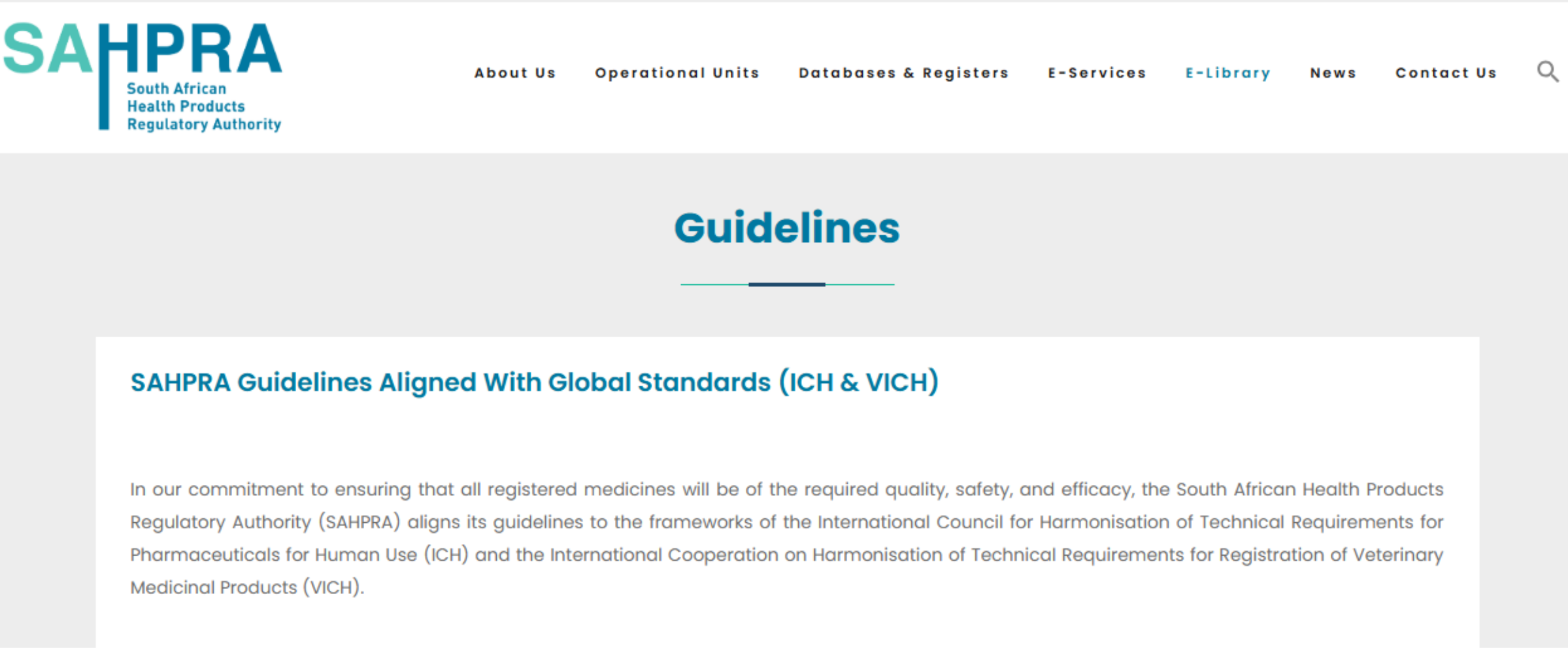
While comments on the published regulations are still awaited, Category D medicines falling under the definition of "medicines" or "scheduled substances" in the Medicines Act will be regulated as outlined in the revised Guideline 7.02. All applications and requests, including licensing, section 21, certificate of free sale, health supplement Annexure B applications, and Category D registration applications, will be reviewed and processed. Products detained at ports of entry under the Customs and Excise Act, 1964 (Act 91 of 1964), or the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972), may continue to be submitted for verification using the online form.

SAHPRA is fully committed to establishing an appropriate regulatory process for "medicines" and "scheduled substances" as defined, recognising the significance of the SCA judgment.

