

Questionnaire on Exceptions and Limitations to Patent Rights

The answers to this questionnaire have been provided on behalf of:

Country: **REPUBLIC OF ZAMBIA**

Office: **PATENTS AND COMPANIES REGISTRATION AGENCY**.....

Person to be contacted:

Name: **ANTHONY BWEEMBYA**.....

Title: **REGISTRAR & CEO**

E-mail: **A.bwembya@pacra.org.zm**.....

Telephone: **+260 211 255151/ 255127**

Facsimile: **+260211 255426**

Section I: General

This section is intended to obtain general information on exceptions and limitations to patent rights that are provided under the applicable laws. For the purpose of this questionnaire, the term “applicable law” refers to relevant national and regional statutory law and, where applicable, case law.

The terms used in the questionnaire are drafted in a general way aiming at providing a broad understanding of each concept used, assuming that the exact wording of these exceptions and limitations might differ under the applicable laws. More detailed explanations of the various exceptions and limitations may be found in the following documents: SCP/13/3, SCP/15/3 and CDIP/5/4.

1. As background for the exceptions and limitations to patents investigated in this questionnaire, what is the legal standard used to determine whether an invention is patentable? If the standard for patentability includes provisions that vary according to the technology involved, please include examples of how the standard has been interpreted, if available. Please indicate the source of law (statutory and-or case law) by providing the relevant provisions and/or a brief summary of the relevant decisions.

The standard for patentability is provided for under Section 2 of the Patents Act, Cap. 400 of the Laws of Zambia: The section provides that “an invention must be new and useful art (whether, process or product) which is not obvious and capable of being used or applied in trade or industry”. Note that this may change once the amended draft patent bill is passed into law.

Correspondingly, please list exclusions from patentability that exist in your law. Furthermore, please provide the source of those exclusions from patentability if different from the source of the standard of patentability, and provide any available case law or interpretive decisions specific to the exclusions.¹

The Patents Act traces its origin or genesis from the United Kingdom, in particular, the British Patent Act, and therefore excludes from patentability the following: diagnostic, therapeutic and surgical methods for treatment of humans or animals,

¹ This question does not imply that the topic of exclusions from patentability is dealt with in this question exhaustively.

plants and animals other than micro-organisms, discoveries, scientific theory or mathematical method; a scheme, rule or method for performing a mental act, playing games or doing business or computer programme; literary and artistic work and presentation of information.

2. As background for the exceptions and limitations to patents investigated in this questionnaire, what exclusive rights are granted with a patent? Please provide the relevant provision in the statutory or case law. In addition, if publication of a patent application accords exclusive rights to the patent applicant, what are those rights?

Section 28 (4) provides that the effect of a patent shall be to grant to the patentee, subject to the provisions of this Act and the conditions of the patent, full power, sole privilege and authority by himself, his agents and licensees during the term of the patent to make, use, exercise and vend the invention within Zambia in such a manner as to him seems meet, so that he shall have and enjoy the whole profit and advantage accruing by reason of the invention during the term of the patent.

3. Which exceptions and limitations does the applicable law provide in respect to patent rights (please indicate the applicable exceptions/limitations):

- Private and/or non-commercial use;
- Experimental use and/or scientific research;
- Preparation of medicines;²
- X Prior use;
- X Use of articles on foreign vessels, aircrafts and land vehicles;
- X Acts for obtaining regulatory approval from authorities;
- Exhaustion of patent rights;
- X Compulsory licensing and/or government use;
- Exceptions and limitations related to farmers' and/or breeders' use of patented inventions.³

If the applicable law provides for any of the above-listed exceptions and limitations, please fill out those parts of Sections II to X that apply to you. If the applicable law does not contain all of the exceptions and limitations provided in Sections II to X, then you should respond only to the other parts of the questionnaire. If the applicable law includes other exceptions and limitations that are not listed above, please answer the questions under Section XI "Other Exceptions".

