

COMPILATION OF VARIOUS LEGAL PROVISIONS ON THE EXCEPTION REGARDING EXTEMPORANEOUS
PREPARATION OF MEDICINES

COMPILACIÓN DE DIVERSAS DISPOSICIONES LEGALES SOBRE LA EXCEPCIÓN RELATIVA A LA
PREPARACIÓN EXTEMPORÁNEA DE MEDICAMENTOS

للأدوية الارتجالي بالتحضير الخاص الاستثناء بشأن القانونية الأحكام مختلف من مجموعة

COMPILATION DE DIVERSES DISPOSITIONS JURIDIQUES SUR L'EXCEPTION RELATIVE À LA PRÉPARATION
EXTEMPORANÉE DE MÉDICAMENTS

关于临时配制药剂例外的各种法律规定汇编

КОМПИЛЯЦИЯ РАЗЛИЧНЫХ ПРАВОВЫХ НОРМ В ОТНОШЕНИИ ИСКЛЮЧЕНИЯ, КАСАЮЩЕГОСЯ
РАЗОВОГО ПРИГОТОВЛЕНИЯ ЛЕКАРСТВЕННЫХ СРЕДСТВ

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ALBANIA

Article 38 c) of the Law on Industrial Property № 9947 of July 7, 2008 (as amended up to Law № 96/2021 of July 7, 2021)

Article 38. Limitation of the Effects of the Patent

The rights conferred by the patent shall not extend to:

[...]

c) the extemporaneous individual preparation of a medicine in a pharmacy according to a medical prescription or with other processes that lead to its preparation.

[...]

ANDORRA

Article 33.1(e) of the Law on Patents № 26/2014 of October 30, 2014

33. Límits dels drets de les patents

1. Els drets conferits per una patent no s'estenen a:

[...]

(e) Actes que consisteixin en la preparació extemporània, per a casos individuals, en una farmàcia o per un metge o un veterinari, d'un medicament d'acord amb una prescripció mèdica, o actes respecte del medicament preparat d'aquesta manera;

[...]

ANTIGUA AND BARBUDA

Section 32(4)(d) of the Patent Act № 22 of 2018

32. Rights conferred by the patent

[...]

(4) The rights under the patent shall not extend to –

[...]

(d) the extemporaneous preparation for individual cases, in a pharmacy, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared; or;

[...]

ARGENTINA

Article 36 b) of the Law № 24.481 of March 30, 1995 on Patents and Utility Models (as amended up to Decree № 27/2018 of January 10, 2018)

36. The right conferred by a patent shall have no effect against:

[...]

b) the routine dispensation of drugs by authorized professionals, individually on medical prescription, or against acts relating to drugs so dispensed;

[...]

ARMENIA

Article 17(1)3 of the Law of the Republic of Armenia of June 10, 2008, on Inventions, Utility Models and Industrial Designs

17. Acts not Recognized as Infringements on the Exclusive Right Conferred by Patent

(1) The use of patented invention, utility model shall not constitute an infringement of the exclusive rights of the patent owner under Article 16 of this Law if used:

[...]

3. for single preparation of medicaments in pharmacies based on physicians' prescriptions;

[...]

AZERBAIJAN

Article 23 of the Law of the Republic of Azerbaijan on Patents 1997 (as amended up to October 20, 2009)

23. Acts not constituting infringement of the exclusive rights of patent owners

The following shall not be deemed as infringements of the exclusive rights of the patent owner:

[...]

the preparation of medicine in a pharmacy in exceptional cases as prescribed by a doctor;

[...]

BELARUS

Article 10 of the Law of the Republic of Belarus № 160-Z of December 16, 2002 on Patents for Inventions, Utility Models, Industrial Designs (as amended up to Law № 275-Z of December 18, 2019)

10. Actions Not Recognized as Infringement of the Exclusive Right of the Patent Owner

The following is not recognized as an infringement of the exclusive right of the patent owner:

[...]

one time manufacturing of drugs at drug stores on the prescription of a doctor with application of the invention protected by the patent;

[...]