Therefore, products with only low-risk, non-therapeutic claims (like nutritional effects) shouldn't be subject to the onerous regulations meant for actual medicines…

South African Health Products Regulatory Authority

www.sahpra.org.za



List Of Registered Veterinary Products

The South African Health Products Regulatory Authority (SAHPRA) has taken a significant step in ensuring the safety and efficacy of veterinary medicines and products by approving and registering a comprehensive list of such products. This register contains detailed information leaflets for each product, providing veterinarians and animal owners with vital information on the correct usage, dosage, and potential side effects of these medicines.

The registration of veterinary medicines and products is crucial in ensuring the health and well-being of animals, as well as safeguarding the public against the potential risks posed by these products. By approving only those products that meet stringent safety and efficacy standards, SAHPRA is playing a crucial role in protecting the health of animals.

Last updated: 07 May 2025

Search

Application no	Registration number	Product name	Dosage Form	Company	Ingredients	Pharmacological Classification	PI
99/15	99/2.6/15	CRONYXIN	Injection	Afrivet Business Management (Pty) Ltd	Each 1.0 ml Liquid contains FLUNIXIN MEGLUMINE A equivalent to FLUNIXIN 50.0 mg	C 0206. NON-NARCOTIC ANALGESICS. ANTIPYRETICS	DOWNLOAD PI
06/07	06/17.1.6/07	MARBOCYL 10 %	Injection	Afrivet Business Management (Pty) Ltd	Each 1.0 ml Solution contains MARBOFLOXACIN A 100.0 mg	C 170106. QUINOLONES	DOWNLOAD PI
06/08	A06/3.1/08	TOLFEDINE INJECTABLE	Injection	Afrivet Business Management (Pty) Ltd	Each 1.0 ml Solution contains TOLFENAMIC ACID A 40.0 mg	C 0301. ANTI-INFLAMMATORY	DOWNLOAD PI

What does the SAVC say about prescribing complementary medications?

Code of Conduct and Practice for Veterinarians

10.2.6 Veterinary botanical medicine

Veterinary botanical medicine is the use of plants and plant derivatives as therapeutic agents. It is recommended that continued research and education be conducted. Since some of these botanicals may be toxic when used at inappropriate doses, it is imperative that veterinary botanical medicine be practised only by licensed veterinarians who have been educated in veterinary botanical medicine. Communication on the use of these compounds within the context of a valid veterinarian/client/patient relationship is important.

10.2.7 Nutraceutical medicine

Nutraceutical medicine is the use of micronutrients, macronutrients, and other nutritional supplements as therapeutic agents. Communication on the potential risks and benefits from the use of these compounds within the context of a valid veterinarian/client/patient relationship is important. Continued research and education on the use of nutraceuticals in veterinary medicine is advised.

New medicines from plants

Bioprospecting: *…the search for new and useful substances, such as medical compounds, from natural resources*

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South Africa signatory to Convention on Biodiversity

Nagoya Protocol
fair and equitable sharing of benefits arising out of the utilization of genetic resources

National Environmental Management Biodiversity Act 10 of 2004 (NEMBA)
Department of Forestry, Fisheries and the Environment

1. no person may, without a permit, engage in the commercialisation phase of bioprospecting involving indigenous biological resources; or
2. export any indigenous biological resources for bioprospecting or research

