Article Content

Title：	Regulations for Registration of Medicinal Products CH
Amended Date：	2023-04-27
Category：	Ministry of Health and Welfare（衛生福利部）
Attachment：	Appendix1：Maximum Drug Package Size Dosage.pdf Appendix 1-1：Prescription Drug’s Package Insert Format.pdf Appendix 2：Documents for the Application forDrug Review and Registration of New Drugs, New Dosage Forms, New Administration Doses and New Unit Strengths.pdf Appendix 3：Technical Documents for the Application for Drug Review and Registration of New Drugs, New Dosage Forms, New Administration Doses and New Unit Strengths.pdf Appendix 4：Documents for the Application for Drug Review and Registration of Generics.pdf Appendix 5：Technical Documents for the Application for Drug Review and Registration of Generics in the Dosage Forms of Liposome or Transdermal Absorption.pdf Appendix 6：Documents for the Application for Drug Review and Registration of Bio-Pharmaceutical Products.pdf Appendix 7：Technical Documents for the Application of Drug Review and Registration of Bio-Pharmaceutical Products.pdf Appendix 8：Documents for the Application of Drug Review and Registration of API.pdf Appendix 9：Technical Documents for the Application of Drug Review and Registration of API.pdf Appendix 10：Documents Required for the Application for Drug Review and Registration of Radiopharmaceutical Drugs.pdf Appendix 11：Technical Documents Required for the Application for Drug Review and Registration of New Drugs, New Dosage Forms and New Dose of Radiopharmaceutical Drugs.pdf Appendix 12.PDF Appendix 12.doc Appendix 12-1：Matters that Should be Applied for Changes of Manufacturing Process and Batch Size of Drug Product.pdf Appendix 12-2：Documents for the Application of Registration Changes of Manufacturing Process and Batch Size of Drug Product.pdf Appendix 13.pdf

Chapter 1 General Principles

Article 1

The Regulations are established pursuant to Article 39 Item 4 of the Pharmaceutical Affairs Act (hereafter the Act).

Article 2 The registration of drugs, and the post-approval change, transfer, extension, or reissue of damaged or lost drug licenses should follow the Regulations. Matters not included in the Regulations are subject to other regulations, orders or announcements made by the central health competent authority.

Article 3 For the registration items mentioned in the preceding article, the applicant should pay the application fees and submit completed application forms and all required dossiers to the central health competent authority for assessment.
The above-mentioned application forms and documents include those for drug review and registration, post-approval changes, extension of validity of drug license, assurance statement, sticking label and package insert, sticking licenses and certificates, and other forms and documents in relation to the application procedure.
“Chinese language” in the Regulations denotes traditional Chinese. For forms and documents requiring Chinese language, please provide information in traditional Chinese characters or documents with translations in traditional Chinese characters.
The license holder may retain the original certificates for future inspection when submitting an application via the electronic submission platform an electronic system, but needs to submit the original drug license to the central health competent authority to have the approval status marked on the license.

Chapter 2 Western Medicine

Section 1 General Provisions

Article 4 The terms used in this chapter are defined as follows:
1.New drugs: the new drugs described in Article 7 of the Pharmaceutical Affairs Act.
2.Generic drugs: pharmaceutical preparations identical to a drug already approved in Taiwan in the aspects of ingredients, dosage form, contents and efficacy.
3.Bio-pharmaceuticals: serum, antitoxin, vaccines, toxic, bacteria sap and products manufactured based on the theories of microbiology and immunology.
4.Substances (Active pharmaceutical ingredients): An active substance or ingredient manufactured through physical and chemical processes or bio-tech procedures and with pharmacological effects that are often used for the manufacturing of drugs, bio-pharmaceuticals or bio-tech

products.
5.Radiopharmaceutical drugs: drugs meeting the definition given i
containing radioactive substances for human uses. After being adm
humans, the drug can diagnose, monitor, treat, alleviate disease
achieve other medical effects.

Article 5 The term “authorization letter” mentioned in this Chapter refers to the documents issued by the foreign manufacturer, headquarters or the license holder of an imported drug to authorize the application of drug registration.
The above-mentioned authorization letter is effective for one year from the issuance date. The authorization letter should include the names and addresses of the manufacturer and the agent, as well as drug name, dosage form and contents. The information should be consistent with those stated in the application form. If the authorization letter is in neither Chinese nor English, a Chinese or English translation should be provided additionally.
If the original license holder has a branch office in Taiwan, the authorization letter can be issued by either the manufacturer’s headquarters or the head office in Asia.

Article 6 The FSC (Free Sales Certificate) from the country of origin mentioned in this Chapter means the original document issued by the highest health competent authority of the country of origin, therein justifies the manufacture and sale of the product in that country. The following conditions should be met:
1.If the required document is in neither Chinese nor English, a Chinese or English translation should be provided additionally.
2.The document is effective for two years from the issuance date, and it should be authenticated by the embassy, representative office or agencies authorized by the Ministry of Foreign Affairs of R.O.C (hereafter the R.O.C foreign affairs offices).The authentication requirement is waived for documents issued by A10 countries, which include Germany, US, UK, France, Japan, Switzerland, Canada, Australia, Belgium, and Sweden.
3.Information of the product name, manufacturer’s name and address, drug formulation, dosage form and contents stated on the document should be consistent with the information on the application form. The product name of exporting drug should be stated in this document; otherwise, a letter issued by the original manufacturer should be provided to explain and to give the product name of exporting drug, as well as to certify that the product is consistent with every description on the CPP (Certificate of Pharmaceutical Product) except for the product name. For capsules, in addition to the full formulation of the drug, the full formulation of soft capsule, or the coloring

agents of hard capsule should be described accordingly. In cases does not state the coloring agents of hard capsule, the original should issue a letter to explain.
4.The CPP should specify the drug manufacturer and state the fact product has been approved for free sale in that country. The desc manufacturing and free sale should be clear.
The following documents can substitute for the above-mentioned FS country of origin:
1.FSC issued by the selling countries approved by the central hea authority;
2.For drugs listed in the United States Pharmacopeia Drug Informa in the Approved Prescription Drug Product with Therapeutic Equiva Evaluations (Orange Book) published by the US FDA, applicants may photocopy of the pages of the product (printouts from the Interne electronic version are acceptable), as well as the FSC issued by authority of the State Government as a replacement for the one is FDA;
3.For products manufactured in Germany, the FSC can be issued by authority of a state government. Notarization from the Federal Go not be necessary;
4.For products manufactured in any of the EU countries, the FSC i European medicinal Agency (EMA) is acceptable; and
5.For toll-manufactured products that have not been sold in the c toll-manufacturers are located, the FSC from the country where th is located together with the manufacturing license from the count manufacturing takes place are acceptable substitute. Another acce alternative is the FSC from the country where the commissioner is which states the manufacturer’s name and address.
Except as otherwise regulated in the Regulations, Paragraph 1 Ite are applicable to the above-mentioned alternative documents and t of changes issued by the country of origin.

Article 7 Except as otherwise regulated in the Regulations, the CPP said in this Chapter should be issued by the highest health competent authority of the issuance country and authenticated of any one of the A10 countries or the EMA.
CPP can be replaced with the following documents:
1.The package insert approved by the reference country or a photocopy of the reference country’s pharmacopoeia (as listed below, as “official formulary”); printouts from the Internet or the electronic version are also acceptable. It does not have to be issued by the highest health competent authority of the reference country, nor be authenticated by the R.O.C. foreign affairs offices. The edition of the cited official formulary should be indicated, and has to be published within 5 years from the citation.
(1) US: Physicians’ Desk Reference (PDR);

(2) UK: British National Formulary (B.N.F.), Medicines Compendium Association of British Pharmaceutical Industries, ABPI);
(3) Japan: Drugs in Japan, the most recent new drugs in Japan;
(4) Switzerland: Arzneimittel-Kompendium der Schweiz;
(5) Canada: Compendium of Pharmaceuticals and Specialties;
(6) France: Dictionnaire VIDAL;
(7) Australia: MIM'S;
(8) Germany: Rote Liste;
(9) Belgium: Repertoire Commente des Medicaments;
(10) Sweden: Farmaceutiska Specialiteter i Sverige (FASS);
2.The approval letter and the approval information on the website health competent authority of any one of the A10 countries or the

Article 8 Except as otherwise regulated, the formulation basis mentioned in this Chapter refers to the pharmacopoeia or official reference books published in the A10 countries of editions published within 5 years from the date of application. Formulation basis should meet the following criteria; its title, edition, year of publication and page numbers should all be indicated. A photocopy of complete reference pages should be provided. If the reference is in neither Chinese nor English, a word for word Chinese translation should be provided; but proper names or technical terms can be listed in English.

1.If USP is submitted, then the USPDI shall also be provided for assessment. Extra pharmacopoeia, which is not an official reference book, is for reference only.

2.If the applied formula is not completely consistent with the submitted reference and some alternations have been made, a statement explaining the alternation should be provided. Information in relation to the actual changes should be submitted as appropriate.

3.Tablets, film-coated tablets and sugar-coated tablets can use the same formulation basis, but not for enteric-coated tablets.

4.The formulation basis of ointment and cream can be used interchangeably, provided that the products are not under pharmacovigilance.

5.If the formulation basis or the CPP is of tablets, the reasons for the application of double-layered tablets should be given. Moreover, the package inserts and labels shall not include exaggerated therapeutic effects associated with the dosage form. Any boost of effects due to dosage forms should be approved and justified by clinical data before they can be indicated in package inserts or labels.

6.If the formulation basis submitted by local manufacturers for drug registration is not pharmacopoeia or reference books published by the A10 countries, the Orange Book or USPDI published by the US FDA can be used instead.

New drugs, new dosage forms, new administration doses or new unit developed in Taiwan do not need to submit formulation basis. Howe researches of formulation design and technical data in relation t should be submitted.

Article 9 The testing specifications, methods and certificate of analysis of raw materials mentioned in this Chapter refer to those for active pharmaceutical ingredients (API) and every substance of the formula (including auxiliary materials and coloring agents added during the manufacturing process).
The testing specifications, methods and certificate of analysis of raw materials said in the preceding paragraph should comply with the following regulations:
1.If using a pharmacopoeia as a reference for raw materials, the applicant should indicate the pharmacopoeia's titles, publication year and editions. The pharmacopoeia is restricted to the Chinese Pharmacopoeia, pharmacopoeias published by the A10 countries, or pharmacopoeias approved by the central health competent authority. The cited edition should be the latest from the date of application. This requirement also applies to any post-approval change of raw materials except excipients.
2. New chemical entities (NCE) are subject to the regulations set by the manufacturers.
3. The reference standards for tests should be indicated whether they are Primary Standard or Working Standard. For Primary Standard, the source should be specified. For Working Standard, the source, batch number, labelled content (or potency), testing specifications, certificate of analysis and calibration procedures should be specified.
4. For coloring agents, testing specifications and methods should be indicated. Testing specifications are not required for aromatics.
5. The certificate of analysis justifying every formulation substance should be the certificates about the substances of the same lot as the finished products.
6. Raw materials should be tested against each specification item. Documented operational procedures of items exempted from tests should be submitted, along with the certificates of analysis of the batch subject to full tests.
7. If test results are in numerical figures, then keep the original data in the document; if the test is a comparison with reference standard, then use "pass" to indicate a satisfactory result.

Article 10 The testing specifications, methods and certificate of analysis of finished products mentioned in this Chapter refer to those performed on pharmaceutical preparations.