Where reference is made to case law, please indicate, if possible, the official source in which the case has been published (for example, the publication number, issue, title, URL, etc.).

² For example, extemporaneous preparation of prescribed medicines in pharmacies.

³ For example, in some countries where patent rights extend to propagated or multiplied material derived from patented biological material, certain uses by farmers of harvested plant material or of breeding livestock or other animal reproductive material under patent protection on his own farm do not constitute patent infringement. Similarly, in some countries, patent rights do not cover uses by breeders of patented biological material for the purpose of developing a new plant variety (see paragraphs 133 to 137 of document SCP/13/3).

Section II: Private and/or non-commercial use

4. If the exception is contained in statutory law, please provide the relevant provision(s):

5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

6. (a) What are the public policy objectives for providing the exception?

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

7. If the applicable law defines the concepts “non-commercial”, “commercial” and/or “private”, please provide those definitions by citing legal provision(s) and/or decision(s):

“Commercial scale” is not defined in the current Patent Act, Cap. 400 of the Laws of Zambia and, therefore, the phrase should be given the ordinary grammatical meaning.

8. If there are any other criteria provided in the applicable law to be applied in determining the scope of the exception, please provide those criteria by citing legal provision(s) and/or decision(s):

N/A

9. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

N/A

10. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

N/A

Section III: Experimental use and/or scientific research ⁴

11. If the exception is contained in statutory law, please provide the relevant provision(s):

This is not provided for in the Patent Act

⁴ Exceptions and limitations on acts for obtaining regulatory approval are dealt with in Section VII of the questionnaire.

12. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

13. (a) What are the public policy objectives for providing the exception?

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

14. Does the applicable law make a distinction concerning the nature of the organization conducting the experimentation or research (for example, whether the organization is commercial or a not-for-profit entity)? Please explain:

N/A

15. If the applicable law defines the concepts “experimental use” and/or “scientific research”, please provide those definitions by citing legal provision(s) and/or decision(s):

N/A

16. If the purpose of experimentation and/or research is relevant to the determination of the scope of the exception, please indicate what that purpose is:

Experimentation and/or research should aim to:

- determine how the patented invention works
- determine the scope of the patented invention
- determine the validity of the claims
- seek an improvement to the patented invention
- invent around the patented invention
- other, please specify: **N/A**

17. If any of the following criteria is relevant to the determination of the scope of the exception, please indicate:

- Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)
- Research and/or experimentation must be conducted with or using the patented invention (“research with”)
- Both of the above

Please explain by citing legal provision(s) and/or decision(s):

N/A

18. If the commercial intention of the experimentation and/or research is relevant to the determination of the scope of the exception, please indicate whether the exception covers activities relating to:
- A non-commercial purpose
 - A commercial purpose
 - Both of the above
 - The commercial intention of the experimentation and/or research is not relevant

19. If the applicable law makes a distinction between “commercial” and “non-commercial” purpose, please explain those terms by providing their definitions, and, if appropriate, examples. Please cite legal provision(s) and/or decision(s):

N/A

20. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

N/A

21. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

N/A

22. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

N/A

Section IV: Preparation of medicines

23. If the exception is contained in statutory law, please provide the relevant provision(s):

This is not provided for in the Patent Act, but in other relevant law.

24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

25. (a) What are the public policy objectives for providing the exception? Please explain:

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

26. Who is entitled to use the exception (for example, pharmacists, doctors, physicians, others)? Please describe:

N/A

27. Does the applicable law provide for any limitations on the amount of medicines that can be prepared under the exception?

- Yes
- X** No

If yes, please explain your answer by citing the relevant provision(s) and/or decision(s):

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.....
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28. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

N/A

29. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

N/A

30. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

N/A

Section V: Prior use

31. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 53 (4) of the Act provides that : "exception for acts of non-infringement where the third party had started making the product before the date of filing the patent application for the invention embodied in the product"; and

Section 8 of the Act (convention applications) gives elaborate information regarding prior use.

