Unofficial Translation

Kingdom of Cambodia
Nation Religion King

Law

On

Compulsory Licensing for Public Health

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Outcome of Final Meeting with Council of Jurists and Literature Expert

Unofficial Translation

CHAPTER 1
GENERAL PROVISIONS

Article 1

The objective of this law is to enhance access to Pharmaceutical Products for public health by granting compulsory licenses for production, exportation and importation of Pharmaceutical Products in cases of National Emergency or Extreme Urgency or Public Non-Commercial Use or any other public health circumstances that defined by Ministry of Health.

Article 2

The purpose of this law is to determine conditions, formalities and procedures for granting and implementing compulsory licenses for public health and in compliance with the Decision of the General Council of the World Trade Organization.

Article 3

This law is applicable to compulsory licenses for public health in relation to patented Pharmaceutical Products in circumstances as indicated in article 1.

The grant of other compulsory licenses not covered under this law is subject to the Law on Patents, Utility Model Certificates and Industrial Designs and to other applicable laws and regulations.

Article 4

The key technical terms used under this law shall be defined as follows:

(1) “Compulsory License for Public Health” refers to the license granted by the Ministry of Health authorized to produce, import or export Pharmaceutical Products imitating the patented Pharmaceutical Products (generic medicines) without the consent of the inventor.

(2) “National Emergency or Extreme Urgency” refers to public health crises as declared by the Ministry of Health in respect to crises of an inadequate supply of Pharmaceutical Products for the diagnosis, prevention and/or treatment of any disease or illness, including AIDS, tuberculosis, malaria or any other diseases or illnesses.

(3) “Public Non-commercial Use” refers to any public use of Pharmaceutical Products produced, imported, exported or distributed for public health purpose through private or public services or non-governmental organizations to ensure in whatever that the people have access to those Pharmaceutical Products..

(4) “Patent” refers to a certificate issued by the Ministry in charge of industry for invention protection determined under the Law on Patents, Utility Model Certificates and Industrial Designs promulgated by Royal Kram No. NS/RKM/0103/005 dated 22 January 2003.

(5) "Applicant for Compulsory License" refers to private or public institutions or national or international organizations recognised by Ministry of Health and authorized to manufacture, import, export, or distribute Pharmaceutical Products.

(6) "Exporting Member Country" is a WTO Member country applying the Decision of the General Council for exportation of Pharmaceutical Products to any Eligible Importing Member.

(7) "Eligible Importing Member" is

a. A Least-developed Country who is a WTO Member; or
b. Any other WTO Member Country that has filed a notification to the Council for TRIPS regarding their intention of using the Decision of the General Council as an Eligible Importing Country; or
c. A non-WTO Member Country that has made an official notification with the Kingdom of Cambodia to comply with the conditions set out by the Decision of the General Council, and to also publish on its webpage the notifications required by the Decision of the General Council.

(8) "Pharmaceutical Product" refers to a Pharmaceutical Product as defined under the Law on Management of Pharmaceutical Products and protected by patents, or a Pharmaceutical Product manufactured through a patented process, of the pharmaceutical sector in Cambodia or a country imported to Cambodia, including active ingredients and reactors for the analysis of those products.

(9) "The Decision of the General Council" refers to the Decision for the implementation of Paragraph 6 of the Doha Declaration on the Agreement on Trade Related Aspects of Intellectual Property Rights and Public Health, adopted by the General Council of the WTO.

CHAPTER 2

COMPETENCE

Article 5

The Ministry of Health, acting on behalf of the Royal Government of Cambodia, shall have the competence:

- to manage, administer and monitor the compulsory license in accordance with the provisions of this law;
- to determine conditions, formalities and procedures for granting the compulsory license;
- to determine circumstances of National Emergency or Extreme Urgency or Public Non-Commercial Use; and
- to determine conditions for the implementation of the compulsory license.

The aforementioned conditions and circumstances shall be determined by the Prakas of the Minister of Health.

Article 6

The Ministry of Commerce, acting on behalf of the Royal Government of Cambodia, shall be the competent ministry to make notifications to the General Council of the granting of the compulsory license for import and export of the Pharmaceutical Products.