The regulations of testing specifications, methods and certificat
finished products said in the preceding paragraph are as follows:
1.If the applied drugs are listed in pharmacopoeias, the testing
attached to the application form should include the pharmacopoeia
publication year and editions. Such reference is restricted to th
Pharmacopoeia, pharmacopoeia published in the A10 countries or ac
the central health competent authority in Taiwan. The cited editi
latest from the date of application. This requirement also applie
approval change of finished products. The publication year has to
years from the date of application. If the item in the pharmacopo
more than two esters or salts, or contains ingredients with cryst
anhydride, the applicants should clearly specify which one is app
application. In vitro pyrogen test methods should be considered a
animal tests.
2.For each active ingredient, the applicant should state its stan
and methods in the testing specifications. Denotation of the iden
assay of the contents should not be simply summarized as “operate
certain pharmacopoeias”.
3.If necessary, upon the request of the central health competent
applicant should provide test records, including the information
all test data to justify whether current regulations and criteria
(1) Sampling venues, quantity, batch numbers or other specific co
sampling and the date when tests were completed;
(2) References to justify every test method;
(3) The weight or volume of samples for each test;
(4) The reference standards for each test should be indicated whe
Primary Standard or Working Standard. For Primary Standard, the s
specified. For Working Standard, the source, batch number, conten
test specifications, certificate of analysis and calibration proc
specified;
(5) Complete data records produced from each test, including equi
charts and spectrums, etc. All data should be clearly described t
confusion;
(6) All calculation records associated with tests;
(7) Conclusions on the comparison between test results and existi
specifications;
(8) For every test, the names of the persons performing the test
the test;
(9) Signatures from reviewers who have checked the original recor
safety and the compliance with existing specifications.
4.Provisions set out in Paragraph 2 Item 5 to Item 7 of the prece
applicable to the certificate of analysis of finished products.
For toll-manufactured pharmaceutical products, the tests of finis
should comply with the Guidelines on Toll-Manufacturing and Contr
Pharmaceutical Products. The purpose of those tests is to ensure
Tests can be performed by the commissioned toll-manufacturers.

Article 11 The Manufacturing and Control Standard mentioned in this Chapter refers to the Manufacturing and Control Standard in compliance with Part 2 of Good Manufacturing Practice Regulations (Good Manufacturing Practices for Pharmaceuticals), including data of the actual amount of material used in batch records.
The manufacturing records mentioned in this Chapter refer to the manufacturing records of the same lot as the samples submitted for tests. In the case where the data of the same lot is not available or the products are exempt from testing, the applicant can submit the manufacturing records of any batch produced within two years from the date of application or a representative batch.
The representative batch is a batch of drug product that is manufactured using the same formulation, manufacturing process, and in-process controls, etc. as the application for drug registration or post-approval changes. The applicant should provide proof of the unaffected product quality for the change of the manufacturing process and in-process controls, and should be approved by the central health competent authority.

Article 12 The term “changed licenses” mentioned in this Chapter includes supporting documents of factory registration, drug company licenses and certificates or official documents of company registration and business registration.
Photocopies or photos of the following documents shall be affixed on the form:
1.Drug company license;
2.Supporting documents of factory registration (imported drugs are exempted); and
3.Certificates or official documents of company registration or business registration.
The affixing form can be exempted, if the documents said in the preceding paragraph are submitted via the electronic submission platform.

Article 13 The original references of data submitted to support the application should be provided, including physicochemical characteristics, pharmacological and toxicological test data, pharmacokinetic data, bioavailability rate, documents of clinical usage and other research reports. They can not be substituted by general descriptive information, summarized data or case reports. If the original references are in neither Chinese nor English, then a translation version in Chinese or English should be submitted along with the translators’ names.

Article 14 Product names should comply with the following regulations:
1.Do not use the other manufacturer’s name or trademark as a product name, except in the case the use has been authorized;

2.Products named after items in pharmacopoeias, common names or c
formulas should include the company’s name or trademark or any di
title as a prefix; but, this naming rule does not apply to export
3.Product names can not be identical to any other exiting product
Counterfeiting or insinuation is not allowed;
4.Product names should not be deceitful or exaggerated, nor shoul
misinterpretation on product efficacy;
5.Chinese product names should not include any foreign letters or
therein lies real meanings;
6.For drugs whose licenses have been revoked pursuant to the Acts
names are banned from use for two years; but, this two-year ban d
the following situations: the application is a re-submission acco
condition stated in Article 72 Paragraph 1; or, the original lice
to export-only license; or, the reasons of the revocation or canc
export-only license are irrelevant to drug safety or effectivenes
central health competent authority’s approval, the manufacturer c
drugs with identical ingredients, dosage form, dose and efficacy
names.
7.If a manufacturer gave compounds with different formulas the sa
then their Chinese product names should contain proper words or t
distinguish their differences in efficacy; and
8.Names that are inappropriate for pharmaceutical products shall
In order of priority, whether product names are identical or simi
trademarks, the manufacturer’s name and other distinguishable nam
the situation described in Item 3 in the preceding paragraph, the
name and trademark will not be included in the comparison.
For drug items already granted with market licenses, the central
authority may reassess their product names pursuant to the previo
paragraphs.

Article 15 Drug packaging materials and the data field of packaging on the application form should comply with the following regulations:
1.The quantity, materials and types of the drug packaging should be specified;
2.Except for oral nutrient liquids, all bottled solutions for oral internal use and syrups, shall not be packed in ampoule. The volume should be indicated on each bottle; and
3.The unit recorded in the data field of packaging on the application form should be identical to the unit dosage form of the formula.
The maximum package size for drugs should follow the standards in the Table of Maximum Package Size. If there are any special purposes for the maximum package size, the purposes should be stated on the packaging. For common pharmaceutical preparations, the minimum package size is the two-day dose for an adult. For syrup containing codeine (phosphate) as an instruction drug, the maximum package size is the three-day dose. Tablets or capsules

containing ephedrine or pseudoephedrine should only be packed in blister foils and boxes. For instruction drugs, the maximum packa seven-day dose for an adult. For drugs for the cold, fever, pain the cough liquid, the package size should be between one single a 4000 ml. The restrictions do not apply to sickness drugs and pest Please see Appendix 1 for the Table of Maximum Package Size as me In the situation where the packaging is over its maximum package application to change the registration should be made by providin purchasing orders from health care providers or academic institut application for changes does not apply to instruction drugs conta or pseudoephedrine.
Appendix1：Maximum Drug Package Size Dosage.pdf

Article 16 The applicant should honestly and completely fill out the application form, including the company name, code, address, telephone number, drug company license number, the person in charge of the business, the pharmacist in charge of the management or manufacturing, and the pharmacist's address, and license number. The information should be confirmed by using private signets. The signets can be exempted, if the application is submitted via the electronic submission platform.
The same signets or stamps used in the application form should be used for any follow-up applications. The applicant should report to the authority if the signet or stamp is lost.
In the situation of toll-manufacturing, the names, codes and addresses of all manufacturers involved in the manufacturing processes should be listed in the data field of manufacturers on the application form.

Article 17 The information given in the data fields for raw materials and contents on the application form should comply with the following regulations:
1.The contents of the formula should be indicated per minimum unit;
2.The contents should be in International System of Units (SI), without including the increasing rate;
3.For pharmaceutical preparations containing ingredients of crude drug, the active ingredients in the formula should be listed in the order of chemical ingredients and the ingredients of crude drugs;
4.Solvent, auxiliary solvent, stabilizers and other excipients used for injections should be described in detail and be suitable for injection. The contents of the formula should be indicated per minimum unit. However, for powder or lyophilized injections, the contents can be indicated per minimum package size;
5.The English names and contents of aromatics, coloring agents,

preservatives and other excipients should be indicated;
6.Artificial flavouring may be added if the use is medically just shall not be added to the nutrient liquid;
7.For capsules, in addition to the full formula of the drug, a de full formula of soft capsules, and coloring agents of hard capsul described accordingly;
8.The ingredient and contents of active pharmaceutical ingredient described in a way consistent with the method used in a pharmacop
9.If the item includes more than two esters or salts or contains crystallized water or anhydride, the applicant should clearly spe is relevant to this application;
10.The sources of active ingredients of drug products (manufactur manufacturers' addresses and the country of origin) should be spe data can be declared electronically after the approval of the reg

Article 18 The information given in the data field of indications on the application form should be based on the drug efficacy or indications approved by the central health competent authority, including the drug re-categorization, drug re-evaluation results, and the Guidelines on the Review of Instruction Drugs. When filling in the information of drug efficacy and indications, in addition to following the regulations stated in the preceding paragraph, the applicant can also provide a summary by taking references from information on new drugs and new indications and formularies of the A10 countries. If there are any changes in efficacy, related information should be provided for review.

Article 19 Assurance Statements (A) and (B) attached to the application form should include the company name, address, person in charge and the date of signature. The information should be confirmed by using the same signets or stamps as those for the application form. In the situation of toll-manufacturing, assurance statements from both the appointer and the appointee are required.

Article 20 Drug labels, package inserts and packaging are subject to Article 75 of the Regulations, and can contain only the information approved by the central health competent authority. The statutory contents and presentation should comply with the following regulations and the print should be easy to read:
1.Package inserts should include information on drug category, packaging, storage and all compulsory matters required by other regulations;
2.The outer packaging of imported drugs should meet the following conditions:
(1) The Product name, active ingredients and contents, and the name and address of the manufacturer or company should be

printed by the original manufacturer. If the manufacturer’s name
not printed on the outer packaging, this information should be pr
sticker adhering to the outer packaging;
(2) The company name, address and license number of the drug comp
category and Chinese product name can be provided on a sticker;
(3) If the information of the manufacturer’s name and address is
the outer packaging by the original manufacturer, it may be print
with the information as stated above in the preceding item (2); a
(4) For toll-manufactured products, with approval from the centra
competent authority, the appointee’s name and address can be subs
country from where the appointee is located.
3.For generic drugs under pharmacovigilance, the package inserts
that of the first approved drug. For the registration or the chan
inserts of generic drugs not under pharmacovigilance, the package
follow the approved drug of the same active ingredient, same dosa
contents and same indication. The supplemented information on pro
characteristics and drug safety also can submit scientific eviden
limited to those who have supplemented information on product cha
drug safety, and submitted scientific evidence for the contents o
supplement. The central health competent authority may ask for re
package inserts if it is necessary.
4.The process of labelling is deemed a part of the manufacturing
subject to GMP Guidelines. For imported drugs, labelling should b
original manufacturer. Packaging and labelling can be commissione
manufacturer or a GMP medical product distribution center in Taiw
the Guidelines on Drug Toll-Manufacturing and Contract Testing. I
the GMP manufacturer or GMP medical product distribution center i
packages and labels drugs in accordance with this paragraph may b
the stickers.
5.Outer packaging and the immediate packaging have to be labelled
English, pursuant to this article. If the immediate packaging doe
enough space to include information in both languages, at least p
contents in Chinese should be provided. Labels listed below are d
compliance with this Paragraph.
(1) Injections that are packed in one injection per box for singl
Chinese information printed on outer packaging;
(2) Drugs that are sold or dispensed in original packaging with t
remaining intact, on which Chinese information is printed; or
(3) Drugs that are classified by the central health competent aut
used only by physicians with outer boxes printed with Chinese inf
6.For the following drug items, if Chinese information is provide
boxes, then only the Chinese or English product name and contents
the immediate packaging to meet the regulations in the preceding
(1) Drugs for rare diseases;
(2) In situations where special storage conditions are required,
need to be refrigerated or frozen; or
(3) Special cases that the central health competent authority’s a

is required.
7.In principle, the information on package inserts should be with pharmacological scope of its active ingredients and major efficac preparations, the scope should be within the scope of the major p functions of mixed active ingredients. Exaggerated terms and word allowed.
8.Contraindications, warnings, side effects, and precautions stat inserts should be indicated in detail and printed in red, framed in boldface to attract the special attention of users.
9.Chinese characters should not be smaller than font size seven.
10.Drugs sold on the market may only provide approved Chinese pac However, if both Chinese and English package inserts are provided of the English version should be consistent with that of the Chin Manufacturers may of their own accord modify the contents of the to fit the Chinese version.
11.Package inserts, labels and packaging materials should not inc wordings that are indecent, offensive or exaggerated.
12.If the distributor’s name is printed on the package inserts, l materials, the font size of the distributor’s name should not be of the manufacturer (license holder). A photocopy of the distribu license should be submitted for reference.
13.The font size of the Chinese product name should not be smalle foreign language. The printing should be clear. As a standard for height of the printing of product name in Chinese should not be l in foreign language.
14.For OTC (Over-the-counter) drugs, the labels and packaging sho significant prints of the product category, i.e. OTC drugs or Cla In principle, printing should be in regular fonts.
15.Whereas the active ingredients, dosage form, dose and administ a licensed drug remain unchanged, the appearances or shapes of it coloring agents or corrective agents without any pharmacological altered but do not affect drug quality or medication safety, then justified by applying for post-approval changes for excipients as new contents. Appropriate descriptions should be given on labels, and outer packaging for clear differentiation. Graphic designs an changed to suit the new descriptions.
16.For drugs packed in aluminum blister foils, each sheet of foil printed with the drug name using Chinese as the main language. Ma name and license number can be provided. The following conditions meet the criteria of this Paragraph:
(1) The product name in Chinese has been printed on (or adhered t packaging of each aluminum blister foil sheet;
(2) Drugs are dispensed or sold in original packaging with the ou remaining intact, on which information in Chinese is printed.
17.Drug labels and packaging should contain information of batch manufacturing date, effective period and expiry date in any of th format:

(1) batch number, manufacturing date and effective period;
(2) batch number and expiry date; or
(3) batch number, manufacturing date and expiry date.
18.The manufacturing date and expiry date as mentioned in the pre
should be written with Arabic numbers using four-digit format for
month and year are shown for the expiry date, either year-month o
format is accepted. For manufacturing date and expiry date contai
components (year, month, day), the date should be written in the
format (from left to right). If other date notations are used due
circumstance, the format used (e.g., dd/mm/yyyy, day/month/year,
clearly expressed on the outer box. But, for products whose valid
over 2 years, the manufacturing date and expiry date can include
only and set at the last day of that labelled month as the expiry
19.Information of the materials that have direct contact with pha
products should be labelled on plastic containers of L.V.P. (larg
package) for infusion.
20.The active ingredient(s) and excipients should be labelled res
package inserts. The excipients may be written in chemical name o
and the excipients not existing in the final product may not be l
21. For new drug registration or change in package inserts of pre
the drafts of package inserts should follow the format (prescript
package insert format in Appendix 1-1).
Concerning locally manufactured drugs for exportation, shall not
the limitations set forth in the preceding paragraph Subparagraph
and 16-21.
Statutory package inserts, labels, outer boxes, aluminum blister
materials or graphic for labelling purpose should comply with the
items required to be printed as announced by the central health c
authority, as well as the drug re-evaluation results, Guidelines
OTC Drugs, drug re-categorization and regulations of standardized
inserts.
In addition to the regulations set out in previous three paragrap
additional printings on labels and packaging of controlled drugs
comply with the Regulations Governing Controlled Drugs as well as
regulations.
Color drafts of outer boxes, package inserts, labels, aluminum bl
other labelling materials should be adhere to the form for sticki
package insert. The affixing form can be exempted, if the documen
preceding paragraph are submitted via the electronic submission p
When collecting license, applicant should submit the electronic f
image of drug appearance, labels, package insert and packaging as
central health competent authority. For applications of post-appr
drug appearance, labelling, package insert or packaging, electron
new contents approved by the central health competent authority s
submitted.
Appendix 1-1：Prescription Drug’s Package Insert Format.pdf

Article 21 Validation requirements for medicinal product are described as follows:

1.When applying for drug review and registration, the applicant may firstly prepare the analytical method validation report and the protocol of the validation of critical manufacturing processes. After receiving approval, the manufacturer should conduct validation studies on three consecutive batches of products. If the results meet all specified criteria, the product can therefore be marketed.

2.The validation studies should be able to assure drug effectiveness and safety and comply with the Guidelines on GMP Validation Requirements as announced by the central heath competent authority.

3.The contents and schedule of a drug validation process are as follows:

(1)Manufacturers should submit the validation documents of the supporting system, equipment and facility, critical manufacturing processes (including cleaning validation) and analytical method of at least one product to the central health competent authority for inspection. The submission deadlines were 31 December 2000 for local manufacturers and 10 June 2002 for license holders of imported drugs. For those failing the submission or the assessment, the authority will make a public list of their company names and all their approved drug licenses in Taiwan, and give a deadline for improvement. These companies are not allowed to file any applications of new drug registration. Companies missing the deadline for improvement will be denied the rights to apply for license extension.

(2)Manufacturers should submit the validation documents of the critical manufacturing processes (including cleaning validation) and analytical method of all products to the central health competent authority for inspection. The submission deadlines were 30 June 2002 for local manufacturers and 10 December 2003 for license holders of imported drugs. Companies failing the submission or the assessment will be handled according to the proceedings stated in item (1).

(3)Manufacturers should fully implement all validation processes and submit the documents to the central health competent authority for inspection. The deadlines for submission are 30 June 2004 for local manufacturers and 10 December 2005 for license holders of imported drugs. Companies failing the submission or the assessment will be handled according to the proceedings stated in Item (1).

(4)Validation would not be necessary for license holders that do not manufacture or import drugs to sell. This exemption took effect from 1 July 2002 for local drugs and from 11 December 2003 for imported drugs. However, licenses of imported drugs may

be extended without validation, if the license holder submits the
and an assurance statement certifying that the drug will be impor
only after all validation documents have been submitted and appro
will be stamped, noting that the drug can not be imported due to
required documents. After all documents are submitted and approve
will be re-stamped, indicating that the drug can now be imported
grounds that full compliance has been met with the DOH’s requirem
(5)Penalties will be imposed on license holders pursuant to the P
Affairs Acts, if drugs have been produced or imported to sell wit

Article 22 The information and local clinical data required for the application of drug registration or post-approval changes should comply with the following regulations:
1.Clinical trials conducted in Taiwan should follow the Regulations for GCP (Good Clinical Practice), as well as the Notices for the Application of Clinical Trials and the Guidelines on Bridging Studies as announced by the central health competent authority.
2.Before conducting a clinical trial, the manufacturer should submit a protocol, a protocol summary and an application form to the central competent health authority for assessment.
3.After the application is approved by the central health competent authority and an official approval letter is issued, the manufacturer should carry out the clinical trial according to the comments provided with the assessment results. After the completion of the clinical trial, the results should be submitted for inspection.
Clinical data from foreign countries submitted together with the application should have a comparison with a control group or a double-blind test design. This data cannot be substituted by a general descriptive document, summarized data or individual case report. The regulations set forth in the preceding item are applicable to the technical data of local clinical trials.

Article 22-1 Except for drugs with relevant local clinical trial data to justify drug efficacy and safety in Taiwan, alone with pharmacokinetic data on ethnic groups in East Asia, the following drug items are subject to a bridging study assessment:
1.New chemical entities and new biologics;
2. Items announced by the central health competent authority as requiring a bridging study assessment.
Drugs received designations of treatment of pediatric or rare severe disease from the central health competent authority, cellular and gene therapy products are exempted from the bridging study assessment.
When applying for a bridging study assessment, manufacturers should fill out the checklist for bridging study assessments and

provide a complete clinical data package, preferably with data on
in East Asia. Applications of bridging study assessments can be f
together with the applications of drug registration.
Bridging study data would not be required for the applications of
registration that have been approved by the central health compet
be exempt from bridging studies. However, there should still be s
clinical data to justify drug efficacy and safety.
If the assessment result suggests that a bridging study is necess
applicant should prepare an appropriate protocol according to the
the assessment and submit the protocol to the central health comp
for assessment. After the protocol is approved, the applicant sho
bridging study and submit study reports and related data to the c
competent authority for inspection.
In situation where a license is granted to a new drug with the su
bridging study data, if in the next 5 years any generic manufactu
manufacture or import generics with ingredients, dosage form and
identical to this new drug, then the generic manufacturer should
required data and a bridging study report up to the standards set
license holder.

Article 22-2 For drugs other than the categories listed in the preceding article, whether an application of a bridging study assessment shall be filed is left to the discretion of manufacturers. For applications without bridging study data, if the central health competent authority considers that a bridging study is necessary, the manufacturer is obliged to conduct a bridging study.

Article 23 If the application for drug registration concerns about a drug involved in toll-manufacturing or contract analysis, then the applicant should submit data required by the Guidelines on Drug Toll-Manufacturing and Contract Analysis and all related information required by Article 64 and Article 66.

Article 24 Except as otherwise regulated, all applications covered in this Chapter are subject to a parallel assessment of dossier review and drug testing. If the submitted dossiers pass the assessment, then the applicant should follow the notice issued by the central health competent authority to collect the license. Once the test specifications are approved, the applicant should follow the notice issued by the central health competent authority to proceed with drug testing.
The following applications only require dossier review, while drug testing can be exempt except for those cases deemed by the central health competent authority as drug testing being necessary.
1.Drug registration:
(1)Pharmaceutical preparations classified as OTC drugs

(including Class B OTC drugs);
(2)Vitamins meeting the criteria for products containing vitamin
(3)Generics;
(4)Pharmaceutical preparations meeting the criteria set out by th
the Review of Over-the-counter Drugs;
(5)General active pharmaceutical ingredients; and
(6)Pharmaceutical preparations and active pharmaceutical ingredie
exportation only.
2.Post-approval changes
As mentioned in the preceding paragraph, for those drugs that onl
dossier review, the applicant should submit color photos or scann
sample product for assessment. If necessary, a reference standard
provided for comparison.

Article 24-1 Except for radiopharmaceutical drugs, cell-based preparations and biopharmaceutical drugs needed to be tested by registration, the applicants should provide samples of new chemical entities, new compound medicine and the first active pharmaceutical ingredient to the central health competent authority for future inspection prior to be on the market.
If the above-mentioned new chemical entities and new compound medicine are applied for a change in the dosage form of Article 52, a change in the formula of Article 53, a change in the excipient of article 56, a change in product appearance of Article 57, a change in the site relocation or the place of production of Article 62 Paragraph 1 Item 2, a change in the pharmaceutical toll-manufacturing of Article 64, and self-manufacturing retrieval after outsourced of Article 65, the applicants should also follow the preceding paragraph.

Article 25 In any of the following situations, applications will be rejected:
1.Applicants don’t have the qualifications required, or manufacturing equipment does not meet the standard, e.g. hardware, software or dosage form equipment does not comply with GMP Guidelines; or there has been no submission of evidence to support compliance with related regulations;
2.No application fees have been paid, or the submitted data is insufficient or does not fit with the contents of the application;
3.The major efficacy of the applied drug is unclear or insignificant; or the drug fails the drug re-evaluation;
4.The applied drug has severe side effects or safety concerns;
5.The contents of toxins or controlled substances contained in the applied drug do not conform to regulated doses;
6.The applied drug contains unapproved coloring agents, preservatives or anti-oxidants;

7.The applied drug contains forbidden ingredients;
8.The applied drug has inappropriate formula, manufacturing metho
form;
9.The ingredients of an oral liquid product are not nutrients, or
Caffeine-like substance;
10.Hormone (including anabolic hormones, steroid), stomachics, pe
sickness drugs or pharmaceutical preparations with effects of ant
antipyretic, antitussive, expectorants or other medical efficacy,
registered in the dosage form of oral liquid;
11.Amino acid and multi-vitamin nutrition that in total contain o
alcohol;
12.Syrup containing codeine (phosphate) with the content of sucro
w/v; or syrup categorized as Over-the-counter (OTC) drugs with th
codeine less that 1g per 100ml and in compliance with the followi
the content of codeine:
(1)The maximum daily dose is 9 mg for syrup for the cold and 18mg
antitussive or expectorants;
(2)For concomitant use with Ephedrine Hydrochloride, dl-Methyleph
Hydrochloride, the dose should be reduced by 20%;
(3)The single dose for an adult should be at least 5ml; and the f
strength should be adjusted accordingly.
13.Pharmaceutical preparations combined with Chinese traditional
western pharmaceutical medicines that contain substances affectin
nerve system, poisons or powerful drugs;
14.Inappropriate testing specifications or data references;
15.Failing to collect licenses or proceed with drug testing withi
deadline; or the drug testing results fail the assessment due to
between the results and the data submitted for the application or
reasons;
16.Failing to produce, change or modify the product packaging, la
inserts in accordance with the approved items; and
17.Any other situations not in compliance with the Regulations, r
regulations, or announcements made by the central health competen

Article 26 In situations where fees have not been paid, application forms not submitted, data insufficient or other matters not in accordance with the Regulations, the applicant should take corrective actions before the deadline specified by the central health competent authority. A two-month period is given for correction.

