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Protecting Livestock – Improving Human Lives

GALVmed / OIE Stakeholder Workshop on harmonisation of registration requirements for Veterinary Medicinal Products

Johannesburg, 9-11 May 2017

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Protecting Livestock – Improving Human Lives

2. Results of Survey on Current Status of Veterinary Vaccine Registration in SADC Countries

Johannesburg June 2017

SUMMARY

1. Terminology/ Definitions
2. Legislation vs Guidance
3. SADC Countries' responses to questionnaire
4. Veterinary Medicines – pharmaceuticals or biologicals?
5. Good Manufacturing Practice
6. Batch testing by AU-PANVAC

1. Glossary of Terms

Applicant: Person or company who applies for permission to sell a medicine.

Registration: Assessment of data on Safety, Quality and Efficacy of medicine which, if acceptable, leads to approval to place the medicine on the market in that country.

Regulatory Authority: Government appointed authority mandated to assess product dossiers submitted by Applicants requesting authorisation to market a medicine.

Veterinary Medicine = Veterinary Pharmaceutical or Drug

Veterinary Immunological Product e.g. Vaccine

Glossary of Terms

Registration dossier: Dossier

including data supporting

SAFETY

QUALITY

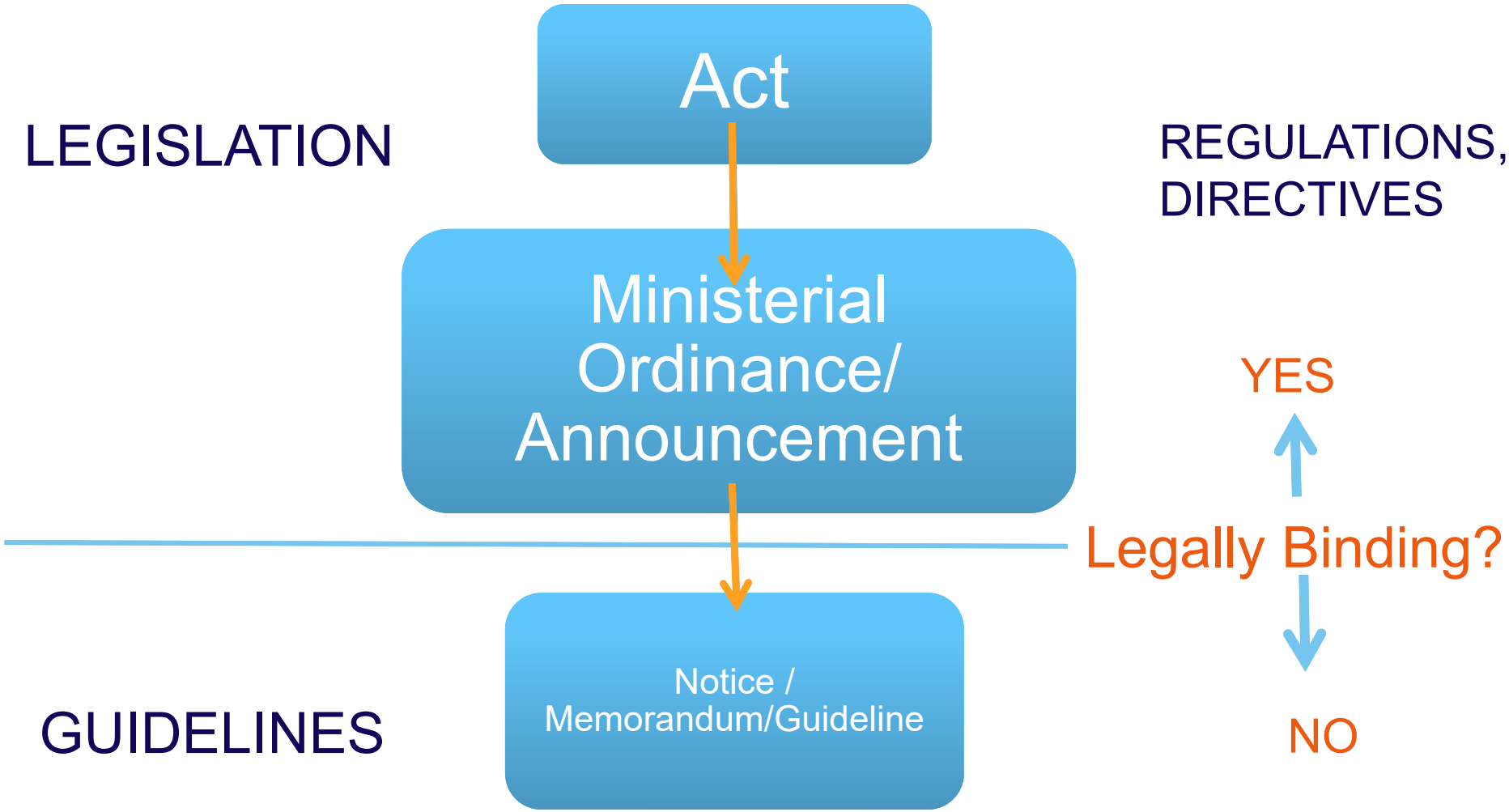
EFFICACY

of a medicinal product.

Product Licence / Marketing Authorisation = authorisation awarded to an applicant by a Regulatory Authority to place a medicinal product on the market for a specified or indefinite period of time.

Import permit – permission to import a consignment of a medicine.