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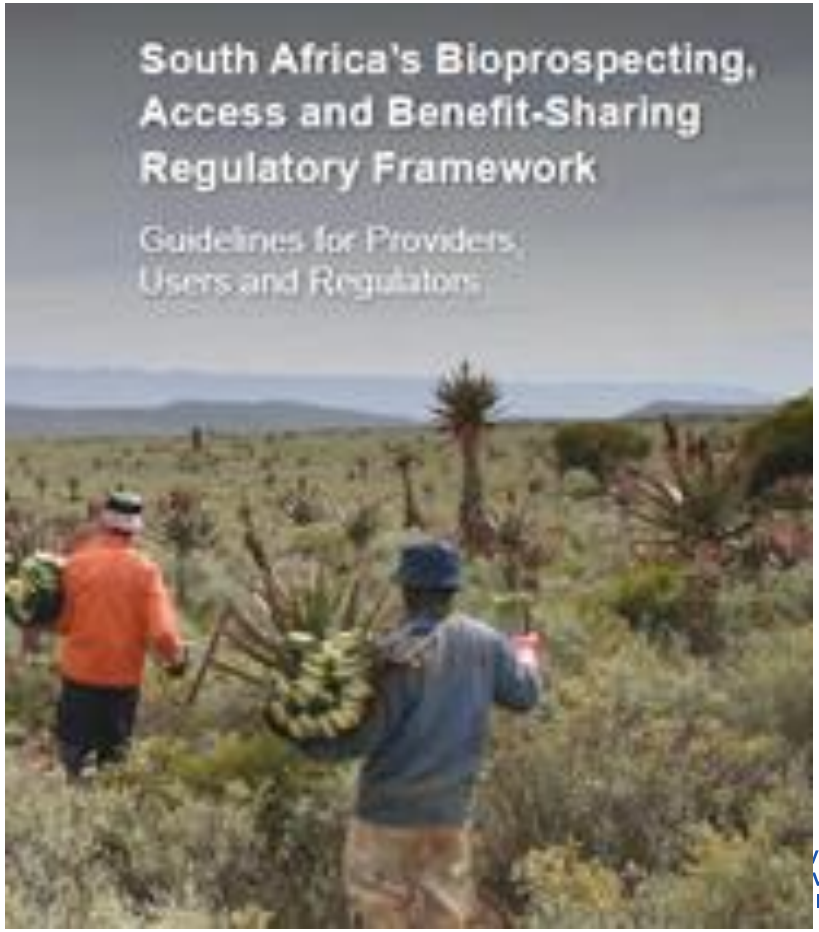
BABS Regulations

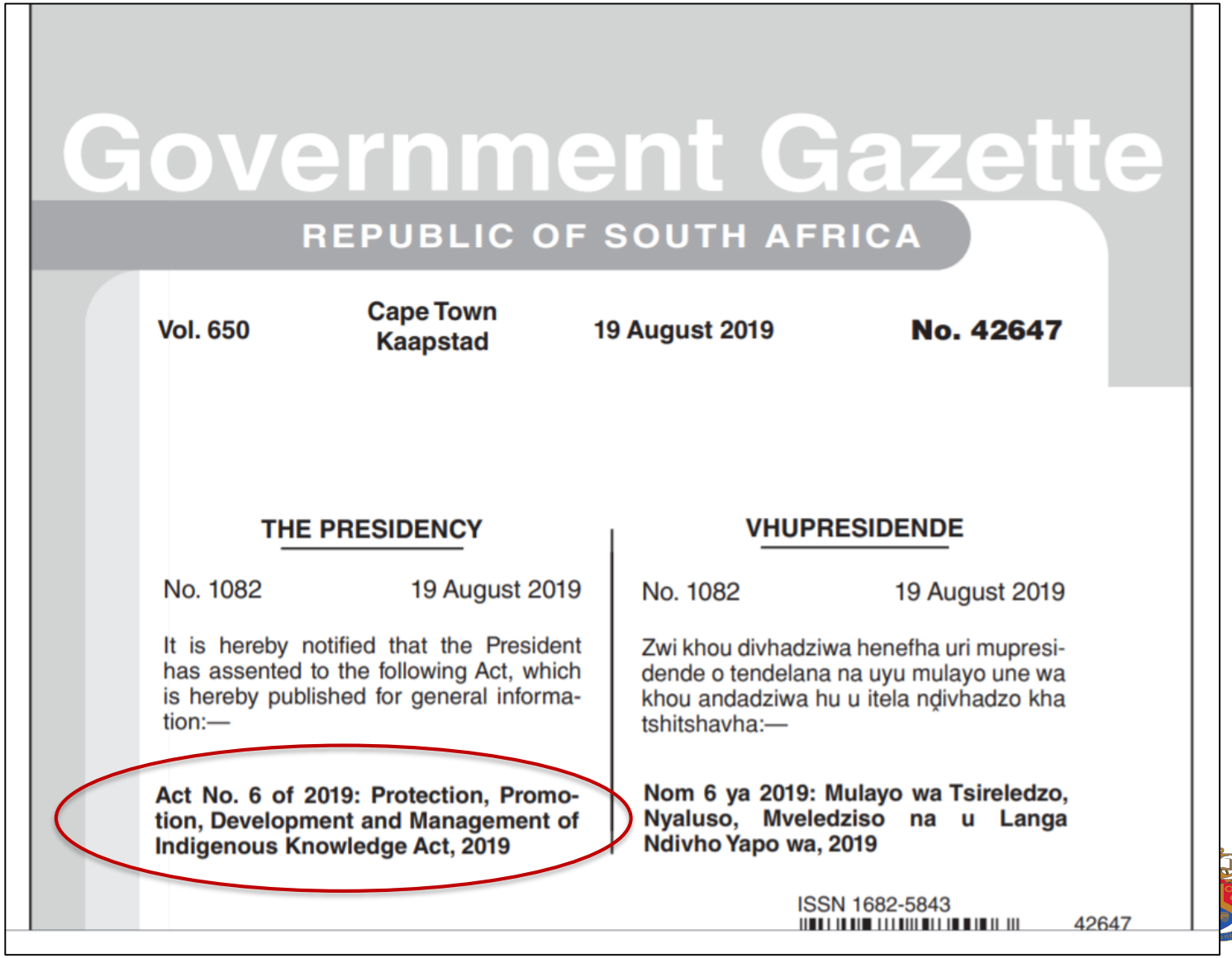
1. Discovery phase – notify Minister
2. Bioprospecting phase – apply for permit (commercialisation)

