

## **Questionnaire on Exceptions and Limitations to Patent Rights**

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

Country: Bhutan  
Office: Intellectual Property Division, Ministry of Economic Affairs, Thimphu

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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.

**Industrial Property Act of the Kingdom of Bhutan, 2001, Section 5 on Patentable Invention states that;**

**(1) An invention is patentable if it is new, involves an inventive step and is industrially applicable.**

**(2) (a) an invention is new if it is not anticipated by prior art.**

**(b) Prior art shall consist of everything disclosed to the public, anywhere in the world, by publication in tangible form or by oral disclosure, by use or in any other way, prior to filing or, where appropriate, the priority date, of the application claiming the invention.**

**(c) for the purposes of paragraph (b), disclosure to the public of the invention shall not be taken into consideration if it occurred within twelve months preceding the filing date or, where applicable, the priority date of the application, and if it was by reason or in consequence of acts committed by the applicant or his predecessor in title or of an abuse committed by a third party with regard to the applicant or his predecessor in title.**

- (3) An invention shall be considered as involving an inventive step if, having regard to the prior art relevant to the application claiming the invention and as defined in subsection (2) (b), it would not have been obvious to a person having ordinary skill in the art.**
- (4) An invention shall be considered industrially applicable if it can be made or used in any kind of industry. "Industry" shall be understood in its broadest sense; it shall cover, in particular, handicraft, agriculture, fishery and services.**
- (5) Inventions, the commercial exploitation of which would be contrary to public order or morality, shall not be patentable.**

**Since the patent registry is not in place, the interpretation of standards of patentability conditions for different technology did not arise.**

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.<sup>1</sup>

**Industrial Property Act of Kingdom of Bhutan, 2001, Section 4 on Definitions states that;**

- (3) The following, even if they inventions within the meaning subsection (2), shall be excluded from patent protection:**
  - (i) discoveries, scientific theories and mathematical methods;**
  - (ii) schemes, rules or methods for doing business, performing purely mental acts or playing games;**
  - (iii) methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practiced on the human or animal body; this provision shall not apply to products for use in any of those methods.**

**There is no other source for such exclusion.**

- 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?

**Industrial Property Act of the Kingdom of Bhutan, 2001, Section 13, Rights Conferred by Patent states that;**

**13. (1) The exploitation of the patented invention in Bhutan by persons other than the owner of the patent shall required the latter's agreement.**

**(2) For the purposes of this Acts, "exploitation" of a patented invention means any of the following acts:**

**a) when the patent has been granted in respect of a product:**

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

- (i) **making, using, offering for sale, selling or importing for these purposes that product;**
  - (ii) **stocking such product for the purposes of offering for sale, selling or using;**
- b) when the patent has been granted in respect of a process:**
- (i) **using the process;**
  - (ii) **doing any of the acts referred to in paragraph (a) in respect of a product obtained directly by means of the process.**

**The second part of the question is not applicable as the Industrial Property Act of the Kingdom of Bhutan has publication only after the grant.**

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;<sup>2</sup>  
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.<sup>3</sup>

**The following exceptions and limitations are provided in our law in respect to patent rights:**

**Experimental use and/or scientific research;**  
**Prior use**  
**Use of articles on foreign vessels, aircrafts and land vehicles;**  
**Exhaustion of patent rights;**  
**Compulsory licensing and/or government use;**

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".

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<sup>2</sup> For example, extemporaneous preparation of prescribed medicines in pharmacies.

<sup>3</sup> 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).

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):  
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5. If the exception is provided through case law, please cite the relevant decision(s) and provide its(their) brief summary:  
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6. (a) What are the public policy objectives for providing the exception?  
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(b) Where possible, please explain with references to the legislative history, parliamentary debates and judicial decisions:  
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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):  
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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):  
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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:

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10. 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 III: Experimental use and/or scientific research <sup>4</sup>**

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

**Section 13 (4) of the Industrial Property Act of the Kingdom of Bhutan states;**

**(4) (a) The rights under the patent shall not extend:**

**(iii) to acts done only for experimental purposes relating to a patented invention; or**

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

**NA**

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

**Promotion of R&D.**

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

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

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, the applicable law does not make a distinction concerning the nature of the organization conducting the experimentation or research.**

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):

**The applicable law does not define the concepts “experimental use” and/or “scientific research.”**

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: .....

**Not specified in the applicable law.**

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

**Research and/or experimentation must be conducted on or relating to the patented invention (“research on”)**

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

**Section 13 (4) of the Industrial Property Act of the Kingdom of Bhutan states;**

**(4) (a) The rights under the patent shall not extend:**

**(iii) to acts done only for experimental purposes relating to a patented invention;**

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

**Not specified in the applicable law.**

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):

**Not specified in the applicable law.**

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):

**Our law does not provide for other criteria to be applied in determining the scope of the exception.**

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:

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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:

**Since we don't have a Patent Registration System, most of the exceptions have not been implemented in our country.**

**Section IV: Preparation of medicines**

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

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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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.....  
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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):

**Section 13 (4) of the Industrial Property Act of the Kingdom of Bhutan states;**

**(4) (a) The rights under the patent shall not extend:**

**(iv) to acts performed by any person who in good faith, before the filing or, where priority is claimed, the priority date of the application on which the patent is granted, was using the invention or was making effective and serious preparations for such use in Bhutan.**