2. General Heirarchy of Law for Human and Veterinary Medicinal Products



3. SADC Countries Questionnaire : Responses received from 12/15 countries

ANGOLA 

BOTSWANA 

D R CONGO 

LESOTHO 

MALAWI 

NAMIBIA 

S. AFRICA 

SWAZILAND 

SEYCHELLES 

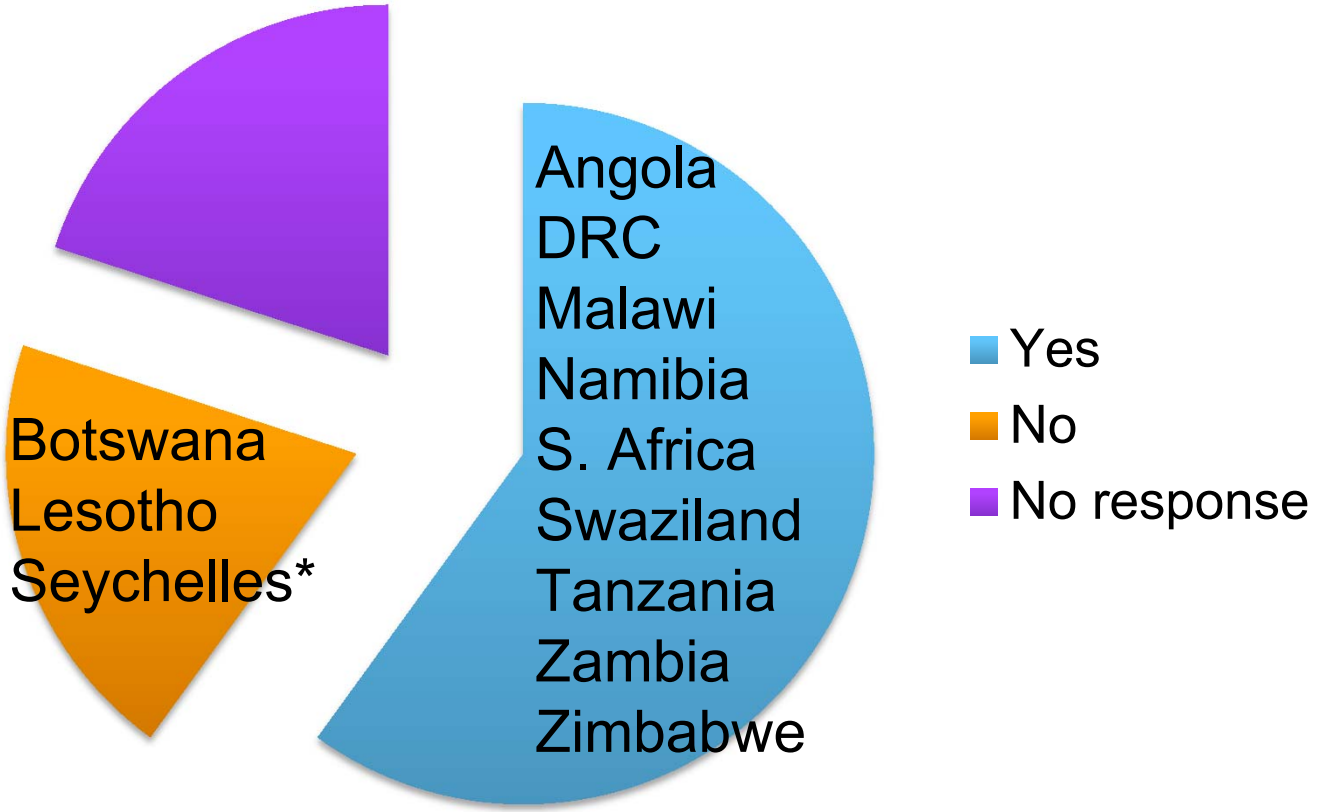
TANZANIA 

ZAMBIA 

ZIMBABWE 

SADC Countries with Regulatory Authorities

Does your country have a Regulatory system for assessing registration dossiers and issuing Marketing Authorisations (MAs)?



* Plans to have one

Same agency for both Human & Veterinary Medicines