    benefit sharing agreements

    material transfer agreements



Indigenous Knowledge Act



Government Gazette

REPUBLIC OF SOUTH AFRICA

Vol. 650 Cape Town Kaapstad 19 August 2019 No. 42647

THE PRESIDENCY

No. 1082 19 August 2019

It is hereby notified that the President has assented to the following Act, which is hereby published for general information:—

Act No. 6 of 2019: Protection, Promotion, Development and Management of Indigenous Knowledge Act, 2019

VHUPRESIDENDE

No. 1082 19 August 2019

Zwi khou divhadziwa henefha uri mupresidende o tendelana na uyu mulayo une wa khou andadziwa hu u itela ndivhadzo kha tshitshavha:—

Nom 6 ya 2019: Mulayo wa Tsireledzo, Nyaluso, Mveledziso na u Langa Ndivho Yapo wa, 2019

ISSN 1682-5843 42647

Indigenous Knowledge Act

To protect IK (and genetic resources and indigenous cultural expressions)

Includes medical, agricultural and scientific practices

GOVERNMENT NOTICES • GOEWERMENTSKENNISGEWINGS

DEPARTMENT OF SCIENCE AND INNOVATION

NO. 2647 **14 October 2022**

PROTECTION, PROMOTION, DEVELOPMENT AND MANAGEMENT OF INDIGENOUS KNOWLEDGE ACT, 2019 (ACT NO. 6 OF 2019)

REGULATIONS RELATING TO THE PROTECTION, PROMOTION, DEVELOPMENT AND MANAGEMENT OF INDIGENOUS KNOWLEDGE

The Minister of Science and Innovation intends, in terms of section 31(1) of the Protection, Promotion, Development and Management of Indigenous Knowledge Act, 2019 (Act No. 6 of 2019), to make the Regulations in the Schedule.