BELGIUM

Article XI. 34. § 1er. e) of the Law of April 19, 2014, on the Insertion of Book XI 'Intellectual Property' to the Code of Economic Law, and Specific Provisions to the Book XI in Books I, XV and XVII of the Code (updated on May 31, 2024)

XI. 34. § 1er. Les droits conférés par un brevet ne s'étendent à aucun des actes suivants

[...]

e) la préparation de médicaments faite extemporanément et par unité dans les officines de pharmacie, sur ordonnance médicale, ou les actes concernant les médicaments ainsi préparés ;

[...]

BELIZE

Section 33(4)(d) of the Patents Act (Cap. 253, Revised Edition 2011)

33. Rights conferred by patent

[...]

(4) The rights under the patent shall not extend to—

[...]

(d) the extemporaneous preparation for individual cases, in a pharmacy, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;

[...]

BOSNIA AND HERZEGOVINA

Article 73 c) of the Law on Patents as of May 28, 2010

73. Exceptions from the Exclusive Rights

The patent holder's exclusive right shall not apply to:

[...]

c) direct or individual preparation of a medicine in a pharmacy on the basis of an individual medical prescription and procedures relating to the medicine so prepared.

BOTSWANA

Section 25(1)(g) of the Industrial Property Act, 2010 (Act No 8 of 2010)

25. (1) The rights conferred by a patent shall not extend to –

[...]

(g) the extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with a prescription given by a medical or dental practitioner, and the use of a medicine so prepared;

[...]

BRAZIL

Article 43.III. of Law No. 9.279 of May 14, 1996 (Law on Industrial Property, as amended up to Law No. 14.200 of September 2, 2021)

43. The provisions of the previous Article do not apply:

[...]

III. to the preparation of a medicine in accordance with a medical prescription for individual cases, carried out by a qualified professional, as well as to the medicine so prepared;

[...]

BRUNEI DARUSSALAM

Section 64(2)(c) of the Patents Order, 2011

64. Meaning of infringement.

[...]

(2) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not be so if –

[...]

(c) it consists of the extemporaneous preparation of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consists of dealing with a medicine so prepared;

[...]

BULGARIA

Article 20, paragraph 3, of the Law on Patents and Utility Models Registration (SG № 27/1993, as amended up to December 23, 2022)

20. The effect of the patent shall not cover:

[...]

3. single and direct preparation of a medicine at a pharmacy upon prescription;

[...]

CABO VERDE

Article 47(b) of the Industrial Property Code (approved by Legislative Decree No. 4/2007 of August 20, 2007)

47. The rights conferred by the patent shall not include:

[...]

(b) the preparation of medicines made up for individual cases by dispensing chemists on a medical prescription, or acts relative to medicines so prepared;

[...]

CHILE

Article 49 c) of the Law № 19.039 of March 6, 2006 (Consolidated Law approved by Decree-Law № 4 of June 30, 2022, incorporating amendments up to Law № 21.355 of July 5, 2021)

Artículo 49

[...]

El derecho conferido por la patente no se extenderá:

[...]

c) A la preparación de medicamentos bajo prescripción médica para casos individuales.

[...]

HONG KONG, CHINA

Article 75(c) of the Patents Ordinance 2017 (Chapter 514) (amended up to E.R. 4 of 2020)

75. Limitation of effect of patent:

The rights conferred by a patent shall not extend to-

[...]

(c) the extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription issued by a **registered medical practitioner** or **registered dentist** (which terms bear the meaning assigned to them by section 2 of the Medical Registration Ordinance (Cap. 161) and section 2(1) of the Dentists Registration Ordinance (Cap. 156) respectively) or acts concerning the medicine so prepared;

[...]

MACAO, CHINA

Article 105 a) of the Decree-Law No. 97/99/M of December 13, 1999, Legal Regime of Industrial Property

Article 105. Limitation on the rights conferred by the patent

The rights conferred by the patent shall not include:

a) The preparation of medicines made up on the spot and for individual cases by dispensing chemists on a medical prescription, nor acts relative to medicines so prepared;

[...]

CROATIA

Article 98(3) of the Patent Act (NN 16/2020 in force from February 20, 2020)

98. The patent holder's exclusive right of exploitation of the invention shall not apply to:

[...]

(3) direct and individual preparation of a medicine in a pharmacy on the basis of an individual medical prescription and acts relating to the medicine so prepared.

