AMENDMENT TO PHARMACEUTICAL AFFAIRS ACT

(amended on December 29, 2017 and promulgated on January 31, 2018)

Added provisions: Article 40-3, title of Chapter 4-1, Article 48-3~Article 48-22, Article 92-1, Article 101

Amended provisions: Article 40-2, Article 100, and Article 106

Article 40-2.

Upon the issuance of approval for any new drug, the central health authority shall publicize the relevant patent numbers or file numbers, which are supplied by the applicants and already disclosed to the public.

Within three (3) years after the issuance of approval for new drug of new chemical entity, any other pharmaceutical firm may not apply for registration of the same by citing the data submitted by the holder of the approval without such holder's authorization.

Other pharmaceutical firms may act upon this Act and relevant regulations to apply for registraiton and market approval from the date immeidately following expiration of the aforesaid period. The central health authority may issue drug approval to those pharmaceutical firms that meet the requirements from the date immediately following expiration of five-year period of the approval issued for the new drug of new chemical entity indicated in the preceding paragraph.

The second paragraph hereof shall only be applicable with the compliance that application for registration of a new drug of new chemical entity shall be filed to the central health authority within three (3) years after it has been first approved for marketing in any other country.

Article 40-3.

Within two (2) years beginning from the date when the central health authority approves the new or changed indications of a drug, other pharmaceutical firms shall not, without consent of the holder of drug approval of the said drug, apply for registration of the same indications by citing the application data submitted by such holder.

Other pharmaceutical firms may act upon this Act and relevant regulations to apply for registraiton and market approval from the date immediately following expiration of the aforesaid period. The central health authority may issue drug approval to those pharmaceutical firms that meet the requirements only from the date immeidately following expiration of three-year period after the new or changed indications have been approved as indicated in the preceding paragraph. However, in the circumstance where the holder of the drug approval for the approved new or changed indications of the said drug conducts clinical trials on the said new or changed

indications in this country, the central health authority shall issue drug approval to other pharmaceutical firms only from the date immediately following expiration of five-year period after the central health authority has approved the new or changed indications.

The regulation of the first paragraph hereof shall be applicable to the application for registration of the new or changed indications filed with the central health authority within two (2) years after the drug of the new or changed indications has been approved for marketing in any other country.

Chapter 4-1 Patent Linkage of Western Pharmaceuticals

Article 48-3.

New drug marketing approval holders who see the necessity of reporting and listing the information of the patent(s) relating to the new drug shall complete the reporting and listing with the central health authority within 45 days beginning from the date immediately following the holders' receipt of the approval by submitting relevant documents and data. The provisions of this Chapter will not apply to the reporting and listing completed after the prescribed 45-day timeframe.

The subject matters of pharmaceutical patents eligible for listing are as follows:

1. Substances;
2. Compositions or formulations; and
3. Medical and pharmaceutical use.

Article 48-4.

The listed patent information as provided in the preceding Article includes:

1. Patent number(s) of the listed invention patent(s), and if the patent(s) covers medical and pharmaceutical use, the specific claim(s);

2. Expiry date(s) of the listed patent(s);

3. Name or designation, nationality, residence, domicile or business premises of the patentee(s) of the listed patent(s), and also the name of representative thereof, if any; the name or designation, nationality, residence, domicile or business premises of the exclusive licensee of the listed patent(s) if and when the patent(s) listed is subject to exclusive licensing and the licensing has been duly registered and recorded in accordance with the Taiwan Patent Act; and

4. Name, residence, domicile or business premises of the designated agent who is authorized by and act on behalf of the patentee(s) of the listed patent(s) or the aforesaid exclusive licensee who has no residence, domicile or business premises in Taiwan.

Where the drug marketing approval holder is not the patentee, the holder shall obtain the patentee's consent for the patent listing. In case of the listed patent(s) being

subject to exclusive licensing duly registered in accordance with the Taiwan Patent Act, only the exclusive licensee's consent will be required.

Article 48-5.

Where the new drug marketing approval holder acquires invention patent right granted and published by the patent agency after the central health authority has issued the drug approval and the patent falls into the scope as set forth in the second paragraph of Article 48-3 herein, the required patent information shall be reported and listed within 45 days beginning from the date immediately following the publication of grant of the invention patent in accordance with the said Article. The provisions of this Chapter will not apply to the reporting and listing completed after the prescribed 45-day timeframe.