CONCLUSIONS

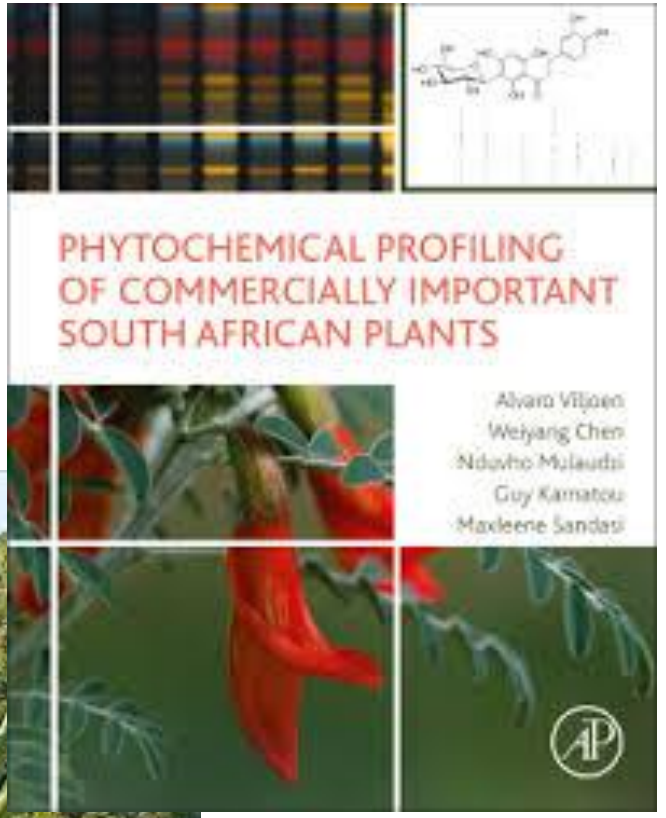
More research needed!