CUBA

Article 47 d) of the Decree-Law № 290 of November 20, 2011 on Inventions and Industrial Designs

47. Los derechos conferidos por la patente no se extienden a:

[...]

d) la preparación de medicamentos realizada de forma habitual, por profesionales habilitados y por unidad, con motivo de la ejecución de una receta médica y los actos relativos a los medicamentos así preparados;

[...]

CYPRUS

Section 27(3)(iv) of the Patents Law of 1998

27.-

[...]

(3) Notwithstanding paragraphs (1) and (2) of this section, the owner of a patent shall have no right to prevent third parties from performing, without his authorization, the acts referred to in subsections (1) and (2) of this section in the following circumstances:

[...]

(iv) Where the act consists of the extemporaneous preparation for individual cases, in a pharmacy or by a medical doctor, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared.

CZECH REPUBLIC

Section 18 c) of the Act № 527/1990 Coll. on Inventions and Rationalization Proposals (as amended up to Act No. 261/2021 Coll.)

§18. The rights of the proprietor of the patent shall not be infringed by use of the protected invention:

[...]

c) in the individual preparation of a medicament in a pharmacy based on a medical prescription including acts concerning the medicament so prepared;

[...]

DEMOCRATIC PEOPLE'S REPUBLIC OF KOREA

Article 63, paragraph 5, of the Invention Law on Inventions of the Democratic People's Republic of Korea (as amended up to Decree № 507 of January 20, 2021 of the Presidium of the Supreme People's Assembly)

63. (Exceptions from Patent Infringement)

Exceptions from patent infringement shall be as follows.

[...]

5. Where an invention is used only for preparation of medicaments necessary for the treatment of an individual patient according to a doctor's prescription.

[...]

DENMARK

Section 3(3)(v) of the Consolidate Patents Act (Consolidate Act № 90 of January 29, 2019)

3.-

[...]

(3) The exclusive right shall not extend to

[...]

(v) the preparation in a pharmacy of a medicinal product according to a medical prescription for individual cases or acts concerning the medicinal product so prepared.

DOMINICA

Section 33(4)(d) of the Patents Act № 8 of October 7, 1999

33.

[...]

(4) The rights under the patent shall not extend to –

[...]

(d) the extemporaneous preparation for individual cases, in a pharmacy, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;

[...]

ESTONIA

Section 16 4) of the Patents Act (consolidated text of August 31, 2023)

§ 16. Acts which do not constitute infringement of exclusive right of proprietor of patent.

The following acts do not constitute infringement of the exclusive right of the proprietor of a patent:

[...]

4) the single preparation of a medicinal product containing the patented invention on the basis of a prescription in a pharmacy and the use of such medicinal product;

[...]

FINLAND

Section 3(5) of the Patents Act (Act No 550/1967 of December 15, 1967, as amended up to Act No 717/2016 of August 25, 2016)

Section 3

[...]

The exclusive right shall not apply to:

[...].

(5) the extemporaneous preparation by a pharmacy, for individual cases, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;

FRANCE

Article L613-5 c) of the Intellectual Property Code (consolidated version as of June 30, 2022)

Article L613-5

Les droits conférés par le brevet ne s'étendent pas:

[...]

c) A la préparation de médicaments faite extemporanément et par unité dans les officines de pharmacie, sur ordonnance médicale, ni aux actes concernant les médicaments ainsi préparés ;

[...]

GERMANY

Section 11, paragraph 3, of the Patent Act (as amended up to Act of August 30, 2021)

Section 11

The effect of a patent does not extend to

[...]

3. the extemporaneous preparation in a pharmacy, in individual cases, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;

[...]

GREECE

Article 10.2.c., of the Law № 1733/1987 on Technology Transfer, Inventions and Technological Innovation

10. Contents of the right

[...]

2. The owner of the patent may not forbid, in the meaning of the preceding paragraph, the following activities:

[...]

c. The preparation of a pharmaceutical product in a pharmacy for a specific individual, following medical prescription as well as the dispensing and use of said pharmaceutical product under the reservation of article 25 paragraph 3 of the present Law.

[...]

GRENADA

Section 30(4)(d) of the Patents Act, 2011

30.–

[...]

(4) The rights under the patent shall not extend to–

[...]

(d) the extemporaneous preparation for individual cases, in a pharmacy, of a medicine, in accordance with a medical prescription or acts concerning the medicine so prepared;

[...]