If the applicant is not able to meet the deadline, a written statement should be submitted to support the application of an extension. The extended deadline is one month after the expiry date of the original correction period. Only one extension will be allowed.

If the applicant fails to make correction within the original or the extended deadline, then the central health competent

authority can reject the application based on the currently avail information.

Article 27 Upon the receipt of the notice of license collection, apart from proceeding with drug testing, the applicant should pay the fees within the deadline for license collection. The procedure for license collection is as follows:

1. Two copies of actual printing materials or color drafts each of drug labels, package inserts and packaging materials that are printed in accordance with the approved draft should be provided. The application submitted via the electronic submission platform may only provide one copy of actual printing materials or color drafts.

2.The notification letter stamped with the applicant’s official seal and the signet of managing director;

3.The approved draft copy of labels, package inserts and outer packaging that were attached to the license collecting notice should be returned.

4.The photocopy of the application form of drug registration that was attached to the license collecting notice should be returned.

5.A photocopy of drug license that was attached to the license collecting notice should be returned.

License should be collected within three months of the notice date. If the applicant is requested to make corrections due to mistakes in the information on the labels, package inserts, packaging or other related materials required for license collection, the applicant should make corrections within the deadline specified by the central health competent authority before the license can be collected.

Except for the reissuance of damaged or lost drug licenses, all approved post-approval changes will be certified by the central health competent authority through noting down the changes on the original drug license with date and official stamps, then returned to the license holder. Fees for the reissuance of a new license copy will be charged.

After the license was collected, if the applicant does not follow related regulations to proceed with drug testing, or the test results are not in accordance with the contents of the application or are disqualified for some reasons, then the license has to be returned according to the central health competent authority’s notice.

Article 28 Upon receipt of a drug testing notice, the applicant should pay the test fees and send the following samples and information to the central health competent authority for testing before the deadline specified in the notice:

1.Three portions of drug samples. Each portion should be quantity carrying out specification analysis for all items;
2.Appropriate quantity of reference standards, if they are needed
3.Form for sample delivery for drug testing;
4.Fee schedule for drug testing charged by the central health com authority;
5.Color photos or scanned images of drug samples.
For applications of drug registration or post-approval changes fi pharmacovigilance period, if the central health competent authori regarding quality or other issues, then the following procedures
1.If the submitted dossiers are complete, the central health comp will inform the applicant to send samples for testing.
2.If the sample passes the tests, but the Bioequivalence (BE) tes clinical trial report has not yet been reviewed, the central heal authority shall issue a notice, conceal the data submitted for dr in a sealed envelope and return it to the applicant. The applican the envelope safe and should not open it without permission. If t the test, punishment will be given pursuant to the Act.
3.After being informed by the central health competent authority of BE test report or clinical trial report, the applicant should sealed envelope along with a photocopy of the notice to the centr competent authority to proceed with the application.
Cases or re-testing will be charged testing fees again.

Article 29 In situations where the applicant proceeds with drug testing prior to the acquirement of license, if the dossiers later fail the review, the applicant shall not request for a refund or return of drug samples.

In situations where the applicant receives a drug license and starts selling the products before the applicant proceeds with drug testing or before the test results are through, the applicant should make an exact list of the manufacturing dates, batch numbers, trading parties and quantities for each batch of products. The list should be submitted to the central health competent authority and local health authorities at 10-day intervals.

In the above-mentioned situations, if the applicant does not comply with related regulations to proceed with drug testing or if the test results are not in accordance with the contents of the applications or for any other reasons it fails the assessment; then, upon receipt of the notice, the applicant should stop manufacturing the products involved and return the drug license immediately. The applicants shall be punished according to the Act.

Article 30 For the application for drug registration of imported drugs, the regulation of testing samples, their quantity and custom

clearance procedure are as follows:
1.In principle, the quantities of samples of testing drugs and re
standards for custom clearance should be consistent with the quan
the letter of notice issued by the central health competent autho
to have the packaging remain intact, the applicant may request th
to deliberate over the factual packaging and release one single c
2.Manufacturers should follow the Regulations Governing Controlle
corresponding implementation rules in compliance with the central
competent authority for approval of the importation and exportati
drugs (including the importation of active pharmaceutical ingredi
controlled drugs for trial manufacturing). This requirement also
not classified as controlled drugs in Taiwan but an importation p
required by the manufacturing country.
The above regulations for testing samples and their quantities an
clearance procedures are also applied to the applications of post
changes of imported drugs.

Article 31 The following procedures apply to drugs already granted with licenses but that have failed the efficacy and safety assessment and to drugs whose formulas should be re-evaluated:
1.If an applicant fails yet again in the appeal after submitting clinical data, then the drug license shall not be extended after its expiration.
2.For those formulas subject to re-evaluation, if the clinical data submitted by the license holder fails the assessment, the drug license shall not be extended after its expiration.
3.For formulas failing the original assessment or those subject to re-evaluation, if the clinical data submitted for re-evaluation passes the assessment, then the post-approval changes or extension of the drug license will be approved. However, if the clinical data is incomplete or the applicant did not resubmit data, the drug license shall not be extended after its expiration.
4.For formulas failing the assessment or those subject to re-evaluation, licenses in relation to the drugs are still valid during the appeal period or before the resubmission of data for re-evaluation. However, if manufacturers do not make appeals or resubmit data, the licenses in relation to the drugs shall not be extended after its expiration.

Section 2 Drug Review and Registration

Article 32 When applying for drug registration, the applicant should provide photocopies of documents to justify that the hardware, software and dosage form equipment of the manufacturers comply with the GMP Guidelines. For toll-manufactured products, the paperwork should include all manufacturers involved in every step of the manufacturing process.

Active ingredients of drug products shall comply with GMP Guideli

Article 33 After a drug license was revoked or cancelled due to drug efficacy or safety reasons, the first application of drug with identical active ingredient, dosage form and contents should follow the regulations for the new drug registration. If the reasons for license revocation or cancelation are irrelevant to drug efficacy or safety issues, then the first application shall follow the regulations of generic drugs.

Article 34 If more than four applications for drug registration are to be filed in the same month, the applicant should apply for an approval by giving reasons and providing information on the manufacturer, including information on the equipment and technical staffs of the manufacturing and quality control departments and the manufacturer's actual manufacturing capacity. This information has to be confirmed by the central health competent authority through dossier review or site inspection of quality control, production records, sample manufacturing processes and on-site supervision.
For manufacturers meeting the validation requirements in accordance with the schedule stipulated in Article 21 Paragraph 3, each manufacturer can file three applications for drug registration every month or 36 cases every year.

Article 35 For the application for drug registration of pharmaceutical preparations, the dosage form should comply with the following regulations:
1.If a drug has two different dosage forms, then separate applications should be made. If there are different unit strengths or concentration levels of the same dosage form, then separate applications are required.
2.For powders for injection, different content volumes can be put in one application; but, injections with different concentration levels should have separate applications.
3.Powders for injection with different solvents for muscular injection and for intravenous injection should have separate applications.
4. The registration of drug may only be approved after the dosage form of the manufacturers is passed the central health competent authority's assessment.
If the medicinal products manufacturing license or approval document said in the preceding item are not available at the time of filing, the applicant shall provide the required documents before approval.

Article 36 The Stability study, in support of the application for drug registration should comply with the following regulations:

1.The stability study should include research on the drug degrada order to estimate the period of efficacy and to ensure the effect safety of drugs in use. The study should be conducted in accordan Guidelines on the Drug Stability Study as announced by the centra competent authority.
2.A stability study protocol and a report should be submitted.
3.In order to ensure the sufficiency and completeness of a stabil applicant should provide any supplementary or necessary informati central health competent authority's request. However, the applic the original data of a stability study for future inspection. No such data is required.
4.In principle, the stability study of toll-manufactured drugs sh conducted to ensure drug quality. It can be conducted by (but not manufacturers involved in the toll-manufacturing process.

Article 37 In situations where Bioavailability/Bioequivalence (BA/BE) studies are required for the application for drug registration, the study should comply with the Regulation of Ba and Be Studies in the aspects of the scope of drugs, items, reference standards, test principles, test period, principles for substitution and other matters in relation to the study.
When conducting BA/BE studies, the applicant should comply with the central health competent authority's regulation and fill out the application forms for the assessment of the BE study protocol and BE study report, the application forms for the assessment of the BA study protocol and BA study report, and for the assessment of the drug dissolution curve comparison report. The applicant should also prepare related information according to the requirements on those forms.

Article 38 The FSC from the country of origin and the CPP are not required for the application of NCE (New Chemical Entity) drugs.
In cases where the FSC from the country of origin and CPP are submitted for the aforementioned application, the central health competent authority may adjust the review process according to the actual situation.
For applications of new therapeutic compound, new administration route, new dosage form, new dose or new strength, FSC from the country of origin has to be submitted prior to license acquirement.
If the country of origin is a member of the A10 countries, then the submission of the FSC from the country of origin also satisfies the submission of CPP. If the CPP submitted by the applicant states the same manufacturer's name, address, formulation, dosage form and contents as the information of the new drug in the application, then the submission of CPP also

satisfies the requirement of submission of the FSC from the count

Article 38-1 Apart from the compliance with Article 39, the following dossiers are required for the submission of an NCE drug application:
1.Dossiers of Phase I clinical trial conducted during the development stage in Taiwan, as well as Phase III pivotal trial conducted simultaneously with other countries; or alternatively, Phase II clinical trial and Phase III pivotal trial conducted simultaneously with other countries.
2.A Post-Approval Risk Management Plan; and
3.Relevant documents and information for site inspection upon the central health competent authority’s request.
The trial results said in point 1 above have to be approved by the central health competent authority and the design of the trials has to meet the following criteria:
(1)In principle, there should be at least 10 valid Taiwanese subjects for a Phase I clinical trial, such as PK study or PD study;
(2)In principle, there should be at least 20 valid Taiwanese subjects for a phase II clinical trial;
(3)In principle, there should be at least 80 valid Taiwanese subjects for a Phase III pivotal trial; and the results have to show the similarity between Taiwan and other countries; and
(4)With the central health competent authority’s approval, the numbers of trials and subjects of the aforementioned three types of clinical trials can be adjusted on grounds of the improvement in quality, safety or efficacy of the drug, the nation’s welfare or special circumstances.

Article 38-2 Apart from the compliance with Article 39, applicants of NCE drugs should submit a CPP issued by any one of the A10 countries, plus the dossiers of clinical trials to clinically and statistically justify drug safety and effectiveness in the population in Taiwan. The results of these clinical trials have to be reviewed and approved by the central health competent authority. If necessary, the central health competent authority may request the submission of post-approval risk management plan.
The aforementioned clinical trials have to meet the following criteria:
1.In principle, there should be at least 10 valid subjects for a Phase I clinical trial, such as PK (Pharmacokinetics) study or PD (Pharmacodynamics) study, conducted in Taiwan.
2.In principle, the number of valid Taiwanese subjects in a multi-national and multi-center Phase II clinical trial should be at least 20 or more than 10% of the total subjects.