"YES"

Angola: will have

Malawi

Namibia

Seychelles

S. Africa (MCC)

Tanzania

Zambia

Zimbabwe

"NO"

DRC

Lesotho, but intend to

S. Africa (DAFF)

Swaziland

Same Department manages both Veterinary Pharmaceuticals and Veterinary Vaccines

"Yes"

(Angola)

Malawi

Seychelles

S. Africa (MC

Swaziland

Tanzania

Zambia

Zimbabwe

"No" Department specifically for veterinary vaccines:

DRC

Lesotho

S. Africa (DAFF)

Is there a difference?

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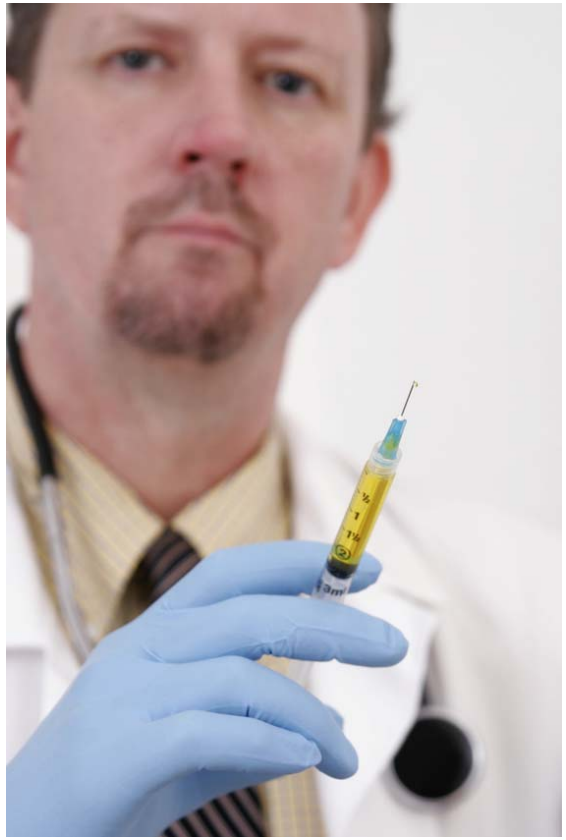
Pharmaceuticals