HUNGARY

Article 19(6)(d) of the Act XXXIII of 1995 on the Protection of Inventions by Patents (updated on August 1, 2023)

19. Rights conferred by the patent

[...]

(6) The exclusive right of exploitation shall not extend to:

[...]

(d) the extemporaneous preparation for individual cases, in a pharmacy, of a medicine in accordance with a medical prescription issued by a medical doctor, or further acts concerning the medicine so prepared.

[...]

ICELAND

Article 3.4 of the Patents Act No 17/1991 (as amended up to Act No 1460/2021)

3. The exclusive right conferred by a patent implies that no person except the proprietor of the patent may, without the proprietor's consent, use the invention by [...]

The following are excepted from the exclusive right:

[...]

4. preparation in a pharmacy of a medicine in accordance with a physician's prescription in individual cases or acts with the medicine so prepared.

IRELAND

Section 42(c) of the Patents Act, 1992 (as amended up to the Patents (Amendment) Act 2012)

42. The rights conferred by a patent shall not extend to –

[...]

(c) the extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription issued by a registered medical practitioner or acts concerning the medicine so prepared;

[...]

ITALY

Article 68.1.c), of the Industrial Property Code, Legislative Decree No. 30 of February 10, 2005 (as amended up to Law No. 102 of July 24, 2023)

68. Limitations of Patent Rights

1. The exclusive power attributed by the patent right does not extend, whatever the object of the invention:

[...]

c) to the extemporaneous preparation, and by unit, of medicines in pharmacies on medical prescription, and to medicines thus prepared, provided that industrially produced active ingredients are not used.

[...]

JAMAICA

Section 64(1)(e) of the Patents and Designs Act (Act No 1 of 2020)

64. Exception to infringement

(1) An act shall not constitute an infringement of a patent, if that act –

[...]

(e) consists of the extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with a prescription given by a registered medical practitioner or registered dental practitioner, or consists of dealing with a medicine so prepared;

[...]

JAPAN

Article 69(3) of the Patent Act, Act No 121 of April 13, 1959 (as amended up to April 1, 2022)

69. Limitations of Patent Right.

[...]

(3) A patent right for a medical invention (whereby medicine refers to a product used in the diagnosis, therapy, treatment or prevention of human diseases; hereinafter the same applies in this paragraph) that is to be manufactured by two or more medicines being mixed together, or for the invention of a process by which a medicine is manufactured by two or more medicines being mixed together has not effect against the act of preparation of a medicine as per a physician's or dentist's prescription, nor against medicine prepared as per a physician's or a dentist's prescription.

[...]

KAZAKHSTAN

Article 12 5) of the Law of the Republic of Kazakhstan No. 427-I of July 16, 1999, on Patents (amended up to Law of the Republic of Kazakhstan No. 128-VII of June 20, 2022)

12. Acts not recognized as infringements on the executive right of the patent owner

The following shall not constitute acts infringing the exclusive right of the patent owner:

[...]

5) in urgent cases, one-time production in pharmacies, based on the prescriptions;

[...]

LATVIA

Section 20 4) of the Patent Law (as amended up to June 15, 2021)

20. Limitations of Exclusive Rights Resulting from a Patent

The exclusive rights resulting from a patent shall not be implemented in relation to:

[...]

4) the single preparation of medicinal products by a doctor's prescription in a pharmacy, as well as the actions with medicinal products prepared in such a way;

[...]

LIBERIA

Section 13.11 b) ix. of the Liberia Intellectual Property Act, 2016

§13.11. Rights Conferred by the Patent; Limitations and Exceptions.

[...]

b) The rights under a patent may not be used to prevent:

[...]

ix. the extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with a prescription, and to dealing with the medicines so prepared.

[...]

LITHUANIA

Article 35.3.3), of the Patent Law № I-372 of January 18, 1994 (as amended up to Law № XIII-2734 of December 19, 2019)

35. Patent proprietor's rights

[...]

3. The proprietor of the patent shall have no right to prevent third parties from performing acts referred to in paragraphs 1 and 2 of this Article, provided that such acts:

[...]

3) consist of preparing medicines for individual cases in a pharmacy upon the prescription of a physician or if it is indicated how to use the medicines so prepared;

[...]

LUXEMBOURG

Article 47(c) of the Law of July 20, 1992, on the Changes in the System for Patents for Invention (as amended up to the Law of December 18, 2009)

47. Limitation of the Effects of the Patent.

The rights afforded by the patent shall not extend to:

[...]

