

Questionnaire on Exceptions and Limitations to Patent Rights

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

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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.

Section 3(9) of the Patents Act as read with section
Section 82 Subsection 3(9) of the Schedule to the Patents Act 26:03
as read with Section 13 of the Patents Act 26:03

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

(a) diagnostic, therapeutic or surgical methods for treatment of human beings
or animals; (b) plants and animals, other than micro organisms; (c) essentially
biological processes for the production of plants or animals other than microbiological
processes (SECTION 2A of PATENTS ACT 26:03)

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

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?

In terms of section 24 of the Patents Act 20:03, the granting of a patent confers positive rights to the patent holder to have full power, sole privilege and authority to make, use, offer for sale products of the invention. (Provision brought into force by Act number 9 of 2002)

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
- Prior use;
- Use of articles on foreign vessels, aircrafts and land vehicles;
- Acts for obtaining regulatory approval from authorities;
- Exhaustion of patent rights;
- 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.).

Section II: Private and/or non-commercial use

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

SECTION 31(6)(a) of the Patents Act (20:03)

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).

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

There is no decided case as of this date.

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

To allow users to make, construct, or use patented products for private or non-commercial use.

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

No available information

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):

No definitions provided for these concepts

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):

Legislation is not clear on the scope of the exception.

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:

The Act is not very clear on this aspect

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

No challenges have been encountered to date.

Section III: Experimental use and/or scientific research⁴

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

SECTION 24B of the Patent Act 26:03

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

There is no decided case as of this date.

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

To allow third parties access to test batches of patent products on patents about to expire for further research purposes.

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

Relevant information from the Parliamentary debates leading up to the adoption of this provision could not be located.

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:

~~No distinction is~~ No distinction is made.

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):

No definition is provided

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

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

- seek an improvement to the patented invention
- invent around the patented invention
- other, please specify: Act is silent on this aspect.

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):

The Act is silent on this aspect.
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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):

No definitions are provided.
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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):

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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:

It's not adequate
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22. 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 IV: Preparation of medicines

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

This exception is not covered in the Act.
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24. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

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

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

- Yes
- No

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

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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):

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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:

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30. 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 V: Prior use

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

This exception is not covered in the Act.

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

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33. (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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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):

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

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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:

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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):

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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:

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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 81 of the Patents Act (26:03)

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

No case law has been decided on this exception.

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

Comply with international obligations (Section See Part XI of the Patents Act 26:03)

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

No data on the subject matter could be ascertained.

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45. The exception applies in relation to:

- Vessels
- Aircrafts
- 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):

The law does apply the terms "temporarily" and "accidentally" but does not give or provide definitions of the said terms.

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 the law provides for restrictions under Sections 81(1)(a)-(b) of the Patents Act. The first section restricts usage of a patented product to on board usage and only for actual needs only and secondly, restriction may be limited to construction or working of aircraft or land vehicle in question.

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:

N/A
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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:

N/A
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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):

This exception is not covered in the Patent legislation

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

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

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55. The exception covers the regulatory approval of:

- any products
- certain products. Please describe which products:

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:.....

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):

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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:

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59. 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 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.....

..... These are not explicitly mentioned in the Act.

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

Section 24A of the Patents Act 26:03
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If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:

There is no case law.
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61. (a) What are the public policy objectives for adopting the exhaustion regime specified above? Please explain:

It is a cost effective measure designed for the benefit of the consumer of patent products.
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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:

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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):

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

No, it is not adequate. This is why the government had to put in place other complementary exceptions, for example compulsory licensing regime.

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

~~There~~ Challenges have been encountered with regards to counterfeit pharmaceutical products that are being imported into the country.

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):

Sections 30A to 35 of the Patents Act 26:03

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

There is no case law.

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

- Non-working or insufficient working of the patented invention
- Refusal to grant licenses on reasonable terms
- Anti-competitive practices and/or unfair competition
- Public health

- National security
- National emergency and/or extreme urgency
- Dependent patents
- Other, please specify: Section 31(6)(f) of the Patents Act 26:03

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

The public policy objectives are contained in Sections 30A to 35 of the Patents Act 26:03.

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

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):

Section 31(6)(a) of the Patents Act 26:03: If the patented invention, being an invention capable of being worked in Zimbabwe, is not being worked therein on a commercial ~~scale~~ 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):

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?

- Yes
- No

If yes, what is the time period? Within six months - Section 31(1) of Patents Act

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?

- Yes
- No

If yes, what are "legitimate reasons"? They are not explicit in the Act.

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 law does not define these terms.

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):

The act does not outline the list of anti-competitive practices.

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:

See Section 30A(a), (b), (c)

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:

Section 32(1)(a) 32(1a)(b) - provides that a reasonable royalty compatible with the successful working of the invention in Zimbabwe on a commercial scale and at a profit, should be provided to the patentee.

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:

The Act does not define the terms, but it lists the conditions under which the licenses are granted - See Section 35 of the Act.

78. Please indicate how many times and in which technological areas compulsory licenses have been issued in your country:

Once in the field of medicine

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:

Its not adequate because the country is yet to
ratify the protocol ammending TRIPS Agreement.

80. Which challenges, if any, have been encountered in relation to the use of the compulsory licensing system provisions in your country? Please explain:

No available information as of this date.

Government use

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

Section ³⁵~~X~~ of the Patents Act

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

There is no case law.

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

- Non-working or insufficient working of the patented invention
- Refusal to grant licenses on reasonable terms
- Anti-competitive practices and/or unfair competition
- Public health
- National security
- National emergency and/or extreme urgency
- Dependent patents
- Other, please specify: See Section 35(f) 35(1)(f)

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

For the well being of the population as well as for
national security purposes.

- (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 Act does not provide for definitions of these terms

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

Nil

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:

It is not adequate because the legislation does not provide for government use for research purposes

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

None

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 exception is not covered in the Act.

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

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

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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:

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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:

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Breeders' use of patented inventions

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

This exception is not covered in the Act.
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96. If the exception is provided through case law, please cite the relevant decision(s) and provide a brief summary of such decision(s):

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

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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:

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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:

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Section XI: Other Exceptions and Limitations

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

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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):

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- (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:

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

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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?):

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

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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:

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[End of Questionnaire]