3.In principle, the number of valid Taiwanese subjects in a multi multi-center Phase III clinical trial should be at least 80 or mo the total subjects.
4.For a multi-national and multi- center Phase III study involvin countries and the trial result is going to be used to support the the US FDA or the EU EMA, one of the following conditions has to (1)In principle, the number of valid Taiwanese subjects should be 5% of the total subjects in a single trial of over 200 (inclusive (2)In principle, there should be at least10 valid Taiwanese subje trail of less than 200 subjects.
5.With the central health competent authority's approval, the num and subjects of the aforementioned four types of clinical trials on grounds of the improvement in quality, safety or efficacy of t nation's welfare or special circumstances.

Article 38-3	With the approval from the central health competent authority, clinical trials in compliance with the regulations set out in the previous two articles can be qualified for an exemption of, or a substitution for bridging studies.
Article 38-4	NCE drug applications with the submission of two or more CPPs issued by the A10 countries should comply with regulations set out in Article 39 and 22-1. If necessary, the central health competent authority may request the submission of a Post-Approval Risk Management Plan.
Article 38-5	For drugs received designations of treatment of pediatric or rare severe disease from the central health competent authority, CPPs are not required for the application of NCE. If FSC from the country of origin are not available at the time of filing, the applicant shall provide it before approval. If relevant domestic clinical trial data to the claimed indications in Taiwan is provided, the FSC from the country of origin is not required.
Article 39	Information that should be submitted for the application for drug registration of new drugs, new dosage forms, new administration doses or new unit strength are as specified in Appendices 2 and 3. Regulations for new drugs stipulated in this Chapter are also applicable to pharmaceutical preparations with new dosage forms, new administration doses and new unit strengths. Appendix 2：Documents for the Application forDrug Review and Registration of New Drugs, New Dosage Forms, New Administration Doses and New Unit Strengths.pdf Appendix 3：Technical Documents for the Application for Drug Review and Registration of New Drugs, New Dosage Forms, New Administration Doses and New Unit Strengths.pdf

Article 40 Information that should be submitted with the application for drug registration of generic drugs are as specified in Appendices 4 and 5.
Appendix 4：Documents for the Application for Drug Review and Registration of Generics.pdf
Appendix 5：Technical Documents for the Application for Drug Review and Registration of Generics in the Dosage Forms of Liposome or Transdermal Absorption.pdf

Article 41 Information that should be submitted with the application for drug registration of bio-pharmaceutical drugs are as specified in Appendices 6 and 7.
Appendix 6：Documents for the Application for Drug Review and Registration of Bio-Pharmaceutical Products.pdf
Appendix 7：Technical Documents for the Application of Drug Review and Registration of Bio-Pharmaceutical Products.pdf

Article 42 Information that should be submitted with the application for drug registration of active pharmaceutical ingredients are as specified in Appendices 8 and 9.
Appendix 8：Documents for the Application of Drug Review and Registration of API.pdf
Appendix 9：Technical Documents for the Application of Drug Review and Registration of API.pdf

Article 43 Information that should be submitted with the application for drug registration of radiopharmaceutical drugs are as specified in Appendices 10 and 11.
The application should comply with the Guidelines on Clinical Trials of Radiopharmaceutical Drugs and the Guidelines on the Assessment of Radiopharmaceutical Drugs as announced by the central health competent authority.
Regulations for new drugs stipulated in this Chapter are also applicable to radiopharmaceutical drugs with new dosage forms and new doses.
Appendix 10：Documents Required for the Application for Drug Review and Registration of Radiopharmaceutical Drugs.pdf
Appendix 11：Technical Documents Required for the Application for Drug Review and Registration of New Drugs, New Dosage Forms and New Dose of Radiopharmaceutical Drugs.pdf

Article 44 When applying for licenses for export products, the applicant should submit the original copy and a duplicate copy of the application form, assurance statement A, assurance statement B, assurance statement for the export-only product, form for sticking package inserts and labels (two copies), form for sticking licenses, the testing specifications, methods and certificate of analysis of API and final product respectively,

and a photocopy of GMP compliance certificate. The manufacturer s
Manufacturing and Control Standards (including the actual amount
used as specified in batch records), batch record, the testing sp
methods and certificate of analysis of excipients, stability stud
validation of analytical methods and validation of critical manuf
processes for future inspection. If necessary, the central health
authority may request the applicant to provide samples for testin
should be answered.
When applying for an export license, if the applicant imports sem
manufacture export-only final products, and has obtained a licens
the semi-products, then in addition to the above mentioned docume
applicant should also provide the original copy of a commission l
authorizing the applicant to register the product in Taiwan and e
other countries. If the applicant does not hold a license for imp
products, then the CPP or the FSC from the manufacturing country
products should also be provided.

Section 3 Post-Approval Changes

Article 45 The stability studies, required for the application of post-approval changes, should comply with the following regulations of execution and data submission:

1.For any changes in drugs subject to the submission of the stability study report, the applicant needs to conduct 6-month accelerated stability studies on a batch of changed products, as well as a long-term stability study that tests through the expiration date. Data of at least 3-month accelerated stability studies should be submitted when applying for post-approval changes. The manufacturer should retain the documentation of operational details and test figures of other accelerated studies and long-term studies.

2.For changes in drug expiration date, manufacturers should conduct long-term stability studies on 3 marketed batches of drugs that tests through the expiration date, and analyze the results. For drugs applied for registration before 1 January 2001, manufacturers can decide whether to conduct storage tests or long-term tests based on the Guidelines on Stability Studies. Manufacturers should retain historical documentations of the operational details and original testing results and other related data for inspection; however the applications for post-approval expiration date changes would not be required.

For the documents that should be retained by manufacturers as mentioned above, the applicant has the obligation to provide relevant information upon the central health competent authority’s request. If the authority finds any discrepancy in the information, the applicant has to recall all products from the market and receive punishment according to the related regulations in the Act.

Article 46 Applications for Post-approval change should be conducted in compliance with the following regulations:
1.Definitions of major changes and minor changes are as announced by the central health competent authority.
2.The following information should be provided for changes in manufacturing of drugs:
(1) For major changes: BE study reports should be submitted;
(2) For minor changes: a drug dissolution profile comparisons should be submitted.
3. The following information should be provided for changes of the manufacturing site of drugs:
(1) A comparison between the formula and the manufacturing process, including the sources of raw materials, specifications and manufacturing equipment;
(2) A drug dissolution profile comparison;
(3) If it is determined that a major change is occurred or the data is insufficient to determine a minor change, a BE study report should be submitted.
4. If the application of post-approval changes involves multiple changes in the formula and manufacturing processes, it shall be followed in accordance with its respective scope of change.
5. BE studies can be substituted by BA studies along with clinical trial reports.
6. BA/ BE studies should be conducted in compliance with the Regulations of Bioavailability and Bioequivalence Studies.
7.Post-approval changes involve the bioavailability and bioequivalence test, the waiver or replacement of the test can follow Article 8 of the Regulations of Bioavailability and Bioequivalence Studies, or contents approved or relevant regulations promulgated by central competent health authority. For drugs already approved on the market, if the manufacturer, of their own accord, conducts a BE study and the report has been approved by the central competent health authority, and subsequent changes involved in the manufacture and manufacturing sites are subject to the regulations in the preceding paragraph. Unless otherwise provided, the requirement for the bioequivalence study or the bioavailability and clinical study report may be waived for drug products that category in the Guidelines on the Review of Over-the-counter Drugs or in the category of the preparations of inherited formulation.

Article 47 Applications of post-approval changes of imported drugs should provide a notice of changes issued by the original manufacturer. The notice should be issued by the registered original manufacturer or its headquarters, or authorized license holders in other countries; and the notice should be within its one-year

validity. The manufacturer’s name and address stated on the notic
identical to those on the approval. The notice should not be issu
affiliates, agencies or distributors or in the form of telegram,
statement, or electronic media.

Article 48 In any of the following situations, manufacturers may, of their own accord, change package inserts, labels, or packaging. However, these changes have to comply with the GMP Guidelines; and the relevant modified operational procedures shall be documented accordingly. Records shall be retained for future inspection. Notification of the post-approval changes in package inserts, labels, and packaging may be declared electronically the approval. Products on the market shall be handled according to the relevant regulations.

1. No changes in the originally approved text:

(1) Only changing the graphic design or colors of labels, package inserts, or outer boxes. The graphic design may not be offensive, indecent, or misleading;

(2) Resizing the approved graphic design or text to fit a different size of packaging, or repositioning the approved graphic design or text;

(3) Changing the fonts of the approved text. However, the font size of English text may not be larger than that of Chinese text;

(4) Changing or adding the corporate identification system (CIS) or anti-counterfeiting labels;

(5) Adding printings on outer boxes or using new outer boxes to replace the labels. The design of text and graphs shall be identical to those approved; or

(6) If an injection is available in different doses, the graphic design and the text on the labels and the outer packaging can be presented in different colors for differentiation.

2. Changes in text without affecting drug quality or medication safety:

(1) Only adding or changing bar-codes, National Health Insurance (NHI) codes, ID codes, “GMP” before the manufacturer’s name, copyright registration number or company trademark approved by the competent authority, trademark registration number, or patent number;

(2) Adding or changing the anti-counterfeiting hotline. Adding or changing the suggested retail price or customer service telephone line of medicines designated by physicians, pharmacists and/or assistant pharmacists, and over-the-counter drugs;

(3) Changing the drug company’s name, the manufacturer’s name or address, or excipients as approved by the central competent health authority, or adding or changing the telephone number,

fax number and contact;
(4) Adding or changing the distributor’s name or address. The fon
distributor’s name may not be larger than that of the license hol
Distributors have to be a qualified pharmaceutical agent;
(5) Adding seal labels (outer boxes) or the changing labels (incl
labels);
(6) Adding items on the labels or package inserts of export produ
request of importing countries;
(7) Adding notes on the approved packaging to indicate that the p
exclusively for the use of certain hospitals or for inpatient use
other appropriate terms such as “not for resale”;
(8) Adding, deleting, or changing the manufacturer’s name added t
the product in English;
(9) Changing the measurement unit of formulas in order to comply
Pharmacopoeia;
(10) Changing the terms used in describing the storage conditions
altering the original requirements. The usage of the phrases shal
with the Chinese Pharmacopoeia.
3. Changes in the text of the methods of administration in order
quality and medication safety.
The adjustment of the manufactiring date and/or expiry date forma
paragraph 1 item 18, is not a label or packaging label change.

Article 49 For drugs with licenses and categorized as medicines designated by physicians, pharmacists and/or assistant pharmacists or in the category subject to the Guidelines on the Review of medicines designated by physicians, pharmacists and/or assistant pharmacists, the central competent health authority’s announcements shall be followed. Missing the deadlines shall be punished according to the relevant regulations in the Act.

Article 49-1 For active pharmaceutical ingredients or active pharmaceutical ingredients of drug products with licenses, the data involving the changes of technical documents shall be submitted in accordance with Appendix 12.
When applying for addition or change of the source of active pharmaceutical ingredients of the drug products, the following documents shall be submitted:
1. Application form for post-approval changes;
2. Original drug license;
3. A GMP compliance certificate for the active pharmaceutical ingredients newly added or changed;
4. The approvals of the technical documents of the active pharmaceutical ingredients issued by the central competent health authority. However, the technical documents of active pharmaceutical ingredients can be substituted by other dossiers as promulgated by the central competent health authority.