Could be Biological

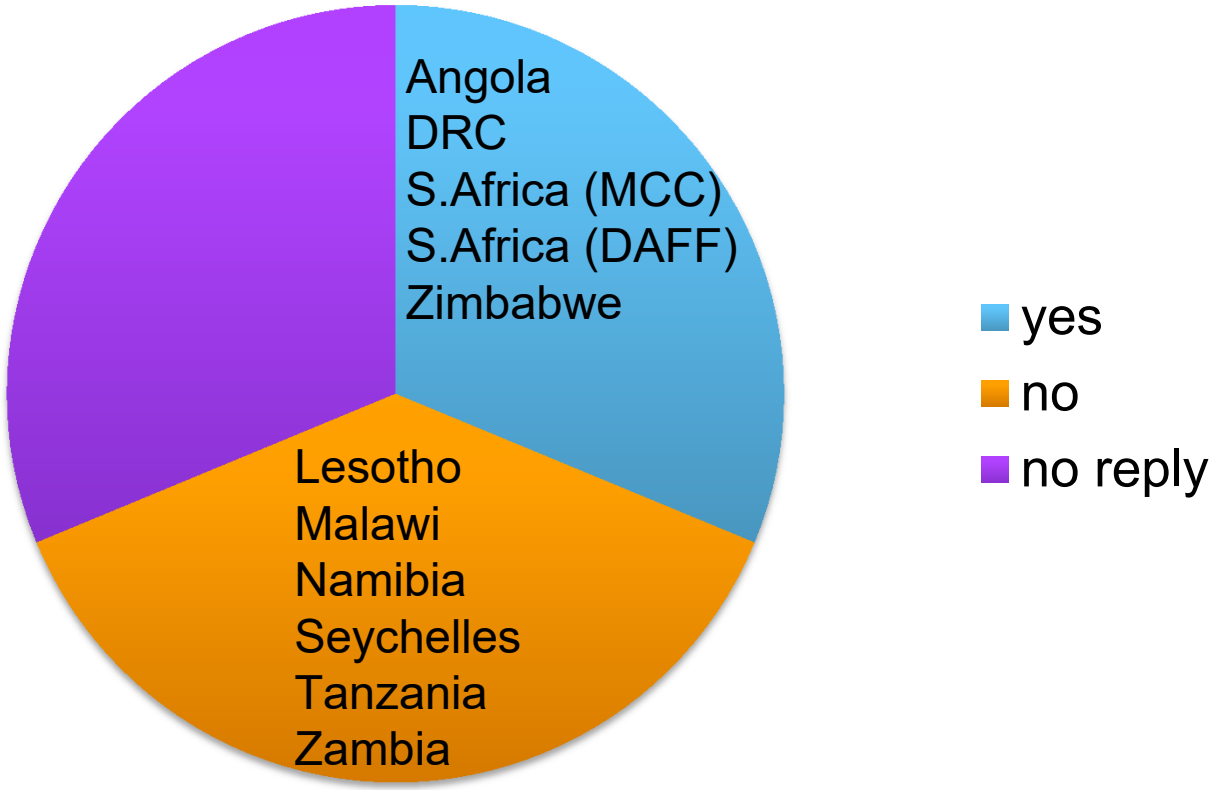


Pharmaceuticals & Biologicals Dossiers

	Pharmaceuticals	Biologicals
Active ingredient	• Molecule/Drug substance	• Antigen (live or inactivated)
Safety	• Pharmacology • Pharmacokinetics • Metabolism • Toxicology in Lab animals & TS • Residues • Withholding time	• Not applicable • Not applicable • Not applicable • Safety in Target Species • Not applicable* • Zero days
Efficacy	• Efficacy – dose / kg bw	•Efficacy – Immunity/protection

*Exceptions, e.g. live zoonotic organisms

SADC Regional Guidelines domesticated



Do you allow the use of unlicensed vaccines in an emergency situation?

Yes	No	Never had a need
Angola	Lesotho	Malawi
DRC	Swaziland	Seychelles
Namibia, for FMD		
South Africa		
Tanzania		
Zambia		
Zimbabwe		

Do you issue Import Permits and if so who issues them?

Yes	Issued by
Angola	Inst Vet Services, Min of Ag
DRC	DVS/CVO
Malawi	Dept Animal Health & Lstock
Namibia, for FMD	Reg Authority (NMRC)
Seychelles	Min of trade (DoH/DVS)
South Africa	MAFF & Min of Health
Swaziland	DVS
Tanzania	TFDA
Zambia	Min of Livestock
Zimbabwe	Min of Ag /DVS

No

Lesotho

Potential for Mutual Recognition of another Country's Authorisation

When no suitable veterinary medicines is authorised is it permissible to use a vaccine that is

	Licensed in another African Country ?	Licensed in a country outside of Africa?	Licensed for use in another species?
Angola	Yes	Yes	Yes
DRC	No	No	No
Malawi	No	No	No
Namibia	No	No	No
Seychelles	Yes	Yes	No
S. Africa	Yes	Yes	No
Swaziland	No	No	No
Tanzania	No	No	No
Zambia	No	No	No
Zimbabwe	Yes	Yes	No

Do you require veterinary medicines to be licensed in the country of origin prior to your approval?

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If from another African country

Yes	No
Angola	Namibia
DRC	S Africa
Lesotho	Tanzania
Malawi	Zambia
Seychelles	Zimbabwe
Swaziland	

Do you require veterinary medicines to be licensed in the country of origin?