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

**NA**

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):

**No, the applicable law does not define the scope of "use" and does not provide for any quantitative or qualitative limitations on the application of the "use" by prior user.**

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

**No, the applicable law does not provide for a remuneration to be paid to the patentee for the exercise of the exception.**

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

Yes  
No

**Yes**

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

**No**

**Section 13(4)(b) of the Industrial Property Act of the Kingdom of Bhutan provides that “The right of prior user referred to in paragraph (a)(iv) may be transferred or devolve only together with the enterprise or business, or with that part of the enterprise or business, in which the use or preparations for use have been made”.**

**The above provision in the applicable law does not address the conditions under which the transfer or licensing of the prior user’s right is allowed. This has not been addressed in other provisions of the applicable law and its rules.**

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

**It has not been specified in our applicable law.**

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

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.....  
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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 13 (4) of the Industrial Property Act of the Kingdom of Bhutan states;**

**(4) (a) The rights under the patent shall not extend:**

**(ii) to the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Bhutan;**

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

**NA**

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:

- Vessels
- Aircrafts
- Land Vehicles
- Spacecraft

**The exception applies in relation to:**

- Vessels**
- Aircrafts**
- Land Vehicles**

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 applicable law does not provide any definition of the terms “temporarily” and “accidentally”.**

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):

**No, the applicable law does not 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)**

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):

**NA**

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):

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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.

**National**

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

**Section 13 (4) of the Industrial Property Act of the Kingdom of Bhutan states;**

**(4) (a) The rights under the patent shall not extend:**

**(i) to acts in respect of articles which have been put on the market in Bhutan by the owner of the patent or with his consent;**

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

**NA**

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

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.....  
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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

**No, the applicable law does not 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.**

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

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

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

**Patent Registration System has not started yet. Therefore, the exceptions available in our law have not been implemented.**

***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):

**Section 15, Industrial Property Act of the Kingdom of Bhutan, 2001:  
Exploitation by Government or Person thereby Authorized**

**15. (1) Where**

**(i) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or**

**(ii) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice:**

**the Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention. The exploitation of the invention shall be limited to the purpose for which it was authorized and shall be subjected to the payment to the said owner of an adequate remuneration therefor, taking into account the economic value of the invention, as determined in the said decision, and, where a decision has been taken under paragraph (ii), the need to correct anti-competitive practices.**

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

**NA**

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:

**Compulsory licenses can be issued on the following grounds:**

1. **Anti-competitive practices and/or unfair competition.**
2. **Public interest**
3. **National emergency and/or extreme urgency including government use**
4. **Refusal to grant licenses on reasonable terms**

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

**Not specified in the applicable law.**

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):

**Not specified in the applicable law.**

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? .....

**NA**



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"? .....

**NA**

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):

**Section 15, Industrial Property Act of the Kingdom of Bhutan, 2001:  
Exploitation by Government or Person thereby Authorized**

**15. (6) A request for the Minister's authorization shall be accompanied by evidence that the owner of the patent has received, from the person seeking the authorization, a request for a contractual license, but that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time.**

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 15, Industrial Property Act of the Kingdom of Bhutan, 2001:  
Exploitation by Government or Person thereby Authorized**

**15. (1) Where**

**(ii) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice:**

**the Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention. The exploitation of the invention shall be limited to the purpose for which it was authorized and shall be subjected to the payment to the said owner of an adequate remuneration therefor, taking into account the economic value of the invention, as determined in the said decision, and, where a decision has been taken under paragraph (ii), the need to correct 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:

**NA**

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:

**No, the applicable law does not 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.**

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:

**Yes, the applicable law provides for the grant of compulsory licenses on the ground of “national emergency” or “circumstances of extreme urgency.” However, their concepts and scope of application have not been specified.**

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

**None.**

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:

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

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*Government use*

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

**Section 15, Industrial Property Act of the Kingdom of Bhutan, 2001:**

**Exploitation by Government or Person thereby Authorized**

**15. (1) Where**

- (ii) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice:**

**the Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention. The exploitation of the invention shall be limited to the purpose for which it was authorized and shall be subjected to the payment to the said owner of an adequate remuneration therefor, taking into account the economic value of the invention, as determined in the said decision, and, where a decision has been taken under paragraph (ii), the need to correct anti-competitive practices.**

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

**NA**

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:

**Following are the applicable grounds for the grant of government use:**

- 1. Anti-competitive practices and/or unfair competition.**
- 2. Public interest**
- 3. National emergency and/or extreme urgency including government use**
- 4. Refusal to grant licenses on reasonable terms**

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

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(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 applicable law does not define these two concepts and their scope of application.**

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

**None.**

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:

.....  
.....  
.....

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

**NA**

***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):

.....  
.....  
.....

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:

.....  
.....  
.....

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

.....  
.....  
.....

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:

.....  
.....  
.....

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:

.....  
.....  
.....

*Breeders' use of patented inventions*

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

.....  
.....  
.....

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

.....  
.....  
.....

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

.....  
.....  
.....

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

.....  
.....  
.....

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:

.....  
.....  
.....

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):

.....  
.....  
.....

(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:

.....  
.....  
.....

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

.....  
.....  
.....

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?):

.....  
.....  
.....

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

.....  
.....  
.....

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:

.....  
.....  
.....

[End of Questionnaire]