NB: The above exceptions only apply to the inventor/applicant/ predecessor in title and not to third parties. Any use thereof before filing the application in the Patent Office would destroy the novelty requirement

32. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

No case law

33. (a) What are the public policy objectives for providing the exception? Please explain:

Policy space for effective implementation of the Act

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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34. How does the applicable law define the scope of “use”? Does the applicable law provide for any quantitative or qualitative limitations on the application of the “use” by prior user? Please explain your answer by citing legal provision(s) and/or decision(s):

N/A

35. Does the applicable law provide for a remuneration to be paid to the patentee for the exercise of the exception? Please explain:

NO

36. According to the applicable law, can a prior user license or assign his prior user’s right to a third party?

- Yes
- No

37. In case of affirmative answer to question 36, does the applicable law establish conditions on such licensing or assignment for the continued application of the prior use exception?

- Yes
- No

If yes, please explain what those conditions are:

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38. Does this exception apply in situations where a third party has been using the patented invention or has made serious preparations for such use after the invalidation or refusal of the patent, but before the restoration or grant of the patent?

- Yes
- No

If yes, please explain the conditions under which such use can continue to apply:

Section 34 (a) provides that:

“In every order restoring a lapsed patent made under section thirty-three, there shall be inserted for the protection of persons who may have availed themselves of the subject-matter of the patent after a lapse of a period of three months from the date on which the renewal fee was due, the following provisions, namely, that the patentee shall not commence or prosecute any action or other proceedings or recover damages:

(a) in respect of any infringement of the patent which has taken place after the lapse of the said period and before the date of the order”.

39. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

N/A

40. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The current law legal framework is not adequate and therefore the draft amendment has broadened the exceptions and limitations

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41. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

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Section VI: Use of articles on foreign vessels, aircrafts and land vehicles

42. If the exception is contained in statutory law, please provide the relevant provision(s):

Section 9 of the Act provides that:

9. **(1) where a vessel or aircraft registered in a convention country or a land vehicle owned by a person ordinarily resident in such a country comes into Zambia temporarily or accidentally only, the rights conferred by a patent for an invention shall not be deemed to be infringed by the use of the invention-**

(a) in the body of the vessel or in the machinery, tackle, apparatus or other accessories thereof, so far as the invention is used on board the vessel and for its actual needs only; or

(b) in the construction or working of the aircraft or land vehicle or of the accessories thereof; as the case may be.

43. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

44. (a) What are the public policy objectives for providing the exception? Please explain:

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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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45. The exception applies in relation to:
- X Vessels
 - X Aircrafts
 - X Land Vehicles
 - Spacecraft
46. In determining the scope of the exception, does the applicable law apply such terms as "temporarily" and/or "accidentally" or any other equivalent term in relation to the entry of foreign transportation means into the national territory? Please provide the definitions of those terms by citing legal provision(s) and/or decision(s):
Yes, the applicable law applies such terms as 'temporarily and/or accidentally', however, there are no definitions for them in the Act.
47. Does the applicable law provide for any restrictions on the use of the patented product on the body of the foreign vessels, aircrafts, land vehicles and spacecraft for the exception to apply (for example, the devices to be used exclusively for the needs of the vessel, aircraft, land vehicle and/or spacecraft)? Please explain your answer by citing legal provision(s) and/or decision(s):
- Yes, if invention is used:-**
(a) in the body of the vessel or in the machinery, tackle, apparatus or other accessories thereof, so far as the invention is used on board the vessel and for its actual needs only; or
(b) in the construction or working of the aircraft or land vehicle or of the accessories thereof;
- (As cited under Section 9 of the Act above)**
48. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):
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49. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
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50. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:
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Section VII: Acts for obtaining regulatory approval from authorities

51. If the exception is contained in statutory law, please provide the relevant provision(s):
- The Patents Act does not provide for this exception and therefore this does not fall under the mandate of the Patent Office. However, the Medicines and Allied Substances Act No. 3 of 2013 provide for regulatory approval**

52. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

53. (a) What are the public policy objectives for providing the exception? Please explain:

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

54. Who is entitled to use the exception? Please explain:

N/A

55. The exception covers the regulatory approval of:

- any products
- certain products. Please describe which products: **N/A**

56. Please indicate which acts are allowed in relation to the patented invention under the exception?

- Making
- Using
- Selling
- Offering for sale
- Import
- Export
- Other. Please specify: **N/A**

57. If the applicable law provides for other criteria to be applied in determining the scope of the exception, please describe those criteria. Please illustrate your answer by citing legal provision(s) and/or decision(s):

N/A

58. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

N/A

59. Which challenges, if any, have been encountered in relation to the practical implementation of the exception in your country? Please explain:

N/A

Section VIII: Exhaustion of patent rights

60. Please indicate what type of exhaustion doctrine is applicable in your country in relation to patents:

- National
- Regional
- International
- Uncertain, please explain.....

If the exception is contained in statutory law, please provide the relevant provision(s):

The Patents Act does not provide for this exception. However, the amended draft bill has provided for this exception

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If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

62. Does the applicable law permit the patentee to introduce restrictions on importation or other distribution of the patented product by means of express notice on the product that can override the exhaustion doctrine adopted in the country?

- Yes
- No
- Uncertain

Please explain your answer by citing legal provision(s) and/or decision(s):

N/A

63. Has the applicable exhaustion regime been considered adequate to meet the public policy objectives in your country? Please explain:

N/A

64. Which challenges, if any, have been encountered in relation to the practical implementation of the applicable exhaustion regime in your country? Please explain:

N/A

Section IX: Compulsory licenses and/or government use

Compulsory licenses

65. If the exception is contained in statutory law, please provide the relevant provision(s):

This is provided for under section 37 of the Patents Act

66. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

67. What grounds for the grant of a compulsory license does the applicable law provide in respect to patents (please indicate the applicable grounds):

- X** Non-working or insufficient working of the patented invention
- X** Refusal to grant licenses on reasonable terms
- X** Anti-competitive practices and/or unfair competition
- X** Public health
- X** National security
- X** National emergency and/or extreme urgency
- Dependent patents
- Other, please specify:

68. (a) What are the public policy objectives for providing compulsory licenses in your country? Please explain:

To protect national/ public interest

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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69. If the applicable law provides for the grant of compulsory licenses on the ground of “non-working” or “insufficient working”, please provide the definitions of those terms by citing legal provision(s) and/or decision(s):

Under Section 37 (6)(a), the terms “non-working” or “insufficient working” have not been defined in the Act . However, the rights in a patent shall be deemed to be abused if the patented invention, being an invention capable of being worked in Zambia, is not being worked therein on a commercial scale and there is no satisfactory reason for such non-working.

70. Does the importation of a patented product or a product manufactured by a patented process constitute “working” of the patent? Please explain your answer by citing legal provision(s) and/or decision(s):

No, section (37)(6)(b) reads:

Any person may apply to the Registrar for the compulsory licence if the working of the invention within Zambia on a commercial scale is being prevented or hindered by the importation of the patented article by the patentee or persons claiming under him, or by persons directly or indirectly purchasing from him or by persons against whom the patentee is not taking or has not taken proceedings for infringement;

71. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide for a certain time period to be respected before a compulsory license can be requested?
- X Yes
 No

If yes, what is the time period? **Section 37(1) provides that “subject to the provisions of subsection (14), any person interested who can show that he has been unable to obtain a licence under a patent on reasonable terms may, after the expiration of a period of three years subsequent to the date on which that patent was sealed or four years subsequent to the date on which the application in respect thereof was lodged, whichever period last expires, apply to the Registrar in the prescribed manner for a compulsory licence on the ground that the reasonable requirements of the public with respect to the invention in question have not been or will not be satisfied”.**

72. In case of the grant of compulsory licenses on the grounds of non-working or insufficient working, does the applicable law provide that a compulsory license shall be refused if the patentee justifies his inaction by legitimate reasons?
- X Yes
 No