If from a non-African country

Yes

DRC

Lesotho

Malawi

Seychelles

S. Africa

Swaziland

Tanzania

Zambia

Zimbabwe

No

Angola

Namibia

If a vaccine is already licensed in an African country do you accept the dossier assessment & MA of the other country?

Yes,

Lesotho 

Seychelles 

No,

all other countries

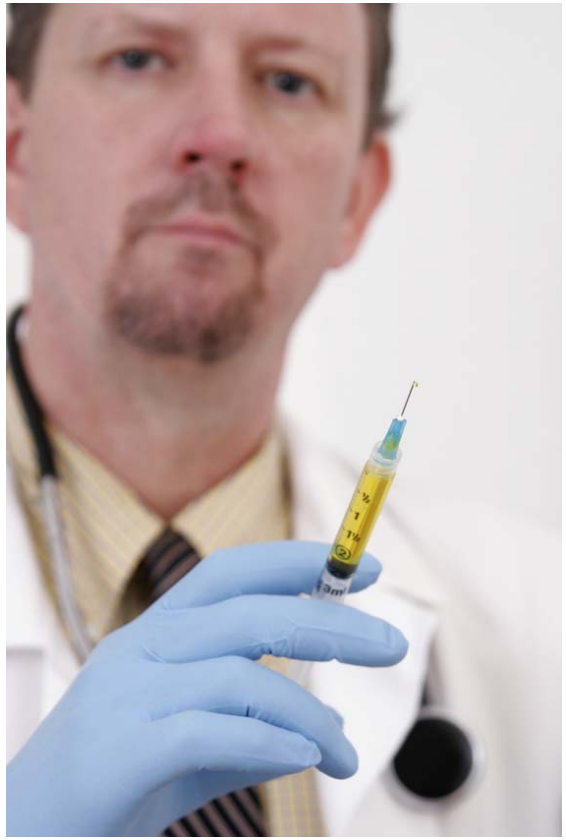
If a vaccine is licensed outside of Africa do you accept the dossier assessment & MA of the other country?

No	Yes
Angola	None
DRC	
Malawi	
Namibia	
Seychelles	
S Africa	
Swaziland	
Tanzania	
Zambia	
Zimbabwe	

Remember there is a difference

Pharmaceuticals

Could be Biological



Are the dossier requirements for a veterinary vaccines the same as for a veterinary pharmaceutical?

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Yes, the same:

DRC

Malawi

Namibia

S. Africa

Seychelles (pharmacology/PK/tox + safety & efficacy required but no quality or stability data)

Zambia

Zimbabwe (but no pharmacology or PK)

No

Tanzania: requires data that is specifically appropriate for immunologicals

How many veterinary vaccines have been registered in your country ?

0 – 10	10 – 50	over 50
2 countries	1 country	6 countries

Do you accept reduced data for vaccines required urgently in the face of a new disease outbreak?