(c) the extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;

[...]

MALTA

Article 27(6)(c) of the Patents and Designs Act (chapter 417) of June 01, 2002 (as amended up to Act XXXV of 2023)

27. Rights conferred by a patent.

[...]

(6) Notwithstanding subarticles (1) and (2), the proprietor of a patent shall have no right to prevent third parties from performing the acts referred to in subarticles (1) and (2)(b) in the following circumstances:

[...]

(c) where the act consists of the extemporaneous preparation for individual cases, in a pharmacy or by a medical or veterinary doctor, of a medicine in accordance with a medical prescription or of acts concerning the medicine so prepared;

[...]

MAURITIUS

Section 21(2)(d) of the Industrial Property Act 2019

21. Rights conferred by patent

[...]

(2) The rights conferred by the grant of a patent shall not extend to –

[...]

(d) acts of extemporaneous preparation in a pharmacy as regards medicine for an individual in accordance with a prescription given by a registered medical practitioner, a dental specialist or a dental surgeon;

[...]

MONTENEGRO

Article 53 3) of the Law on Patents

53. The exclusive rights of a patent holder referred to in Articles 49 and 50 of this Law shall not apply to:

[...]

3) the direct, individual preparation of a drug in a pharmacy based on a single prescription, and to the placement of such drug on the market.

MOROCCO

Article 55(c) of the Law No 17-97 on the Protection of Industrial Property (as amended up to Law No 23-13)

55. The rights afforded by a patent shall not extend to:

[...]

(c) the extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;

[...]

MOZAMBIQUE

Article 75(e) of the Industrial Property Code (approved by Decree Nº 47/2015 of December 31, 2015)

75. Limitation of the rights derived from a patent

The rights of the patent holder shall not extend to the following:

[...]

e) Acts relating to the preparation in a pharmacy of provisional medication for an individual in accordance with prescription given by a registered medical practitioner.

MYANMAR

Article 54(g) of the Patent Law (Law Nº 7/2019 of March 11, 2019)

54. The patent rights shall not extend to the followings:

[...]

(g) acts of extemporaneous preparation for an individual in a pharmacy in accordance with prescription given by a registered medical or dental practitioner.

NAMIBIA

Section 43(1)(e) of the Industrial Property Act, 2012 (Act Nº 1 of 2012)

43. Limitations of rights.

(1) The following acts do not constitute an infringement of the rights under a patent, namely –

[...]

(e) the use of a patented invention in a pharmacy or by a medical doctor for the preparation of a medicine in accordance with a medical prescription for individual cases;

[...]

NETHERLANDS (KINGDOM OF THE)

Article 53, paragraph 3, of the National Patent Act 1995 (Kingdom Act of December 15, 1994, status as of June 1, 2023)

53. Rights and Obligations of the Patent Proprietor

[...]

3. The exclusive right shall not extend to acts solely serving for research on the patented subject matter, including the product obtained directly as a result of using the patented process. The exclusive right shall likewise not extend to the preparation of medicines in pharmacies for immediate use in individual cases on medical prescription, or to acts related to medicines prepared in this manner.

[...]

NORTH MACEDONIA

Article 91(3) of the Law on Industrial Property adopted on January 12, 2009

91. The right of the patent holder laid down in Article 89 of this Law regarding the exclusive utilisation of the invention shall not relate to:

[...]

(3) direct and individual preparation of the medicine in pharmacy on the basis on single medical recipe and of procedures which relate to so prepared medicine.

NORWAY

Section 3, paragraph 4, of the Patents Act (Act No 9 of December 15, 1967, as amended up to July 1, 2019)

3. The exclusive right shall not include:

[...]

4. Preparation in a pharmacy of a medicine in accordance with a prescription in individual cases, or acts carried out with a medicine so prepared.

[...]

PHILIPPINES

Section 72, paragraph 72.5, of the Intellectual Property Code of the Philippines (Republic Act No 8293) (2015 Edition)

72. Limitations of Patent Rights.

The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in Section 71 hereof in the following circumstances:

[...]

72.5. Where the act consists of the preparation for individual cases, in a pharmacy or by a medical professional, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;

[...]