If yes, what are “legitimate reasons”? **Section 37(6) proviso provides that: The application may be refused if the he High Court is of the opinion that the time which has elapsed since the sealing of the patent has by reason of the nature of the invention or for any other reason been insufficient to enable the invention to be worked within Zambia on a commercial scale. The High Court may make an order adjourning the hearing of the application for such period as will in its opinion be sufficient for that purpose.**

73. If the applicable law provides for the grant of compulsory licenses on the ground of refusal by the patentee to grant licenses on “reasonable terms and conditions” and within a “reasonable period of time”, please provide the definitions given to those terms by citing legal provision(s) and/or decision(s):

The phrases “reasonable terms and conditions” and “reasonable time” have been used in relation to compulsory licences under section 37(1) and (6) of the Act. However, these phrases are not defined by the Act.

74. If the applicable law provides for the grant of compulsory licenses on the ground of anti-competitive practices, please indicate which anti-competitive practices relating to patents may lead to the grant of compulsory licenses by citing legal provision(s) and/or decision(s):

**Section 37(6)(f) provides that:
Any person may apply to the Registrar for the compulsory licence if any condition which under the provisions of section forty-nine is null and void as being in restraint of trade and contrary to public policy, has been inserted in any contract made in relation to the sale or lease of or any licence to use or work any article or process protected by the patent**

75. If the applicable law provides for the grant of compulsory licenses on the ground of dependent patents, please indicate the conditions that dependent patents must meet for a compulsory license to be granted:

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76. Does the applicable law provide a general policy to be followed in relation to the remuneration to be paid by the beneficiary of the compulsory license to the patentee? Please explain:
Yes, section 37 (11) provides that:
The order directing the grant of an exclusive licence under this section shall operate to divest the patentee of any right which he may have as patentee to work or use the invention, and to revoke all existing licences, unless otherwise provided in the order, and may, if considered fair and equitable by the High Court, be made subject to the condition that the licensee shall give proper compensation to be fixed by the High Court for any money or labour expended by the patentee or any existing licensee in developing or working the invention.
77. If the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:
Section 41 (1) and (2): The Act provides for the phrase ‘period of emergency’ and not ‘circumstances of extreme urgency’.
Section 41(1) provides that: “For the purposes of this section, the expression “period of emergency” means any period beginning on such date as may be declared by the Minister by statutory notice to be the commencement, and ending on such date as may be so declared to be the termination, of a period of emergency, .e.g. a national emergency was declared in 2004 in an effort to respond to HIV and Aids pandemic”.
78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:
Once in 2004 on the invention relating to pharmaceutical products
79. Is the applicable legal framework for the issuance of compulsory licenses considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:
The legal framework is not adequate, e.g. the circumstances for issuance of compulsory licence are narrow and therefore these have been enlarged in the amended draft law to be enacted.
80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:
Insufficiency or no manufacturing capacity on the part of the local industries to produce generic pharmaceutical products when the compulsory licence is issued by government

Government use

81. If the exception is contained in statutory law, please provide the relevant provision(s):
Section 40 (1) provides that:
“ Notwithstanding anything in this Act, any Government department or any person authorised in writing by the Minister may make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the State in accordance with the provisions of this section”.

82. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

N/A

83. What grounds for the grant of government use does the applicable law provide in respect to patents (please indicate the applicable grounds):

- X** Non-working or insufficient working of the patented invention
- X** Refusal to grant licenses on reasonable terms
- Anti-competitive practices and/or unfair competition
- X** Public health
- X** National security
- X** National emergency and/or extreme urgency
- Dependent patents
- Other, please specify:

84. (a) What are the public policy objectives for providing government use in your country?