5. Description of the differences in specification between the ne
of active pharmaceutical ingredient and the evidence;
6. Comparison and evaluation data of the finished preparations ac
characteristics of the dosage forms;
7. If the results compared according to the preceding paragraph a
a dissolution test shall be conducted. If the comparison results
curves are dissimilar (f2<50), a drug BE test report shall be sub
Appendix 12.PDF
Appendix 12.doc

Article 50 The following documents are required for the application of changes in the Chinese or English product name.
1.Application form of post-approval changes;
2.The original copy of drug license;
3.An assurance statement (A) should be submitted to certify the changes in the Chinese or English product names of a locally manufactured drug, or the change in the Chinese product name of an imported drug. If available, a photocopy of the trademark registration certificate or approval letter issued by the Bureau of Intellectual Property of the Ministry of Economic Affairs (MOEA) should be submitted; and
4.The application of the change in the English product name of an imported drug should be accompanied with a notification letter of post-approval changes issued by the original manufacturer and the CPP from the manufacturing country.

Article 51 The following documents are required for the application of changes in drug categorization:
1.Application form of post-approval changes;
2.The original copy of drug license;
3.The safety test, clinical references and the pharmacopoeia or formularies of the A10 countries; and
4.A notification letter of post-approval changes issued by the original manufacturer for imported drugs.
5. If the first applicant applying for the category change of prescription drug, the global adverse drug reaction notification report and the plan of pharmacist training are required.
If the change in drug category is ordered by the central health competent authority based on an assessment result, then Items 3-5 in the preceding paragraph can be exempt.
If a license reissue is required, the original copy of the application form for drug registration should be provided.

Article 52 The change of dosage form is restricted to changes among tablets, sugar-coated tablets and film-coated tablets; between cream and ointment or among gel, cream and ointment for external use provided that drugs with identical ingredients, dosage form and dose have been approved by the central health competent

authority.
The following documents are required for the change of dosage for
1.Application form for post-approval changes;
2.The original copy of drug license;
3.Manufacturing and Control Standard, or the batch records of the finished products;
4.Stability study results;
5.For locally manufactured drugs, the testing specifications, met certificate of analysis of the finished products, as well as the statement (A) and supporting documents of factory registration;
6.For imported drugs, the testing specifications, methods and cer analysis of the finished products and active substances used for well as a notification letter of post-approval changes issued by manufacturer and the CPP issued by the country of origin are need

Article 53 No active pharmaceutical ingredients can arbitrarily be changed. Re-application for drug registration is required for such changes. In any of the following situations, the application of post-approval changes can be filed:
1. Adding declaration of salt forms in vitamin preparations, if those salts are not listed on the license;
2. Changing the measurement units of the antibiotic preparations from weight to potency;
3. Modification is required according to the central competent health authority’s concerns over safety or ban on certain ingredients in the formula;
4. Imported drugs certified by the supreme competent health authority of the country of origin wherein the formula change is necessary. The manufacturing methods, testing methods, specifications, stability, or drug re-evaluation reports from the original manufacturer shall be submitted.
The following documents are required for the application of changes of formula.
1. Application form for post-approval changes;
2. Original drug license;
3. Standard Manufacturing and Control Procedures and the amount of all starting materials in the batch record or the batch record of the same lot as the finished product;
4. Data on the stability test;
5. Declaration (A);
6. For locally manufactured drug products, the testing specifications, testing methods, and certificates of analysis for the finished products;
7. For imported drugs, the testing specifications, testing methods, certificates of analysis for the finished products and the raw materials of the same lot as the finished products, a notification letter of post-approval changes issued by the

original manufacturer, and CPP from the manufacturing country.
In any of the following situations, reapplication of drug registr
required, but it is not applicable to post-approval change.
1. Same active pharmaceutical ingredients with different doses;
2. The original manufacturer no longer manufactures the originall
product, which is to be replaced by a new preparation whose produ
formula are different from those of the approved drug.

Article 54 The following documents are required for changes in indications:
1.Application form for post-approval changes;
2.The original copy of drug license;
3.Two copies of complete clinical trial report or related references of the claimed indications;
4.For locally manufactured drugs, an official reference book recording the new indications is needed. For imported drugs, approval of new indications issued by the central health competent authority of the country of origin and authenticated by the R.O.C foreign affairs offices is needed. If these documents are not available at the time of filing, the applicant shall provide the required documents before approval. The authentication requirement is waived for documents issued by A10 countries or the EMA. The above-mentioned documents can be replaced with the approval information on the A10 countries highest health competent authority or the EMA’s official website and approval letter of new indications issued by the of A10 countries or the EMA;
5.An original approved copy of the form with labels and package inserts attached along with the central health competent authority’s stamp on the seams. The above-mentioned documents can be exempted when the original copy was approved via the electronic submission platform;
6.Two actual packaging materials (or color photos) or drafts of package inserts, labels, outer boxes, and aluminum blister foil sheets. For imported drugs, two copies of package inserts in the original foreign language are needed;
7.For imported drugs, the notification letter of post-approval changes issued by the original manufacturer is needed.
8.The comparison table of changes of package inserts or drafts of package inserts with tracking revisions and comments.
If there is evidence from clinical trials conducted in Taiwan to justify that the drug is effective and safe for the new indication, then the first applicant applying for the addition of the new indication can be exempt from the requirement described in Item 4 in the preceding paragraph.
The first applicant of the addition of a new indication (including changes of indications and addition of indications) may decide whether or not to conduct local clinical trials. If a

local clinical trial has been conducted by the first applicant to
drug is effective and safe for the new indication, then during th
years, other applications filed by other manufacturers of drugs w
ingredients, dosage form and dose, either for licensing the new i
extending an existing license, should also provide local clinical
up to the standard conducted by the first successful applicant in
the required documents set out in Paragraph 1 Item 1, 2 and 5-7.
If the first successful applicant of a new indication (including
indications and addition of indications) did not conduct local cl
or the approval was issued more than 5 years ago, then any other
drugs with the same ingredients, dosage form and dose, either for
new indication or for adding the new indication to an existing li
provide all the required documents set out in Paragraph 1 Item 1,
If labels and package inserts are revised according to the indica
by the central health competent authority, the license holder sho
application form for post-approval changes and the original copy
when applying for post-approval changes of indications.

Article 55 The following documents are required for the changes in drug administration and dosage:

1.Application form for post-approval changes;

2.Photocopy of drug license (front and back sides);

3.Two copies of complete clinical trial report or related references of the claimed drug administration and dosage;

4.An original approved copy of the form with labels and package inserts attached along with the central health competent authority’s stamp on the seams. The above-mentioned documents can be exempted when the original copy was approved via the electronic submission platform;

5.Two actual packaging materials (or color photos) or drafts of Chinese package inserts, labels, outer boxes, and aluminum blister foil sheets. For imported drugs, two copies of package inserts in the original foreign language are needed;

6.A photocopy of official reference books, or certificates claiming drug dosage and administration approved by the central health competent authority and authenticated by the R.O.C. foreign affairs offices is needed. If these documents are not available at the time for filing, the applicant shall provide the required documents before approval. The authentication requirement is waived for documents issued by A10 countries or the EMA. The above-mentioned documents can be replaced with the approval information on the A10 countries highest health competent authority or the EMA’s official website and approval letter of new drug administration and dosage issued by the of A10 countries or the EMA;

7.For imported drugs, a notification letter of post-approval changes issued by the original manufacturer;

8. The comparison table of changes of package inserts or drafts o
inserts with tracking revisions and comments.

Article 56 The following documents are required for the change in excipients:
1.Application form for post-approval changes;
2.If the change in excipients could affect the characteristics of the drug, the applicant should follow the notice issued by the central health competent authority to perform drug testing and to provide two copies each of the testing specifications, methods, and certificate of analysis, as well as one copy each of the safety data, BE test data and stability test data;
3.Photocopy of the drug license;
4.For imported drugs, a notification letter of post-approval changes issued by the original manufacturer and the CPP from the country of origin.
The application of the above-mentioned changes has to comply with Article 46.
Whereas the active ingredients, dosage form, dose and administration route of a licensed drug remain unchanged, the appearances or shapes are altered by changing its aromatics, coloring agents or flavours without any pharmacological effects, and do not affect drug quality or medication safety, then it can be justified by applying for post-approval changes for excipients as the addition of new contents. Appropriate descriptions should be given on labels, package inserts and outer packaging for clear differentiation. Graphic designs and colors may be changed to suit the new descriptions.

Article 57 The following documents are required for changes of drug testing specifications, methods and product appearance:
1.Application form for post-approval changes;
2.Photocopy of drug license (front and back sides);
3.Two copies each of the testing specifications, methods and certificate of analysis of changed drugs, and an explanation of the differences in specifications before and after the changes;
4.For imported drugs, a notification letter of post-approval changes issued by the original manufacturer.
If the changes of testing specifications and methods are according to the update on pharmacopoeias, then the application form should include details of the cited pharmacopoeias, including the title, publication year and edition. The cited pharmacopoeias are restricted to Chinese Pharmacopoeia and pharmacopoeias published in the A10 countries or acknowledged by the central health competent authority and should be the latest edition from the date of application.
If the change does not involve the testing items and testing

methods, the submission of documents mentioned in Item 3 of the p
paragraph can then be exempt. However, manufacturers should retai
data and figures for future inspection.

Article 57-1 The changes of manufacturing process and batch size of drug product as specified in the Appendix 12-1 should be applied to the central health competent authority for the applications of post-approval changes.
The documents involving the above-mentioned changes shall be submitted as specified in Appendix 12-2.
Appendix 12-1：Matters that Should be Applied for Changes of Manufacturing Process and Batch Size of Drug Product.pdf
Appendix 12-2：Documents for the Application of Registration Changes of Manufacturing Process and Batch Size of Drug Product.pdf

Article 58 The following documents are required for changes of immediate packaging materials:
1.Application form for post-approval changes;
2.Original copy of drug license;
3.The Stability study report
4.For injections or liquid dosage forms, the testing specifications, methods and certificate of analysis of finished products. For injections packed in syringes or soft bags, the testing specifications, methods and certificate of analysis and leachables and/or extractables assessments of containers;
5.For locally manufactured injections, a photocopy of formulation basis. If the formulation basis is not available, the applicant should provide the safety data of packaging and go through the testing procedure as requested by the central health competent authority.
6.For imported drugs, a notification letter of post-approval changes issued by the original manufacturer;
7.If soft bags are added as a new packaging material of injections, Standard Manufacturing and Control Procedures and the amount of all starting materials in the batch record or the batch record of the same lot as the finished product should be submitted.

Article 59 The following documents are required for changes in the filling quantity of injections (under conditions of no changes in unit strength and container materials):
1.Application form for post-approval changes;
2.Original copy of drug license;
3.For locally manufactured drugs, a photocopy of the reference of drug administration and dosage; for imported drugs, a notification letter of post-approval changes issued by the original manufacturer;

4.The stability study data in situation where the filling quantit

Article 60 The following documents are required for changes in the pharmaceutical company’s name without transfer of rights:
1.Application form for post-approval changes;
2.Original copy of drug license;
3.A list of all drug licenses;
4.A photocopy of the changed drug company licenses. No supporting documents of factory registration are required when the complete manufacturing process is commissioned to toll-manufacturers. For imported drugs, the applicant may submit a photocopy of the changed drug company licenses.
When applying for changes mentioned in the preceding paragraph, the applicant can include all drug licenses in one application. If the applicant divides the licenses in different applications, the follow-up applications should quote the document reference number of the first approval or attach a photocopy of the approval letter to the follow-up applications. A photocopy of the drug company’s license is not required.
If the merger of multinational companies causes the changes of a drug company’s name and the reorganization of different subsidiaries and agents in Taiwan, the application of changes should comply with the following regulations. If the merger involves the transfer of rights, the applications should be jointly filed by both sides.
1.Application form for post-approval changes: The application should be signed jointly by the companies involved in the merger, specifying that the change is due to the merger of multinational companies. However, if the original drug company name is no longer available after the reorganization, then the application can be filed only by the new drug company under the new name;
2.The notification letter of the company merger issued by the foreign manufacturer, its headquarters or the foreign license holder, or officially certified by responsible competent authorities;
3.An original copy of the authorization letter issued by the foreign manufacturer or its headquarters after the merger, or by the foreign license holder. The authorization letter should be authenticated by the R.O.C. foreign affairs offices;
4.Photocopy of the drug company license after the merger;
5.Assurance statement signed by the person in charge of the drug company after the merger. By signing the statement, the drug company assures that all drugs are imported and sold in compliance with related regulations and the company will take full responsibilities. The company should also make a statement to certify that the manufacturer does not have other products of

the same formulation.
6.If prior to the merger, the drug company already held some drug
the original copies of all drug licenses and a list of all licens
drugs should be attached to the application of changes. In princi
transfer for all licenses is done in a single application. After
is approved, the applicant should, of their own accord, change th
on all labels, package inserts, outer boxes, aluminium blister fo
materials should be submitted upon request for inspection;
7.If prior to the merger the drug company has some drug applicati
in progress, the applicant should fill in another application for
and duplicate copies), therein stating the new drug company name.