Yes: Namibia, South Africa, Zambia

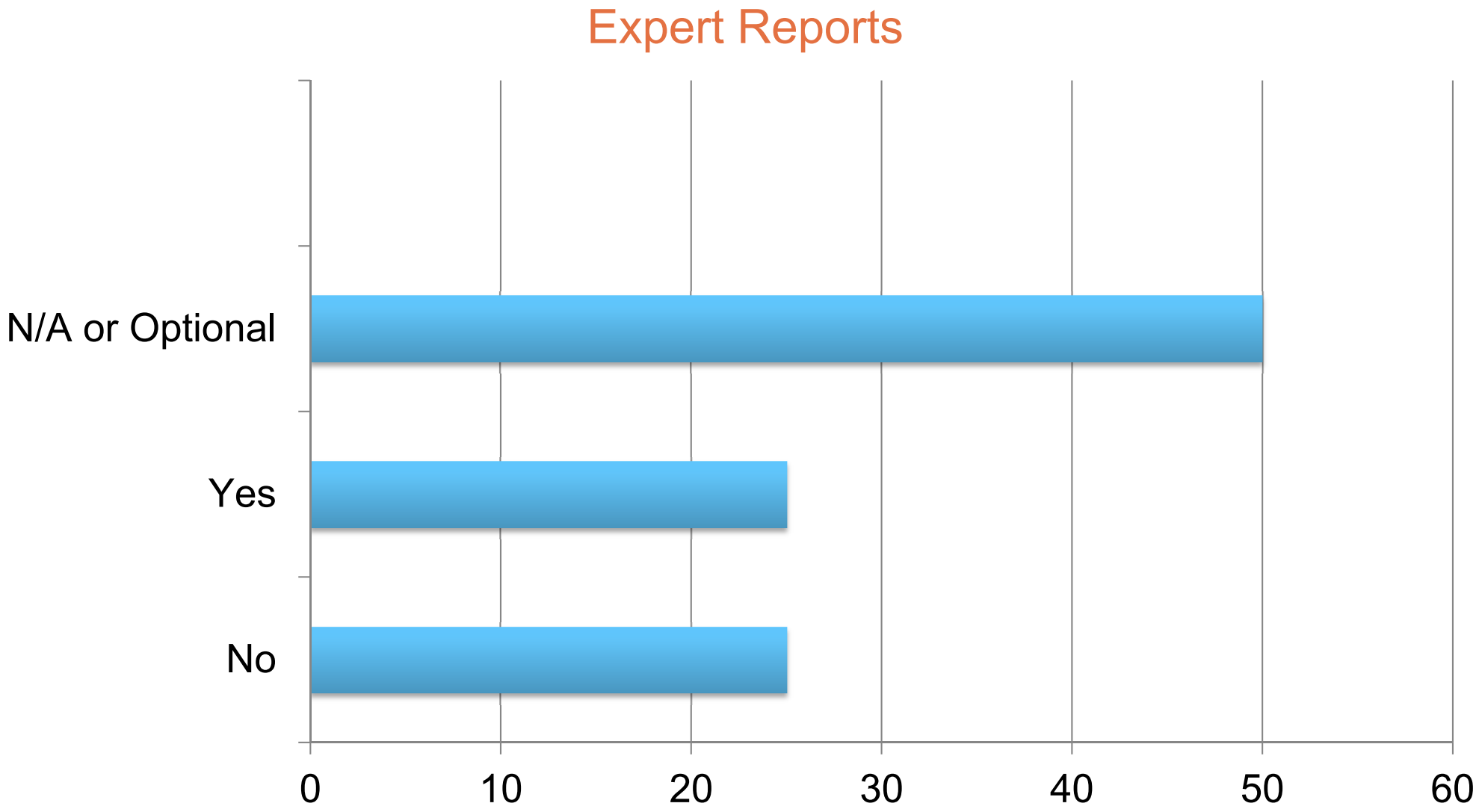
Do you expect to see data from challenge studies demonstrating protection?

Country	OIE	Ph EUR	9CFR
DRC	✔		
S. Africa	✔	✔	✔
Tanzania	✔	✔	✔
Zambia	✔	✔	✔
Zimbabwe	✔	✔	✔

Average time from receipt of a registration dossier to issuing a Marketing Authorisation

Country	Time in months	
DRC	3.5	
Malawi	<6	
Namibia	12	
S. Africa	30	
Swaziland	<3.0	
Tanzania	12	
Zambia	6 - 9	
Zimbabwe	19 – 28	Applicants have 60 days to respond to questions each time

Are independent Expert Reports required?



Is there a timetable laid down in the regulatory framework from receipt of dossier to issuing MA

Tanzania – Yes: 120 days for fast track; 240 days for normal track

Zimbabwe:

Acknowledgement of receipt of an application 1 month,

Screening 3 months,

Evaluation 3-6 months,

Regulatory decision 12 -18 months.

Applicants are given 60 days to respond to queries each time. The time-lines listed above do not include the applicant's time taken to respond to queries.

All other countries - No

Average time from receipt of a registration dossier for a veterinary vaccine to issuing a Marketing Authorisation