Article 48-6.

The new drug marketing approval holder shall request for change or deletion of the listed patent information within the 45-day timeframe beginning from the date immediately following the occurrence of any of the following events:

1. Patent term extension as approved and published by the Patent Agency;
2. Claims correction as approved and published by the Patent Agency;
3. Patent right revocation with final and binding effect;
4. Patent right extinguishment;
5. Change of listed patent information as set forth in the 3rd subparagraph and 4th subparagraph of the 1st paragraph of Article 48-4 herein.

Where the drug marketing approval holder is not the patentee or the exclusive licensee, the second paragraph of Article 48-4 herein shall apply *mutatis mutandis* before request for change or deletion of the listed patent information.

Article 48-7.

Any person may issue a notice to the central health authority in writing by stating reasons and providing evidence in any of the following circumstances:

1. The listed invention patent is not related to the granted drug;
2. The listed invention patent does not fall into the scope of the eligible subject matters as specified in the second paragraph of Article 48-3 herein;
3. The listed patent information is incorrect;
4. The request for change or deletion required in the events as set forth in Article 48-6 is not duly completed.

The central health authority shall notify the new drug marketing approval holder of the aforesaid notice within twenty (20) days beginning from the date immeidately following its receipt of such a notice.

The new drug marketing approval holder shall respond to the central health authority in writing by stating reasons within 45 days beginning from the date immeidately following receitp of such a notice form the central health authority, and shall request

for change or deletion of the listed patent information when necessary.

Article 48-8.

The central health authority shall establish a western pharmaceuticals linkage system for patent listing and for publication of the patent information reported and listed by new drug marketing approval holders. The system shall be also for change or deletion of the listed patent information.

Where the listed patent information falls into any of the circumstances as specified in Article 48-7, the central health authority shall make public the request made by the said person who makes a notice and the new drug marketing approval holder's written response.

Article 48-9.

For applying for drug marketing approval for generic drugs, the generic drug applicant shall make any of the following certifications with the central health authority in regard to the patent(s) listed by the new drug approval holder:

1. No patent information has been listed for the granted new drug;
2. The listed patent(s) corresponding to the granted new drug has expired;
3. The marketing approval of the generic drug shall be issued by the central health authority after the listed patent(s) has expired;
4. The listed patent(s) is invalid or is not infringed by the generic drug for which the application is submitted.

Article 48-10.

For generic drug marketing approval applications that are filed with the certifications of subparagraph 1 and 2 of Article 48-9 and have been examined and approved, the central health authority shall issue marketing approval thereto.

Article 48-11.

For generic drug marketing approval applications that are filed with the certification of subparagraph 3 of Article 48-9 and have been examined and approved, the central health authority shall issue marketing approval thereto after the listed patent(s) has expired.

Article 48-12.

For generic drug marketing approval applications that are filed with the certification of subparagraph 4 of Article 48-9, the generic drug applicant shall notify, in writing, the new drug approval holder and the central health authority of its certification within twenty (20) days beginning from the date immediately following its receipt of notification from the central health authority that the application for drug marketing approval has been completed for review. If the new drug approval holder is not the listed patentee or the exclusive licensee, the same notice shall be issued to the listed patentee or the exclusive licensee.

In the notice indicated in the preceding paragraph, the generic drug applicant shall state reasons and provide evidence with respect to its certification that the listed patent(s) is invalid or is not infringed by the generic drug.

Where the generic drug applicant fails to issue a notice as required in the preceding two paragraphs, the central health authority shall deny its generic drug marketing approval application.

Article 48-13.

The patentee or exclusive licensee of the listed patent who intends to initiate patent infringement action on the listed patent(s) after receiving the notice provided in the first paragraph of the preceding Article must do so within forty five (45) days after receiving the notice and shall keep the central health authority informed of the same.