POLAND

Article 69.1.v) of the Act of June 30, 2000, on Industrial Property (as amended up to Act of March 9, 2023)

69.

1. The following shall not be considered acts of infringement of a patent:

[...]

v) the extemporaneous preparation of a medicine in a pharmacy on a physician's prescription.

[...]

PORTUGAL

Article 103.1.b), of the Industrial Property Code (approved by Decree-Law № 110/2018 of December 10, 2018 and amended by Decree-Law № 9/2021 of January 29, 2021)

103. Limitation of rights conferred by a patent

1. The rights conferred by a patent do not extend to:

[...]

b) The extemporaneous preparation of medications for individual cases in pharmacy laboratories in accordance with a medical prescription or acts concerning the medicine so prepared.

[...]

REPUBLIC OF KOREA

Article 96(2) of the Patent Act № 950 of December 31, 1961 (as amended up to Act № 17730 of December, 2020)

96. (Limitations on Effects of Patents)

[...]

(2) The effects of a patent on the invention of a medicine manufactured by mixing at least two medicines (referring to products used for the diagnosis, relief, treatment, therapy, or prevention of human diseases; hereinafter the same shall apply) or on the invention of a process for manufacturing medicines by mixing at least two medicines shall not extend to the preparation of prescriptions and medicines prepared according to such prescriptions under the Pharmaceutical Affairs Act.

REPUBLIC OF MOLDOVA

Article 22(1) c) of the Law № 50-XVI of March 7, 2008 on the protection of Inventions (as amended up to Law № 254 of December 1, 2017)

22. Limitation of Effects of a Patent

(1) The rights conferred by a patent shall not extend to:

[...]

c) extemporaneous preparation for individual cases, in a pharmacy, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;

[...]

RUSSIAN FEDERATION

Article 1359 5) of the Civil Code of the Russian Federation (Part Four, Part Four, as amended up to June 29, 2023)

1359. Actions Not Deemed an Infringement of the Exclusive Right to an Invention, Utility Model or Industrial Design

The following are not deemed an infringement of the exclusive right to an invention, utility model or industrial design:

[...]

5) the one-off manufacturing of medicines with the use of the invention in a chemist's shop on a physician's prescription;

[...]

SAINT KITTS AND NEVIS

Section 32(4)(d) of the Patents Act, Chapter 18.25 (Revised Edition showing the law as at December 31, 2002)

32. Rights conferred by a patent.

[...]

(4) The rights in a patent referred to in subsection (3) of this section shall not extend to

[...]

(d) the extemporaneous preparation for individual cases, in a pharmacy, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;

[...]

SAINT LUCIA

Section 62(2)(c) of the Patents Act No 16 of August 27, 2001

62. Meaning of infringement

[...]

(2) An act, which apart from this subsection would constitute an infringement of a patent for an invention shall not do so if –

[...]

(c) it consists of the extemporaneous preparation of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consists of dealing with a medicine so prepared;

[...]

SAINT VINCENT AND THE GRENADINES

Section 27(1)(c) of the Patents Act (Act No 39 of 2004)

27. Limitation of effect of patent

(1) The rights conferred by a patent shall not extend to –

[...]

(c) the extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;

[...]

SAN MARINO

Article 28.10.b), of the Law No 79 of 25 May 2005 – Industrial Property Consolidation Act

28. Rights conferred by the patent

[...]

10. The exclusive rights conferred by a San Marino patent do not cover:

[...]

b) extemporary preparation by units of medicines in pharmacies upon medical recipe, and the medicines so prepared;

[...]

SAO TOME AND PRINCIPE

Article 105.1.b) of the of the Intellectual Property Code (approved by Decree-Law No 23/2016)

105. Limitation of the rights derived from a patent

1. The rights conferred by the patent do not cover:

[...]

b) The preparation of medicines for individual cases, on medical prescription and in pharmaceutical laboratories, nor the acts relating to the medicines so prepared;

[...]

SERBIA

Article 21 3) of the Law on Patents of January 4, 2012 (Official Gazette of the Republic of Serbia No 99/2011, 113/2017, 95/2018, 66/2019 and 123/2021)

21. Exceptions to Exclusive Rights

The exclusive rights of a right holder referred to in Articles 14 and 15 of this Law shall not apply to:

[...]

3) the direct, individual preparation of a drug in a pharmacy based on a single prescription, and to the placement of such drug on the market.