Article 7

An Applicant for Compulsory License who wishes to import the Pharmaceutical Products into Cambodia may request for assistance from the competent ministry in fulfilling legal requirements of the Exporting Member Country.

Article 8

The Ministry of Health shall organize a Secretariat in charge of compulsory license in order to process the implementation of the compulsory license and to settle and coordinate any complaint in case there is any dispute concerning the compulsory license.

The organization and functioning of the compulsory licensing Secretariat shall be determined by the Prakas of the Minister of Health.

CHAPTER 3
CONDITIONS, FORMALITIES AND PROCEDURES FOR GRANTING OF COMPULSORY LICENSE

Article 9

The granting of the compulsory license for importation, production and exportation shall comply with the following conditions:

a) The licence shall be non-exclusive;
b) The compulsory license shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such license;
c) Within twenty one (21) working days from the grant of such compulsory license, the Ministry of Health shall notify the patent holder or patent holders that a compulsory licence has been granted under the provisions of this law;
d) A prior agreement from the holder of the patent shall not be required for the grant of a compulsory licence for importation, production or exportation;
e) The Ministry of Health shall, upon request and subject to the fulfilment of the requirements of this law, grant a compulsory licence for exportation, importation or local production of a Pharmaceutical Product;
f) The grant of the compulsory license for importation and local production shall be made in circumstances of National Emergency or Extreme Urgency or Public Non-Commercial Use or any other public health circumstances defined by Ministry of Health;
g) The grant of the compulsory licence for importation and local production shall be predominantly for the supply of the market in the Kingdom of Cambodia;

h) The grant of the compulsory licence for the exportation of the Pharmaceutical Products to an Eligible Importing Member shall be made in quantities and situations as stipulated under paragraph (g) of this article as if these situations existed in the Kingdom of Cambodia.

Article 10

The grant of the compulsory license shall comply with the following procedures:

(1) An application for a compulsory licence shall be examined after the Ministry of Health verifies that the applicant has fulfilled all the formalities required under this law.

(2) The Ministry of Health shall notify the applicant of its decision in writing of approval or rejection within twenty one (21) working days counted from the date of receiving the correct application.

(3) In case of rejection, the Minister of Health shall specify in writing the concrete reasons therefore. The applicant may request a competent court for review of the decision of rejection of the application for a compulsory licence.

(4) In case of special necessity, the Ministry of Health may designate a legal entity to be granted with a compulsory license to produce in or import into the Kingdom of Cambodia the Pharmaceutical Products**.**

(5) The formalities and procedures for granting the compulsory licence shall be determined by the Prakas of the Minister of Health.

Article 11

(1) The production, importation or exportation of the Pharmaceutical Products under a compulsory licence shall be subject to payment of remuneration to the patent holder.

(2) Payment of remuneration shall be exempted for the importation, provided that such remuneration has already been paid in the Exporting Member Country.

(3) The method and criteria of the rate of remuneration to be paid shall be determined by the Prakas of the Minister of Health or a joint Prakas between the Minister of Health and Minister of Economic and Finance.

Article 12

The Ministry of Commerce has duties to notify the General Council of the importation by:

- specifying the names and expected quantities of the Pharmaceutical Product(s) needed;
- indicating that the Kingdom of Cambodia has no or lack of sufficient capacity to produce those Pharmaceutical Products;
- confirming that, if the Pharmaceutical Product is patented in the Kingdom of Cambodia, a compulsory licence has been granted or that the Government intends to grant a compulsory licence to address the National Emergency or

Extreme Urgency or Public Non-Commercial Use.

Article 13

The Ministry of Commerce has duties to notify the General Council of the exportation by indicating:

a. The name and address of the licensee;
b. The Pharmaceutical Products for which the compulsory licence has been granted;
c. The quantity for which the compulsory licence has been granted;
d. The country or countries to which the Pharmaceutical Products are to be exported;
e. The address of the website of the licensee;
f. The validity of the compulsory license; and
g. Other conditions concerning the compulsory licence as specified in paragraph (b) of article 9 of this law.