To protect public/nation interest

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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85. If the applicable law provides for the grant of government use on the ground of “national emergency” or “circumstances of extreme urgency”, please explain how the applicable law defines those two concepts and their scope of application, and provide examples:
The phrases are not defined in the Act. However, this may be inferred from what is provided under section 41(2) which reads:

.....
“During any period of emergency the powers exercisable in relation to an invention by a Government department or a person authorised by the Minister under section forty, shall include power to make, use, exercise and vend the invention for any purpose which appears to the Minister necessary or expedient-

- (a) for the efficient prosecution of any war in which the Republic may be engaged;**
- (b) for the maintenance of supplies and services essential to the life of the community;**
- (c) for securing a sufficiency of supplies and services essential to the well-being of the community;**
- (d) for promoting the productivity of industry, commerce and agriculture;**
- (e) for fostering and directing exports and reducing imports or imports of any classes, from all or any countries and for redressing the balance of trade;**
- (f) generally for ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community; or**
- (g) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any part of Her Britannic Majesty's dominions or any foreign countries that are in grave distress as the result of war; and any reference in that section or in section forty-two to the services of the State shall be construed as including a reference to the purposes aforesaid.**

86. Please indicate how many times and in which technological areas government use has been issued in your country:

Once in 2004 on the invention relating to pharmaceutical products

87. Is the applicable legal framework for the issuance of government use considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

The legal framework is not adequate in the sense that the circumstances for issuance of government use are narrow. To cure the deficiency, the circumstances under which the licence may be issued have been widened in the amended draft law to be enacted by including exhaustion of patent rights (based on international principle).

88. Which challenges, if any, have been encountered in relation to the use of the government use mechanism in your country? Please explain:

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Section X: Exceptions and limitations related to farmers' and/or breeders' use of patented inventions

Farmers' use of patented inventions

89. If the exception is contained in statutory law, please provide the relevant provision(s):
This is not provided for in the Patent Act. However, the amended draft Patent bill contains this provision.

90. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

N/A

91. (a) What are the public policy objectives for providing the exception related to farmers' use of patented inventions? Please explain:

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

92. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

N/A

93. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

N/A

94. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to farmers' use of patented inventions in your country? Please explain:

N/A

Breeders' use of patented inventions

95. If the exception is contained in statutory law, please provide the relevant provision(s):
This is not provided for in the Patent Act. However, this provision may be found in the relevant Act, the Plant Breeders Rights Act No. 18 of 2007, which law is administered by Ministry of Agriculture.

96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

N/A

97. (a) What are the public policy objectives for providing the exception related to breeders' use of patented inventions? Please explain:

N/A

(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

98. Please explain the scope of the exception by citing legal provision(s) and/or decision(s) (for example, interpretation(s) of statutory provision(s) on activities allowed by users of the exception, limitations on their use, as well as other criteria, if any, applied in the determination of the scope of the exception):

N/A

99. Is the applicable legal framework of the exception considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen)? Please explain:

N/A

100. Which challenges, if any, have been encountered in relation to the practical implementation of the exception related to breeders' use of patented inventions in your country? Please explain:

N/A

Section XI: Other Exceptions and Limitations

101. Please list any other exceptions and limitations that your applicable patent law provides:

N/A

102. In relation to each exception and limitation, please indicate:

(i) the source of law (statutory law and/or the case law) by providing the relevant provision(s) and/or a brief summary of the relevant decision(s):

N/A

(ii) the public policy objectives of each exception and limitation. Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

N/A

(iii) the entitlement and the scope of the exception and limitation by citing legal provision(s) and/or decision(s):

N/A

In addition, in relation to each exception and limitation, please explain:

(i) whether its applicable legal framework is considered adequate to meet the objectives sought (for example, are there any amendments to the law foreseen?):

N/A

(ii) if there have been any challenges encountered in the practical implementation of the exception in your country:

N/A

103. If other mechanisms for the limitation of patent rights external to the patent system exist in your country (for example, competition law), please list and explain such mechanisms:

The country has a Competition and Consumer Protection Act No. 24 of 2010, which law is administered by a different Institution.

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[End of Questionnaire]