Article 61 The following documents are required for the application of changes in the drug company name while the address remains the same:
1.Application form for post-approval changes;
2.Original copy of drug license;
3.A list of all drug licenses;
4.For local manufacturers, a photocopy of each changed license;
5.For manufacturers of imported drugs, a notification letter of post-approval changes issued by the original manufacturer and documents certifying the change in the manufacturer’s name issued by the highest health competent authority of the country of origin, and authenticated by the R.O.C. foreign affairs offices. The authentication requirement is waived for documents issued by A10 countries.
If the only change is the name of the manufacturer or foreign license holders, while the address remains the same and there is no transfer of rights, the following documents should be submitted for the application of post-approval changes:
1.Application form for post-approval changes;
2.Original copy of drug license;
3.A list of all drug licenses;
4.Notification letter of post-approval changes issued by the original manufacturer.

Article 62 For post-approval change, the following documents are required for the changes of the drug manufacturer’s address:
1.If the change is due to building-numbering adjustment, then the following documents shall be submitted:
(1) Application form of post-approval changes;
(2) Original drug licenses;
(3) A list of all drug licenses;
(4) For local drug manufacturers, a photocopy of each changed license, and the documents issued by the household registration authorities to prove the implementation of building-numbering adjustment;

(5) For foreign manufacturers of imported drugs, a notification l
approval changes issued by the original manufacturers and documen
the relevant household registration authorities. The documents sh
authenticated by the R.O.C. Foreign affairs offices. The authenti
requirement is waived for documents issued by A10 countries.
2.The following documents are required for site relocation or cha
place of production:
(1) Application form of post-approval changes;
(2) Original drug licenses;
(3) For local drug manufacturers, a list of all drug licenses, a
each changed license, and a photocopy of the GMP certificate for
after relocation;
(4) For foreign manufacturers of imported drugs, a letter of prox
notification letter of post-approval changes issued by the origin
CPP from the manufacturing country, a photocopy of the GMP compli
certificate, the Standard Manufacturing and Control Procedures an
all components in the batch record or the manufacturing records o
for the final products, the testing specifications, the testing m
certificate of analysis for the final products and the raw materi
lot, and data of stability tests. If the holder the GMP complianc
not the applicant, then this documentation can be replaced by a l
authorization issued by the original manufacturer or the local dr
holding the certificate, therein specifying the approval number o
certificate.
(5) For foreign manufacturers of imported drug substances, a lett
original notification letter of post-approval changes issued by t
manufacturer, the GMP compliance certificate of the active pharma
ingredients, and the relevant technical documents as specified in
(6) Article 46 should be followed for documentation submission.
(7) If renewal of license is required, the original application f
submitted.
For imported drugs, if the foreign manufacturing site’s address r
but the address of the drug company or the foreign license holder
there is no transfer of rights, then the following documents shal
1.Application form for post-approval changes;
2.Original drug license;
3.A list of all drug licenses;
4.Notification letter of post-approval changes issued by the orig
manufacturer.

Article 63 The following documents are required for changes in package inserts, labels, outer boxes and aluminum blister foil or for the reissuance of the originally approved copy that was lost:
1.Application form of post-approval changes;
2.Photocopy of the drug license (front and back sides);
3.Originally approved copy of the form for sticking label and package insert with the central health competent authority’s

stamp on the seams. The above-mentioned documents can be exempted
original copy was approved via the electronic submission platform
of reissuance of the approved copy can be exempt from this submis
4.Two actual packaging materials (or color photos) or drafts of p
labels, outer boxes, and aluminum blister foil sheets. If there i
the package insert, the changes should be highlighted in the draf
inserts, both in Chinese and in foreign language and the comparis
changes of package inserts or drafts of package inserts with trac
and comments. For imported drugs, the original package inserts an
Chinese translation should be provided. The Chinese version shoul
translated from the original version. If the changes only occurre
inserts, then the applicant can just submit package inserts witho
packaging materials;
5.For applications of the reissuance of lost original license, an
statement should be submitted to certify that the document is mis
6.A notification letter of post-approval changes issued by origin
is required for imported drugs, except for applications of the re
license.

Article 64 Applications for registration of pharmaceutical toll-manufacturing shall comply with the Regulations on Pharmaceutical Toll-Manufacturing and Contract Analysis and shall submit the following documents:

1. Application form for toll-manufacturing;
2. A photocopy of toll-manufacturing contracts, therein stating the details about the management of toll-manufacturing;
3. Application form for post-approval changes;
4. Original drug license;
5. A list of all drug licenses categorized by dosage forms, but it is exempted for toll-manufacturing only one drug license;
6. A description of each toll-manufacturing process. This requirement can be exempted, if a complete manufacturing process is commissioned to the toll-manufacturers;
7. Standard Manufacturing and Control Procedures and the amount of all components in the batch record or the batch record of the same lot as the finished product. This document can be exempted if the local manufacturers have no intention to start the manufacture yet. The certificates should be noted with the phrase: “Manufacturing is not allowed”. Manufacturers are required to submit the Standard Manufacturing and Control Procedures and obtain approval from the central competent health authority prior to production;
8. A photocopy of the contract giver’s company license;
9. A photocopy of each of the contract acceptor’s factory registration license and drug manufacturing permit. For imported drugs, those documents can be replaced with a photocopy of the acceptor’s GMP compliance certificate. If the holder of the GMP

compliance certificate is not the applicant, then this document c
by a letter of authorization issued by the original manufacturer
drug company who holds the certificate, therein specifying the ap
the original certificate.
10. The testing specifications and methods of the finished produc
contract acceptor;
11. Documents of rescission with previous acceptors. Those enteri
manufacturing contract for the first time can be exempted from th
12. If the imported drugs were toll-manufactured, a notification
approval changes issued by the original manufacturer and the CPP
of origin shall be submitted. For the imported drug substances, t
exempt. However, the relevant technical documents for changing to
specified in Appendix 12, are required.
Drug license holder should comply with Article 46 when applying f
pharmaceutical toll-manufacturing or changing the original pharma
manufacturing.
The change of the licenses mentioned in Paragraph 1 will be proce
the original license rather than issuing another one. However, in
where the assessment results show that an import permit is requir
into a manufacturing permit, a new license has to be issued.
Under such circumstances, the applicant shall complete the checkl
manufacturing dossiers, and provide all relevant documents, as we
application form for drug registration and the Declaration (A).
After the application is approved, the applicant shall, of their
modify the labels, package inserts, outer boxes, aluminum blister
Those materials should be submitted upon request for inspection.

Article 65 The following documents are required, if the manufacturer intends to manufacture a drug which used to be toll-manufactured.
1.Application letter for the shift from toll-manufacturing to self-manufacturing;
2.Application form for post-approval changes;
3.Original copy of drug license;
4.Original copy of the application form of drug registration;
5.Assurance Statement (A);
6.A photocopy each of the changed certificates and licenses;
7.Manufacturing and Control Standard and the amount of all components in the batch record or batch records of the tentative production batch;
8.The testing specifications, methods and certificate of analysis of the finished products;
9.If the applicant was originally not a GMP manufacturer, then certificate for the GMP compliance should be submitted.

Article 66 Applications for contract analysis should follow the Regulations on Pharmaceutical Toll-Manufacturing and Contract Analysis and

provide the following documents:
1.Application letter for contract analysis;
2.Application form for contract analysis;
3.Photocopy of the contract, therein specifying the scope of cont
and related issues;
4.The standard operation plan for contract analysis (including sa
sample storage method, sample delivery and transfer conditions, e
established by the appointer and the appointee;
5.Testing specifications and methods of the contracted items.
The central health competent authority may carry out site inspect
necessary.

Article 67 Concerning locally manufactured drugs for exportation, the following documents are required for the applications for changes or additions in immediate packaging materials, maximum package size, labels, package inserts, outer boxes, drug names, indications, excipients, testing specifications, methods and appearance:
1.Application form for post-approval changes;
2.Original copy of drug license for the application of changes in drug name, indications, immediate packaging materials and maximum package size;
3.Photocopy of the front and back of drug license for the application of changes or addition of labels, package inserts, outer boxes, excipients, testing specifications, methods, and product appearance ;
4.Assurance statement for drug exportation;
5.Two copies of the drafts of package inserts, labels, outer boxes and aluminium blister foil for changes of in package inserts, labels, outer boxes and aluminium blister foil;
6.For changes of testing specifications and methods, a description of the differences in specifications before and after the changes. The new testing specifications, methods and certificate of analysis should be retained by the manufacturer for future inspection.

Article 68 The following documents are required for changes in drug storage conditions:
1.Application form for post-approval changes;
2.Photocopy of drug license;
3.The stability study report;
4.For imported drugs, a notification letter of post-approval changes issued by the original manufacturer.

Article 69 The following documents are required for changes in virus strain for a flu vaccine:
1.Application form for post-approval changes;
2.Original copy of the drug license;

3.Two copies of post-change testing specifications, methods and c
analysis of the ingredients, manufacturing processes, raw materia
products;
4.Drug stability study report. If the stability study report for
virus strain is not yet available at the time of application, the
submit the stability study report of the old strain, then submit
the new strain when the test is finished;
5.Clinical reference in relation to the new virus strain
6.The originally approved copy of the form for sticking label and
The above-mentioned documents can be exempted when the original c
via the electronic submission platform;
7.Two copies of the draft of labels, package inserts and outer bo
changes, and the comparison table of changes of package inserts o
package inserts with tracking revisions and comments.;
8.For imported drugs, the notification letter of post-approval ch
the original manufacturer and the CPP from the country of origin.
mentioned documents can be replaced with the approval letter of n
issued by the of A10 countries or the approval information on the
website of A10 countries highest health competent authority or th
approval letter of new virus strain issued by the A10 countries o
origin. If the above mention documents are not available at the t
the applicant shall provide it before approval.

Section 4 License Transfer, Renewal and Reissuance

Article 70 The application for transferring a domestic drug license or an imported drug distributor’s license should be filed by both parties. The following documents should be provided:
1.Application form for post-approval changes signed by both parties;
2.Original copy of the drug license to be transferred;
3.A list of drug licenses to be transferred, therein recording the license number, formula, dose and dosage form;
4.The assurance statement made by the transferee to certify the responsibility. For the transfer of the license of locally manufactured drugs, the assurance statement should also certify the absence of drugs of the same formula;
5.The following documents are required for the application for license transfer of locally manufactured drugs:
(1) Photocopy of the transfer approvals issued by the health competent authorities of the local governments where the transferor and transferee are located;
(2) A list of valid drug licenses held by the transferee, a record of the license number, formula, dose and dosage form;
(3) An assurance statement (A);
(4) A photocopy each of all changed certificates and licenses;
(5)Manufacturing and Control Standard. This document can be exempted, if local manufacturers have no intention to initiate

production at present. The certificates should be noted with the "Manufacturing is prohibited". Manufacturers have to submit the M Control Standards and obtain an approval from the central health authority before production can be started.