Article 14

The application for a compulsory licence for exportation shall include the following letters from the Eligible Importing Member:

(1) A letter indicating its intention to import a Pharmaceutical Product or such other evidence in support of the application;

(2) A copy of the notification to the WTO of its intention if the Eligible Importing Member is not a least developed country Member of the WTO;

(3) A copy of the official commitment, with notification to the WTO, to the Kingdom of Cambodia that it will comply with the conditions set out by the Decision of the General Council, and to also publish on its webpage the notifications required by Paragraph 1(b) and 2(a) of the Decision of the General Council, if the Eligible Importing Member is not a Member of the WTO.

Article 15

The granting of a compulsory licence for exportation shall comply with the following conditions:

a. The quantity of the Pharmaceutical Product(s) made under the compulsory licence for exportation shall be limited to that necessary to address the needs of the Eligible Importing Member, including for purposes of testing and regulatory approval;
b. All Pharmaceutical Products exported under the compulsory license shall be clearly identified through specific labeling or marking and distinguished through special packaging and/or special coloring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and
c. The licensee shall, prior to shipment of the Pharmaceutical Product(s) to be

exported, post on its website or on a website established for the purpose by the WTO:

i. The quantities of Pharmaceutical Product(s) to be supplied to each destination; and
ii. The distinguishing features as required under the preceding paragraph (b).

In cases where the Eligible Importing Member requires the supply of additional quantities of the Pharmaceutical Products, the Ministry of Health shall grant permission upon request of the licensee, provided that the requirements of the Article 13 and all conditions of this law shall be fulfilled.

Article 16

The Ministry of Health shall have the authority to review, upon the request of the patent holder, the continuation of a compulsory licence granted under this law:

- after two years from the date of permission for making availability of the Pharmaceutical Products locally produced or imported under a Compulsory licence or from the date of exportation of the Pharmaceutical Products; or
- in cases where the reasons that justified the grant of the compulsory licence have ceased to exist and are unlikely to recur.

Such review shall take into consideration the adequate protection of the legitimate interests of the licensee to which the compulsory licence was granted.

If the request for a review is denied or no decision is notified to the patent holder after ninety (90) working days from the date the review is filed, the patent holder may submit a request for review of the compulsory licence to the competent court.

The request for a review either before the Ministry of Health or the competent court shall not suspend the execution of the compulsory licence granted under this law. The competent court shall not issue any provisional measure until a final decision on the case is made. Any decision by the competent court shall be subject to adequate protection of the legitimate interests of the licensee to which the compulsory licence was granted.

Article 17

The protection conferred to test data and other undisclosed information shall not be invoked to prevent, impede or delay the execution of a compulsory licence granted under this law.

Article 18

The Ministry of Health shall determine the requirements for the assessment of the quality, safety and efficacy of the Pharmaceutical Product to be imported, produced and exported under the compulsory license having in view the circumstances that justified the grant of a compulsory licence.

These formalities, procedures and requirements shall be determined by the Prakas of the Minister of Health.

CHAPTER 4
PENALTIES

Article 19

The illegal distribution of Pharmaceutical Products imported or produced pursuant to this law shall be subject to fines and penalties under applicable laws of the Kingdom of Cambodia.

Article 20

Any person that violates the conditions of a compulsory licence granted to it under this law shall be subject to transactional fines from one (1) million Riels to ten (10) million Riels. In case of repeatedly committed, the transactional fines shall be double.

Article 21

The transitional fine prescribed by this law shall be made by the Judicial Police Officers of the Ministry of Health who are in charge of inspecting the pharmaceutical products.

Article 22

Procedures and conditions for imposing the transactional fines shall be determined by a Joint Prakas of the Minister of Health and the Minister of Economy and Finance.

CHAPTER 5
TRANSITIONAL PROVISION

Article 23

In accordance with the decision on extension of the transitional period for least developed countries under the TRIPS Agreement, the Kingdom of Cambodia shall implement this law following 01 July 2021. Any requirement to implement this law prior to this date shall be in cases when the Kingdom of Cambodia graduates from the status of the least developed countries.

CHAPTER 6
FINAL PROVISION

Article 24

Any provision which is contrary to this law shall be repealed.

This law is passed by the National Assembly of the Kingdom of Cambodia on dd/mm/yyyy, At …sessions of the National Assembly, … term
Phnom Penh, dd/mm/yyyy

President of the National Assembly