The central health authority shall within twelve (12) months beginning from the day immediately following the new drug approval holder's receipt of the notice provided in the first paragraph of the preceding Article suspend the issuance of the drug approval. Notwithstanding, the central health authority may, subject to full compliance with this Act as is examined and confirmed, issue the drug approval in case of any of the following:

1. The patentee or exclusive licensee fails to initiate patent infringement action within forty five (45) days after receiving the notice provided in the first paragraph of the preceding Article;

2. The patentee or exclusive licensee fails to initiate patent infringement action on the patent(s) which had been listed prior to the filing date of the application for generic drug approval;

3. The patentee or exclusive licensee duly initiated patent infringement action pursuant to the first paragraph hereof and the action is dismissed by the court pursuant to the first and second paragraph of Article 249 of the Code of Civil Procedure;

4. The court finds the patent(s)-at-issue in all pending infringement actions initiated on it should be invalidated, or the applicant seeking generic drug approval is found non-infringing by the court.

5. All of the patents indicated in the certification made by the applicant seeking generic drug approval pursuant to subparagraph 4 of Article 48-9 are invalidated according to the written decision issued by the Special Patent Authority on the relevant challenge of the patents;

6. The parties meet their minds on the consummation of a settlement or the results of mediation;

7. All of the patents indicated in the certification made by the applicant seeking generic drug approval pursuant to subparagraph 4 of Article 48-9 are duly lapse.

The time period provided in subparagraph 1 of the preceding paragraph shall be counted from the later of patentee's or the exclusive licensee's receipt of the notice.

Where the patentee or exclusive licensee wins the infringement action on the listed patent(s) and the court judgment entered on the action becomes final with binding effects within the 12-month period provided in the second paragraph, the central health authority shall continue suspending the issuance of the generic drug approval until the patent duly lapses.

Where it is found that the patentee or the exclusive licensee has *ab initio* abused patent right to have initiated the infringement action pursuant to the first paragraph, the patentee or exclusive licensee shall be liable for the loss (if any) incurred by the applicant seeking generic drug approval as a result of the suspended issuance of drug approval.

Article 48-14.

Where the applicant of application seeking generic drug approval is the same and the generic drug for which the application is filed is the same, the central health authority will suspend issuance of the drug approval on that application pursuant to the second paragraph of preceding Article once and once only.

Article 48-15.

Where the central health authority completes the examination of the application for generic drug approval during the period of suspension of issuance of drug approval provided in the second paragraph of Article 48-13, the central health authority shall notify the applicant of that application.

The drug approval applicant may after receiving the notice provided in the preceding paragraph apply with the National Health Insurance Administration, Ministry of Health and Welfare for recording of the drug and approval of the price proposed for national health insurance payment. Notwithstanding, no preparation or importation of the drug will be allowed before the generic drug approval is issued by the central health authority

Article 48-16.

The first applicant to have produced complete in full the materials required of its application filed with subparagraph 4 of Article 48-9 for approval of the generic drug will be granted an exclusive marketing term of 12 months, and the central health authority shall issue no other drug approval of the same generic drug until the said term duly expires

The first applicant to have produced complete in full the materials required of the application for generic drug approval shall be replaced by the second applicant to have done so if

1. All certifications under subparagraph 4 of Article 48-9 are changed during the

examination of the application for generic drug approval;

2. The first applicant does not receive the notice of completion of examination of its application for drug approval provided in the first paragraph of the preceding Article within 12 months beginning from the day immediately following its production of complete in full the materials for its application; or

3. The circumstances provided in the fourth paragraph of Article 48-13 exist.

Where there are two or more applicants to have produced complete in full on the same day the materials required of their applications for generic drug approval as provided in the first paragraph, they shall be jointly granted the 12-month exclusive marketing term.

Article 48-17.

The holder of a generic drug approval shall distribute the generic drug within 6 months beginning from the day immeidately following its obtaining the drug approval and file a request with the central health authority within 20 days from the date immeidately following its first distribution of the generic drug for the central health authority to approve the grant of the exclusive marketing term and to determine the start date and end date of the term granted.

The exclusive marketing term provided in the preceding paragraph shall be counted from the date when the drug is actually distributed.

Where the exclusive marketing term is granted to two or more applicants for generic drug approval, the exclusive marketing term shall be counted from the first day when any of the generic drugs is actually distributed.

Article 48-18.