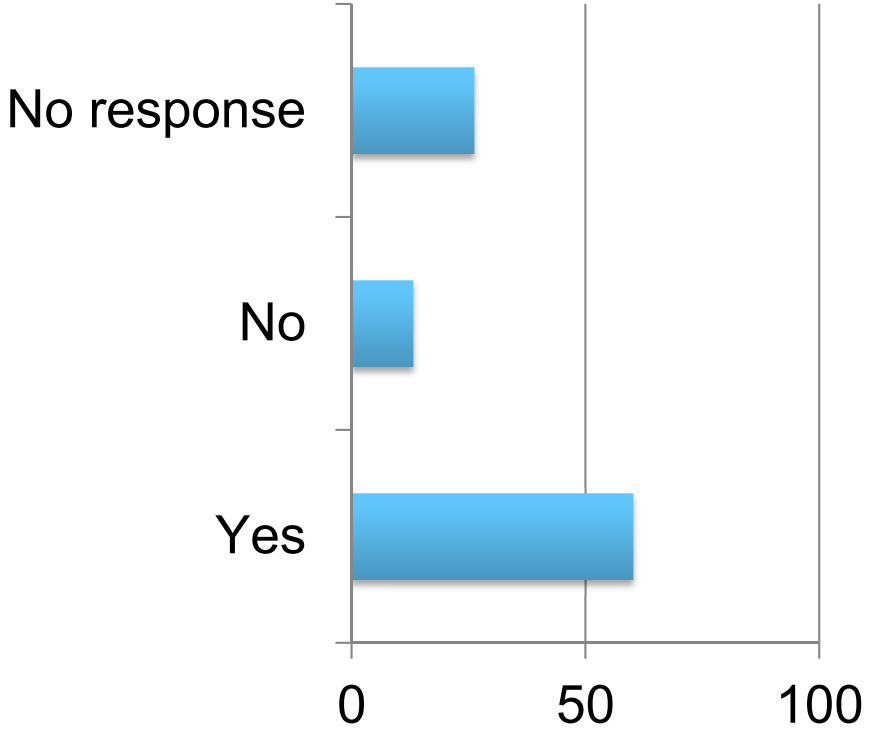
Country	Total time in months	Months for applicant to respond
DRC	3.3	
Malawi	6	
Namibia	12	
S.Africa	30	
Swaziland	3	
Tanzania	20	
Zambia	6-9	
Zimbabwe	30	2

Validity of MA before Renewal. Fees for MA/Renewal.

	MA Fee	1 year	3 years	5 years	Indefinite /retention fee	Renewal fee
DRC	$1000		✔			
Malawi	$1000				✔ $500	
Namibia	$220	✔				$31
S. Africa DAFF	R 8630		✔			R 4352
S. Africa MCC	R30,000			✔		
Tanzania	$2000			✔		
Zambia	$2,100					
Zimbabwe	$2000				✔ $300	

Good Manufacturing Practice (GMP)

1. Do you conduct GMP inspections?



2. Do you recognise GMP inspections carried out on veterinary vaccine manufacturers

a) In Africa b) in other countries?

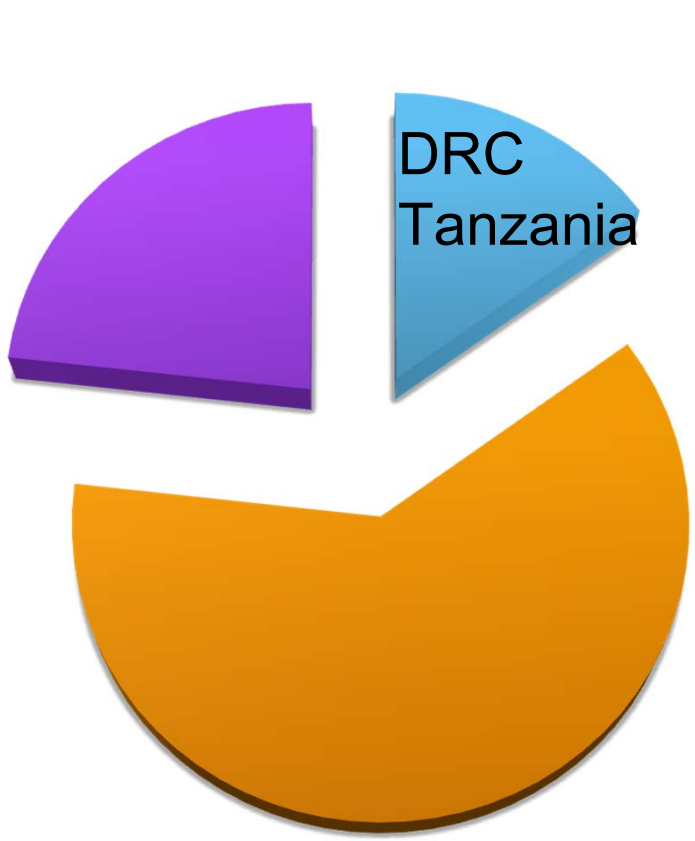
Namibia a) Yes; b) No

All other countries:

a) No b) No

Zimbabwe* does not inspect manufacturers in countries with Stringent Regulatory Authorities (SRAs), e.g. EU, Japan, USA and Australia