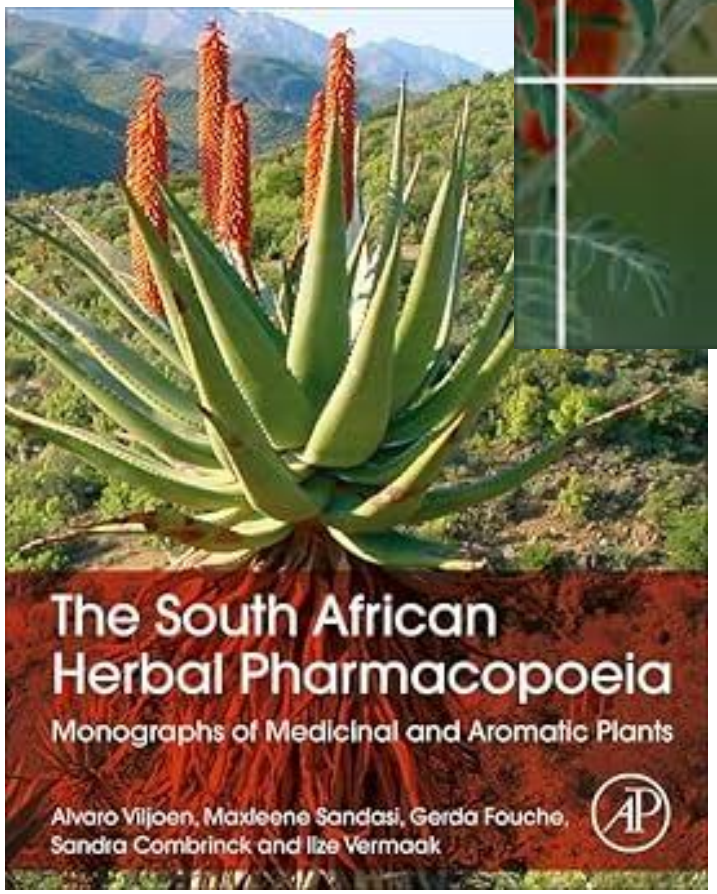
Quality, safety, efficacy

Residues

Legislation exists

Maximum benefit from herbal veterinary treatments





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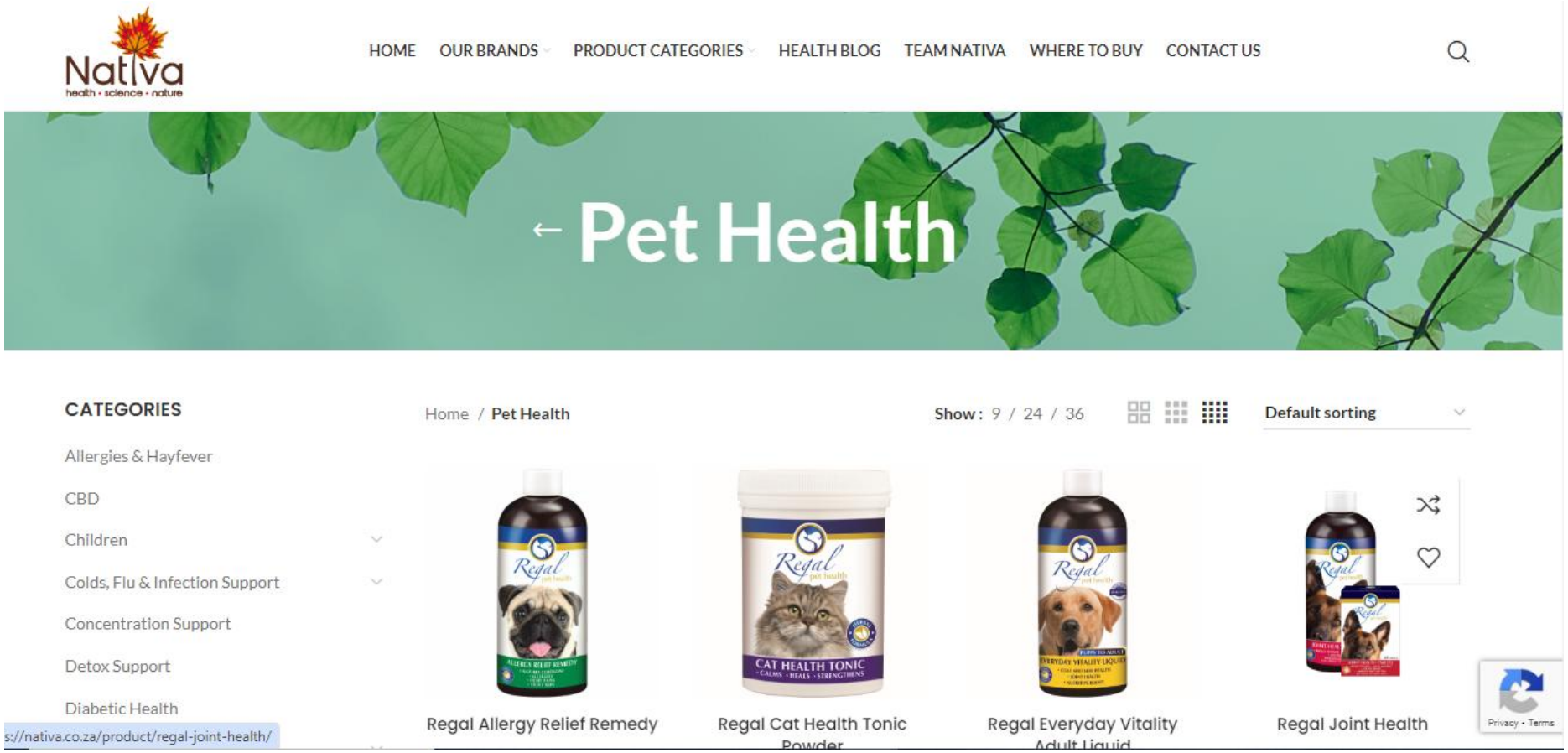
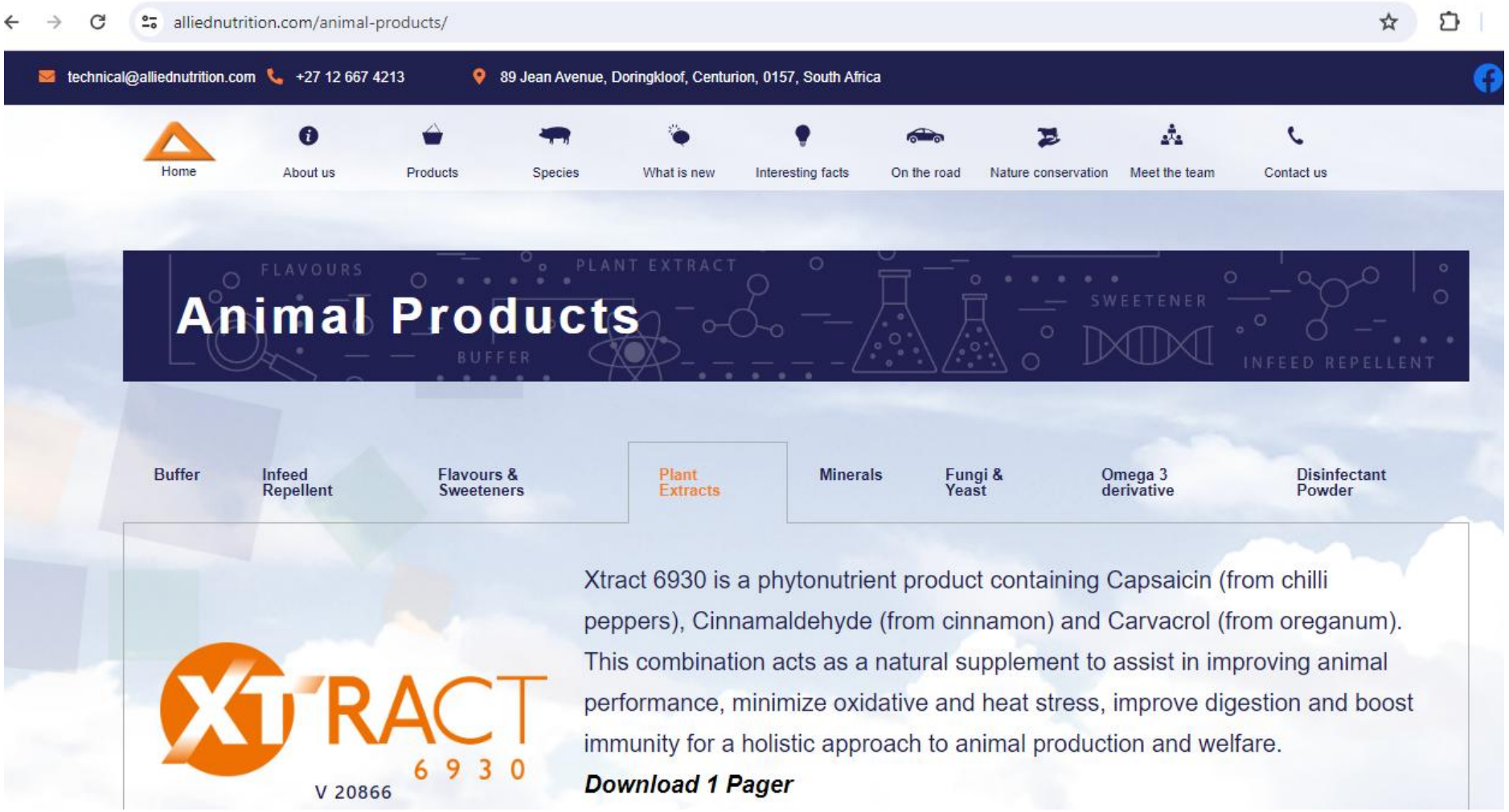