The central health authority may issue the generic drug approval to another applicant in any of the following circumstance when the restrictions provided in the first paragraph of Article 48-16 shall not apply:

1. The applicant for generic drug approval who is granted the exclusive marketing term fails to collect the drug approval within the time period specified in the notice issued by the central health authority or

2. Fails to act in accordance with the first paragraph of the preceding Article; or

3. All of the patents indicated in the certification under subparagraph 4, Article 48-9 duly lapse.

Article 48-19.

Where the settlement or other arrangement entered by and between (or among) a new drug approval applicant, new drug approval holder, generic drug approval applicant, generic drug approval holder, patentee or exclusive licensee of a

pharmaceutical patent involves the provisions of this Chapter with respect to the preparation, distribution of drug and the exclusive marketing term, the parties to the settlement or arrangement shall report the same to the central health authority within 20 days beginning from the date following the consummation of the settlement or arrangement, and where reverse payment is involved, report the same to the Fair Trade Commission.

Rules governing the method, substance and other compliance matters of the report provided in the preceding paragraph shall be prescribed by the central health authority in conjunction with the Fair Trade Commission.

The central health authority may inform the Fair Trade Commission of any apprehension over possible Fair Trade Act violation involved in the arrangement reported pursuant to the first paragraph hereof.

Article 48-20.

The provision of Article 48-9 to Article 48-15 concerning the application for generic drug approval shall apply with appropriate and necessary alterations to all new drugs other than those new drugs of new chemical entity.

The provisions of Article 48-13 to Article 48-18 concerning suspension of issuance of drug approvals and grant of exclusive marketing term do not apply to the generic drug approval application provided in Article 48-12 if the application runs into either of the contexts as follows:

1. The listed patent(s) of a granted new drug is valid in good standing and a medical usage patent provided in subparagraph 3, paragraph two of Article 48-3

2. The applicant for generic drug approval excludes the indications of the medical usage patent provided in the preceding paragraph and makes a certification that the generic drug is non-infringing upon the patent provided in the preceding subparagraph.

Rules governing the exclusion of indications, certification, and other compliance matters provided in the preceding paragraph shall be prescribed by the central health authority

Article 48-21.

For the pharmaceutical patents which meet the requirements provided in the second paragraph of Article 48-3 and which remain valid in good standing before the amendment of December 29, 2017 to this Act comes into force, the new drug approval holder may report and list the patent information pursuant to Article 48-4 within three (3) months after the above amendment comes into force.

Article 48-22.

Rules governing the method, substance, change or deletion of the report and the listing and publication of patent information provided in Article 48-4 to 48-8,

certification made by the generic drug approval applicant provided in Article 48-9, method and substance of the written notice issued by the generic drug approval applicant provided in Article 48-12, method and substance of the notice issued by the central health authority of completion of its examination of the generic drug approval application provided in Article 48-15, and the counting and termination of the exclusive marketing term and other compliance matters provided in Article 48-16 to Article 48-18 shall be prescribed by the central health authority.

Article 92-1.

Where the new drug marketing approval holder does not respond to the central health authority within the prescribed time limit as set forth in the third paragraph of Article 48-7 and further fails to make a response within another time limit set by the central health authority, the central health authority will impose an administrative fine of no less than TWD30,000 and no more than TWD500,000 on the approval holder.

Where no report is made in accordance with the method and substance designated in the first and second paragraph of Article 48-19, the central health authority will impose an administrative fine of no less than TWD30,000 and no more than TWD2,000,000.

Article 100.

Unless otherwise provided, the administrative fines specified in this Act shall be imposed by the municipal or county (city) health authority.

Article 100-1.

In the event that any new drug marketing approval holder reports and lists patent information in accordance with Article 48-3 through Article 48-6 hereof in deceptive or false methods and thus involves criminal liabilities, such new drug marketing approval holder shall be referred to the judicial authority for investigation.

Article 106.

This Act shall come into force from the date of promulgation.

The date of enforcement of Article 53 of this Act, which was promulgated on May 7, 1997, shall be decided by the Executive Yuan. Articles promulgated on May 5, 2006 shall take effect from July 1, 2006.

The date of enforcement of Chapter 4-1, Article 92-1, Article 100, and Article 101 promulgated on December 29, 2017 shall be decided by the Executive Yuan.