[...]

SEYCHELLES

Section 19(e) of the Industrial Property Act 2014 (Act No 7 of 2014)

19. Limitations of right

The rights of the patentee shall not extend to –

[...]

(e) acts of extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with prescription given by a registered medical or dental practitioner;

[...]

SINGAPORE

Section 66(2)(c) of the Patents Act (Chapter 221, Revised Edition 2020, amended up to the Statutes (Miscellaneous Amendments) Act 2022)

66. Meaning of infringement

[...]

(2) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not be so if —

[...]

(c) it consists of the extemporaneous preparation of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consists of dealing with a medicine so prepared;

[...]

SLOVAKIA

Section 18(1)(d) of the Act No 435/2001 Coll. on Patents, Supplementary Protection Certificates and Amendment of Some Acts [Patent Act (as amended up to Act No. 291/2018 Coll.)]

18.

(1) Rights of a patent owner shall not be infringed if an invention is exploited:

[...]

(d) in individual preparation of a medicine in a pharmacy according to a medical prescription or in activity related to a medicine prepared in this way,

[...]

SLOVENIA

Article 19 c) of the Industrial Property Act (Official Gazette of the Republic of Slovenia, No. 45/01 of June 7, 2001, as amended up to March 29, 2020)

19. Limitation of patent rights

The rights referred to in Article 18 of this Act shall not apply to:

[...]

c) the extemporaneous individual preparation of a medicine in a pharmacy in accordance with a medical instruction or prescription, nor acts concerning the medicine so prepared;

[...]

SPAIN

Article 61.1.d) of the Law No 24/2015 of July 24, 2015 on Patents (as amended by Law No 6/2018, of July 3, 2018)

61. Límites generales y agotamiento del derecho de patente.

1. Los derechos conferidos por la patente no se extienden:

[...]

d) A la preparación de medicamentos realizada en las farmacias extemporáneamente y por unidad en ejecución de una receta médica ni a los actos relativos a los medicamentos así preparados.

[...]

SWEDEN

Article 3, paragraph 5, of the Patent Act No 837 of 1967 (as amended up to Order (2023:216))

3. [...]

The following acts are exempted from the exclusive right:

[...]

5. acts of preparation in pharmacies of medicines in accordance with a prescription by a physician in an individual case or acts relating to medicines prepared in such cases.

SWITZERLAND

Article 9, paragraph h, of the Patent Act of 25 June, 1954 (status as of 1 July, 2023)

9. The effects of the patent do not extend to:

[...]

h. the direct individual preparation of medicinal products in pharmacies in accordance with a doctor's prescription or to acts concerning medicinal products prepared in this way.

[...]

SYRIAN ARAB REPUBLIC

Article 24 3-b of the Law No. 18 of 2012 on Grant, Registration, and Publication of Patents, and the Rights Arising from the Registration

Article 24

[...]

3- It shall not be considered as infringement on that right the following practices of a third party:

[...]

b- Preparing medicines in pharmacies immediately and individually based on a medical prescription and the work related to medicines prepared in this way.

[...]

TAJIKISTAN

Article 30 of the Law of the Republic of Tajikistan № 17 of February 28, 2004 on Inventions (as amended up to Law № 956 of March 19, 2013)

30. Actions not recognized as an infringement of an exclusive right

The following actions shall not be deemed infringements of a patent owners' exclusive right:

[...]

- one-time production of medicines in pharmacies on a doctor's prescription;

[...]

THAILAND

Section 36(3) of the Patent Act B.E. 2522 of March 11, 1979 (as amended up to Patent Act (№ 3) B.E. 2542 of 1999)

36. No other person except the patentee shall have following rights:

[...]

The preceding paragraph shall not apply to:

[...]

(3) the compounding of a drug specifically to fill a doctor's prescription by a professional pharmacist or medical practitioner, including any act done to such pharmaceutical product;

[...]

TRINIDAD AND TOBAGO

Section 42(c) of the Patent Act № 21 of 1996 (Chap. 82:76, as last amended by the Act № 54 of 2000)

42. Limitation of effect of patent.

The rights conferred by a patent shall not extend to –

[...]

(c) the extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;

[...]

TUNISIA

Article 47(c) of the Patents Act № 2000-84 of August 24, 2000

47. The rights conferred by the patent shall not extend to the following:

[...]