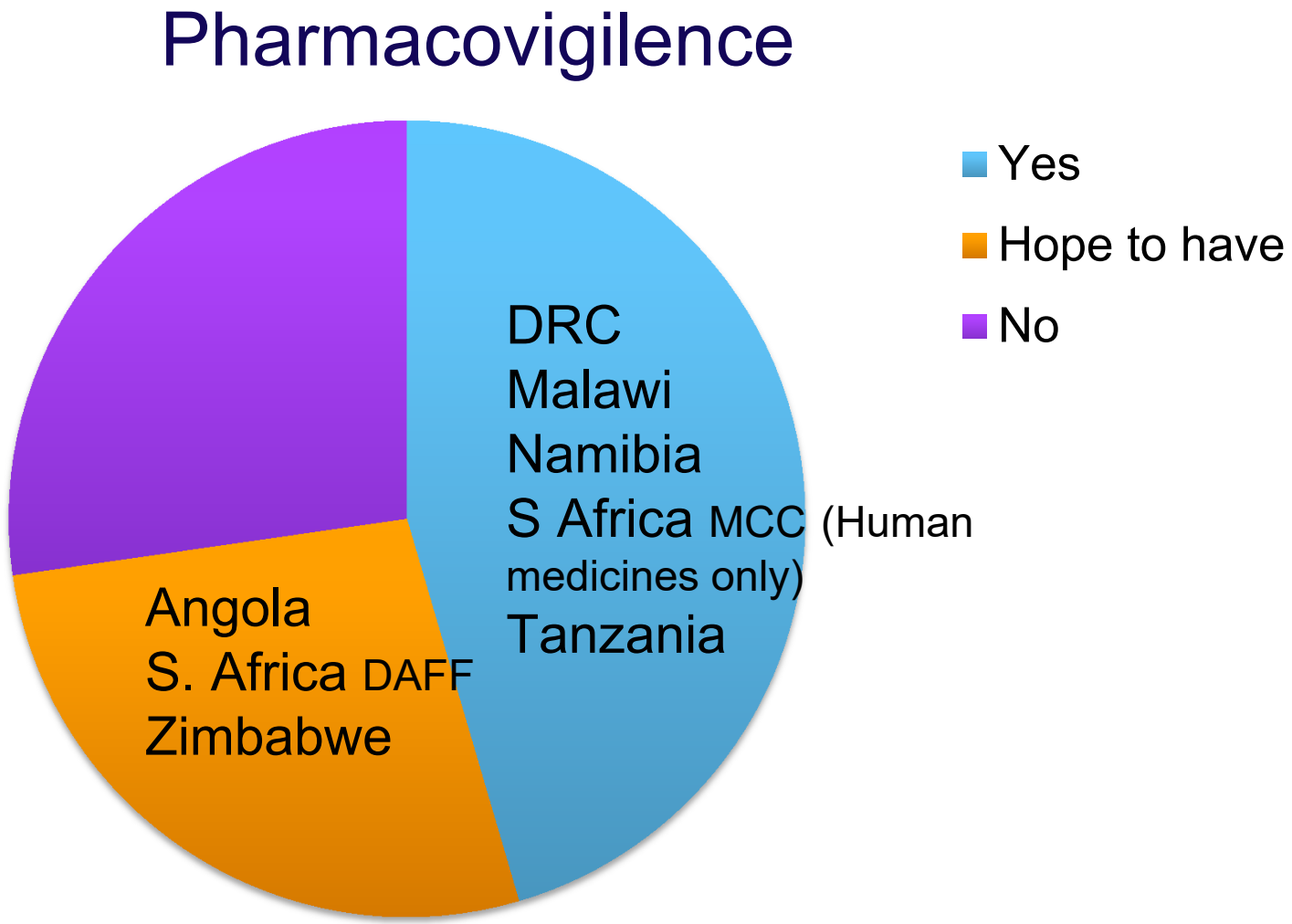
Does your country require batch testing of Veterinary Vaccines by AU-PANVAC?



Each batch, before placing on the market?

Batches taken from Distributors' fridges?

Do you have a post-marketing surveillance system in place?




Thank you for your attention