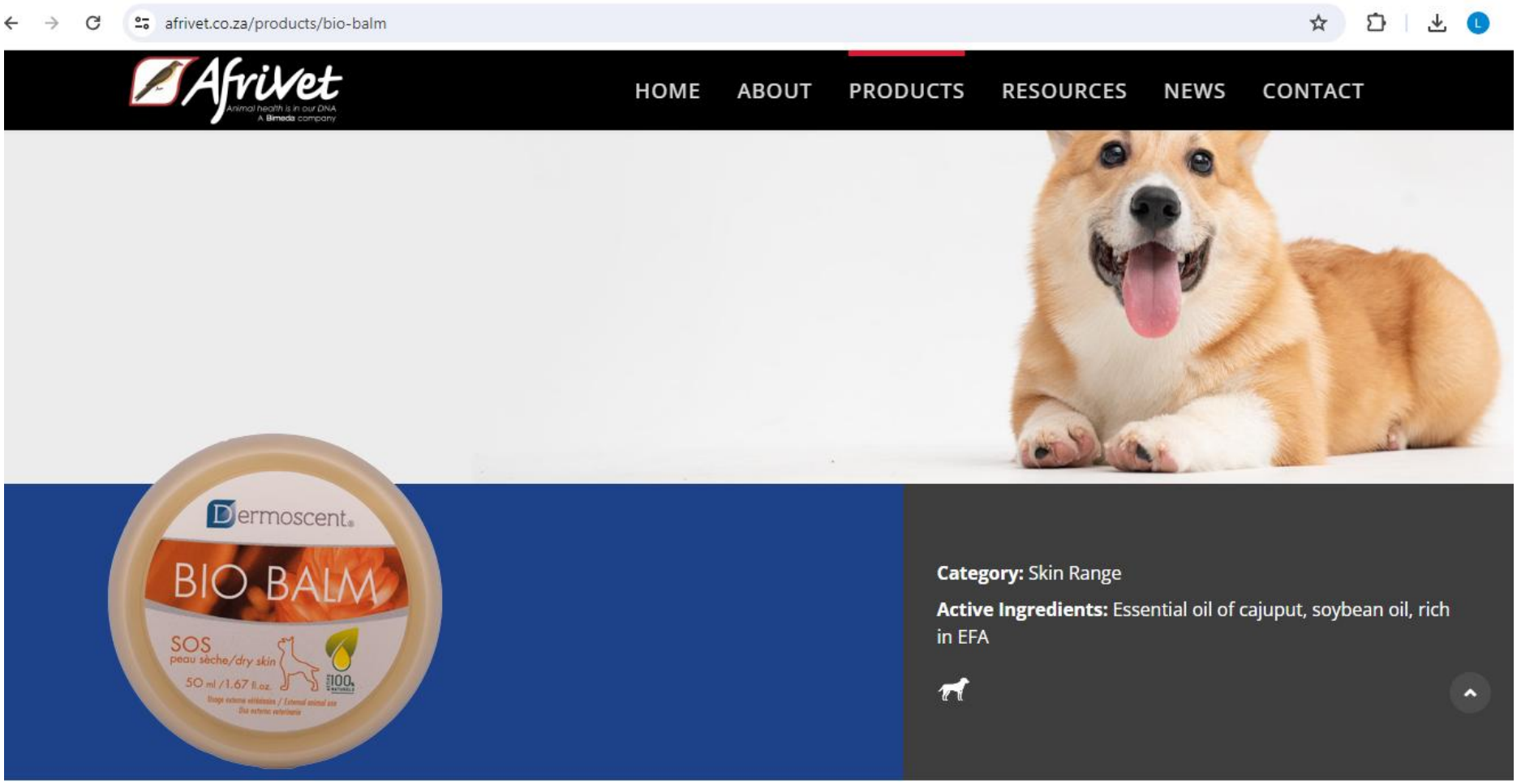
https://nativa.co.za/product-category/pet-health/



https://alliednutrition.com/animal-products/



https://www.afrivet.co.za/products/bio-balm



Homeopathic remedies

https://ecovet.co.za/resources/

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https://natura.co.za/

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Eco-Vet products are registered with the Department of Agriculture in terms of Act no. 36/1947

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