(c) the individual preparation of medically prescribed drugs by dispensing chemists, or acts relating to drugs so prepared;

[...]

TURKMENISTAN

Article 13(5) of the Law on the Legal Protection of Inventions (№ 629-V of November 4, 2017)

13. Действия, не признаваемые нарушением исключительного права патентообладателя

Не признаётся нарушением исключительного права патентообладателя:

[...]

(5) разовое изготовление в аптеке по рецептам врачей лекарственных средств с использованием запатентованного изобретения;

[...]

TÜRKIYE

Article 85(3)(ç) of the Industrial Property Law (Law № 6769 of December 22, 2016)

Scope of a patent right and its limits

85. [...]

(3) The practices mentioned below shall be out of the scope of the rights provided by a patent:

[...]

(ç) using the drugs prepared in pharmacies without a mass production in order to prepare only one prescription and practices regarding drugs prepared this way;

[...]

UGANDA

Section 44(d) of the Industrial Property Act, 2014

44. Exception to exclusive rights

It is not an infringement of a patent to use the patented invention without the authorization of the patent holder in any of the following circumstances—

[...]

(d) to make use of the patented invention in relation to the preparation for individual cases, in a pharmacy or by a medical doctor, of a medicine in accordance with a medical prescription;

[...]

UNITED ARAB EMIRATES

Article 22, paragraph 3, of the Federal Law № 11 of 2021 on the Regulation and Protection of Industrial Property Rights

22. Rights Not Covered by Patent or Utility Certificate

Rights conferred by patent or utility certificate shall not cover the following:

[...]

3. Combining more than one medication for the purpose of medical treatment by a licensed pharmacist.

UNITED KINGDOM

Section 60(5)(c) of the Patents Act 1977 (Chapter 37, updated on August 21, 2022)

60. Meaning of infringement

[...]

(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if –

[...]

(c) it consists of the extemporaneous preparation in a pharmacy of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consists of dealing with a medicine so prepared;

[...]

URUGUAY

Article 39(b) of the Law № 17.164 of September 2, 1999, on Patents (as amended up to Law № 19.924 of December 18, 2020)

39. The rights conferred by patents shall not cover the following acts:

[...]

(b) the preparation of a medicine for a single patient, according to a medical prescription and under the supervision of an authorized professional;

[...]

UZBEKISTAN

Article 12 of the Law of the Republic of Uzbekistan № 1062-XII of May 6, 1994 on Inventions, Utility Models and Industrial Designs (as amended up to Law of the Republic of Uzbekistan № ZRU-446 of September 14, 2017)

12. Действия, не признаваемые нарушением исключительного права патентообладателя

Не признается нарушением исключительного права патентообладателя:

[...]

разовое изготовление лекарственных средств в аптеках по рецептам врача.

VANUATU

Section 41(2)(c) of the Patents Act № 2 of 2003

41.

[...]

(2) An act does not constitute an infringement of a patent if:

[...]

(c) it consists of:

(i) the extemporaneous preparation of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner; or

(ii) dealing with a medicine prepared in that way.

ZAMBIA

Section 75(1)(j) of the Patents Act 2016 (Act No 40 of 2016)

75. Limitations of patent rights.

(1) Despite any other provision of this Act, rights under a patent shall be limited to industrial or commercial activities and shall not extend to the following:

[...]

(j) the preparation for individual cases, in a pharmacy or by a medical doctor, of a medicine in accordance with a medical prescription;

[...]

UNIFIED PATENT COURT

Article 27(e) of the Agreement on a Unified Patent Court of June 1, 2023

27. Limitations of the effects of a patent

The rights conferred by a patent shall not extend to any of the following:

[...]

(e) the extemporaneous preparation by a pharmacy, for individual cases, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;

[...]

EURASIAN PATENT ORGANIZATION (EAPO)

Rule 19 of the Patent Regulations under the Eurasian Patent Convention (as adopted on December 1, 1995, with the amendments and addenda adopted as up to January 1, 2024)

19. Actions not Infringing the Eurasian Patent

The following cases of the use of the patented invention shall not constitute an infringement of the Eurasian patent:

[...]

use for the occasional preparation, in a pharmacy, of a medicine on a medical prescription;

[...]

[End of the Appendix and of document]