6.The following documents are required for the application of imp distributor's license transfer:

(1) A photocopy of the company license of both transferor and tra

(2) Original copy of the transfer agreement with signets of both

(3) Original copy of the authorization letter issued by the origi manufacturer, stating the termination of the distributing contrac transferor and the exchange of new contract with the transferee, addresses of both parties and the drug items involved in the tran authorization letter should be authenticated by the R.O.C. foreig offices;

(4) A statement certifies that the same manufacturer does not hav of the same formulation as the transferred drug.

When applying for domestic drug license transfer, if the product license includes a prefix of the transferor's company name which authorized to be used by the transferee, then an application for product name should be filed at the same time. If domestic drug l includes toll-manufactured, then the application should comply wi

Article 71 The following documents are required for the renewal or reissuance of damaged or lost drug licenses:

1.Application form for post-approval changes;

2.A photocopy of drug license (front and back sides). Original drug license is required, if the application is filed due to damages to licenses;

3.Original copy of the application form for drug registration;

4.Assurance statement certifying the loss of drug licenses. This document would not be required for cases of damaged licenses.

5. For locally manufactured drugs appling for changes in license number, one copy each of the originally approved copy of labels and package inserts and two copies of the form for sticking label and package insert. The affixing form can be exempted, if the documents said in the preceding paragraph are submitted via the electronic submission platform.

6.For imported drugs, the original copy of an authorization letter issued by the original manufacturer. The letter has to be authenticated by the R.O.C. foreign affairs offices.

Section 5 License Extension

Article 72 Applications for license extension should be filed within six months prior to the expiration date. Applications filed after the deadline will not be processed and the applicants will have to re-apply for drug registration. Those re-applying for drug registration within three months from the expiration of a

license are eligible for a simplified procedure as stated in Arti
If an application of license extension also involves other post-a
then these applications should be made separately.
If the space on the license for specifying the expiration date is
manufacturer can apply for a new copy of license by submitting th
of the application form for drug registration.

Article 73 The following documents are required for application for license extension:
1. Original drug license;
2. Application form for drug license extension;
3. For drugs manufactured domestically, supporting documents of GMP compliance certificate and full formula contents shall be provided; for drugs manufactured by toll-manufacturers, the contract of toll-manufacturing shall also be attached;
4. For imported drugs, the original CPP from the country of origin, the original letter of authorization issued by the original manufacturer and a photocopy of the GMP compliance certificate for the foreign manufacturing site of imported drugs shall be included. If the holder the GMP compliance certificate is not the applicant, then this document can be substituted by a letter of authorization issued by the original manufacturer or the local drug company holding the certificate, therein specifying the approval number of the original certificate. For the imported drug substances, the CPP can be exempted.
5. The supporting documents of the GMP compliance certificate of the active pharmaceutical ingredients.
6. The post-approval letter of the specifications and testing methods according to the latest edition of pharmacopoeia or the manufacturer’s specifications. If the specifications are not changed, the assessment statement should be provided.

Chapter 3 Chinese Medicine

Section 1 General Provisions

Article 74 The testing specifications for Chinese medicine, as provided in this Chapter, are based on the Taiwan Herbal Pharmacopeia, Chinese Pharmacopoeia, or other foreign pharmacopoeias or announcements acknowledged by the central health authority. References can only be taken from the last two editions; nevertheless, the testing specifications for Chinese medicine preparation shall be based on the latest edition of the Taiwan Herbal Pharmacopeia or Chinese Pharmacopoeia.
In the event that the testing specifications set forth in the preceding paragraph are not listed in the Taiwan Herbal Pharmacopoeia or Chinese Pharmacopoeia or are not covered by any other foreign pharmacopoeias or announcements acknowledged by

the central health authority, manufacturers and importers shall e
testing specifications at their own discretion based on their act

Article 75 The formulation basis of Chinese medicine shall be in compliance with any of the following regulations:
1. For the formulas included in the “Standard Formulas of Chinese Medicine” announced by the central health competent authority, the dosage form and formula contents shall be identical to those stated in the “Standard Formulas of Chinese Medicine”.
2. The formulas conform to those listed in well-established publications or any other publications recognized by the central health competent authority.
3. The formulas conform to those listed in the drug licenses held by other drug companies. However, formulas that are listed in the drug licenses issued by the Ministry of the Interior or renewed by the central health competent authority but not listed in any of the well-established publications shall not be used as the formulation basis.
4. In the case of export licenses, the formulas shall be included in the importing country’s pharmacopeia or standard formulas or shall meet purchase order requirements.
The well-established publications mentioned in Subparagraph 2 of the preceding paragraph refer to “Yi Zong Jin Jian (Golden Mirror of Medicine)”, “Yi Fang Ji Jie (Analytic Collection of Medical Formulas)”, “Ben Cao Gang Mu (Compendium of Materia Medica)”, “Ben Cao Gang Mu Shi Yi (Supplement to Compendium of Materia Medica)”, “Wai Ke Jheng Zhong (Orthodox Manual of External Disease)”, “Ben Cao Bei Yao (Essentials of Materia Medica)”,“Grand Dictionary of Chinese Medicine”, and “Chinese Materia Medica Grand Dictionary”.
The license number or publication title, edition number, and page numbers shall be indicated in the “formulation basis” field of a registration application form. A photocopy of the formulation basis shall be submitted.
The dosage form of products to be manufactured or imported shall be identical to the dosage form that is indicated in the formulation basis submitted in accordance with the preceding paragraph, except for the cases where the powder and capsule forms are interchangeable or where all forms of concentrated Chinese medicine preparations are interchangeable.

Article 76 The name of a Chinese medicine product shall comply with the following regulations:
1. Single ingredient preparations: Products are named by adding the manufacturer’s name, brand name or trademark, and dosage form to the name of the Chinese medicine. If a merchandise name

is used, then the name of the Chinese medicine shall be added to
product name in brackets.
2. Compound preparations: Products are named by adding the manufa
brand name or trademark, and dosage form to the compound name ind
pharmacopoeia. If a merchandise name is used, then the compound n
a pharmacopoeia shall be added to the end of the product name in
If the name of a Chinese medicine product, as set forth in the pr
paragraph, is used for export only, the foregoing limitations sha

Article 76-1 If a Chinese medicine product has a name that is used for export only or any of the following conditions occurs, and a photocopy of the purchase order placed by a company in the importing country and indicating the name that is used for export only, or a photocopy of the trademark registration certificate is submitted along with an application for registration, the manufacturer’s name may not be included in the product name:
1. The applicant is a proprietor of a registered trademark.
2. The applicant is not a proprietor of a registered trademark but a licensee of such a trademark. The proprietor of such a trademark is a manufacturer commissioned by the applicant to manufacture products. Moreover, a trademark license is submitted.
3. The applicant is not a proprietor of a registered trademark but a licensee of such a trademark. The proprietor of such a trademark is not a manufacturer commissioned by the applicant to manufacture products. Registration has been filed with the trademark authority, and a trademark license and registration documents have been submitted.

Article 76-2 The name of a Chinese medicine product shall not contain the drug trademark or name of another manufacturer, unless the applicant has acquired the trademark rights to use the manufacturer’s name or has obtained a letter of consent from the commissioned manufacturer to use its name in the case of commissioning others to manufacture products.

Article 76-3 A Chinese medicine product is named in Chinese or a foreign language:
1. Chinese: No combination with foreign letters or Arabic numerals is allowed, unless they directly convey a meaning.
2. Foreign languages: They may be translated from Chinese by means of transliteration or semantic translation.
Up to three product names, as set forth in the preceding paragraph, shall be provided for the central health competent authority to approve one of them.
Chinese medicine product names that are used for export only shall not be subject to the quantitative limitation set forth in the preceding paragraph if they are directly transliterated from

Chinese. However, if such names are not directly transliterated f
more than three names shall be approved for each application.

Article 76-4 The merchandise name of a Chinese medicine product shall not be similar or identical to the merchandise name of any product of other drug companies, and shall not involve counterfeiting or insinuation.
If an applicant intends to name a new product after another of the applicant’s approved drugs with an annotation, then the annotation shall not cause inappropriate association or confusion between the original and annotated product names.

Article 76-5 Chinese medicine with the same formula but in different sizes of pills, tablets, or capsules and excipients are made of different aromatics, coloring agents or flavors, shall have the same product name, provided that an identifiable name is added in brackets to the end of the product name. Medicines with the same formula but in different dosage forms may have different product names.
A drug company shall not give products with different formulas the same product name.

Article 76-6 If the name of a Chinese medicine product involves the efficacy, the name shall be appropriate to the efficacy and indication. If necessary, clinical efficacy evaluation results shall be provided for justification.

Article 76-7 The name of a Chinese medicine product shall not misrepresent or exaggerate the efficacy and safety of the product, cause inappropriate association or confusion in regard to the product name and efficacy, or encourage drug abuse.

Article 76-8 In the case of an application for license transfer or the change of a product name or any inconsistency between the name of a Chinese medicine product and the provisions of the preceding seven articles, the central health competent authority may re-assess the product name.

Article 77 The “packaging” field on the application form for Chinese medicine registration shall contain such information as quantity, materials, and types of packaging. The minimum packaging unit used for indicating the quantity shall be consistent with the dosage form unit stated on the application form for drug registration.
The weight of the packaging for Chinese medicated patches, as indicated on the labels, shall not include the weight of the films.

Article 77-1

The maximum quantity for each packaging unit of Chinese medicine products is as follows:
1. Tablets, pills, and capsules: No more than 1000 units
2. Powders, granules, gels, ointments, and plasters: No more than 1000 grams
3. Liquid for internal use, liquid for external use, plasters for internal use, wines, and distillates: No more than 1000 milliliters
4. Flakes: No more than 1000 packs
5. Medicated patches: No more than 1000 pieces
The minimum packaging size for multiple-dose Chinese medicine products shall be the minimum two-day dosage for adults.
For the Chinese medicines concerned in applications for export only, for use by drug companies and food manufacturers as raw materials, or for use by medical institutions and academic organizations, the maximum or minimum packaging quantity shall not be subject to the limitations set forth in the preceding two paragraphs. However, for the products concerned in applications for use by medical institutions, the packaging quantity shall not exceed two times the maximum packaging quantity requirements. If the packaging quantity exceeds twice of the maximum packaging quantity, the certificate of purchase from the medical institutions shall also be attached.
Provided that the packaging of Chinese medicines conforms to the requirements set forth in the preceding three paragraphs, manufacturers may, at their own discretion, make adjustments to suit the market needs without filing an application for post-approval changes. If the packaging does not conform to the requirements set forth in the preceding three paragraphs, manufacturers are required to file an application for post-approval changes.

Article 78 Information given in the “name of raw materials” and “contents” fields on the application form for Chinese medicine registration shall comply with the following regulations:
1. The name of raw materials shall be labeled in Chinese.
2. Chinese medicine materials shall be those listed in the “Ben Cao Gang Mu (Compendium of Materia Medica)”, “Taiwan Herbal Pharmacopoeia”, or other pharmacopoeias or medicine formularies acknowledged by the central health competent authority. Contents shall be indicated in metric measurements.
3. The full formula shall be listed in the order of monarch, minister, assistant, guide, and excipients. If the product adopts a standard formula announced by the central health competent authority, the list shall be made in the order consistent with that of the standard formula.
4. Units for labeling:
(1) Traditional tablets, pills, and capsules: The contents of each raw material shall be indicated in the minimum unit.
(2) Traditional powders, granules, gels, ointments, plasters, and medicated patches: The contents of each raw material shall be indicated per gram.
(3) Liquid, plasters for internal use, wines, and distillates:

The contents of each raw material shall be indicated per millilit
(4) Flakes: The contents shall be indicated per pack.
(5) Concentrated Chinese medicine preparations: The contents of s
preparations shall be indicated per gram, while those of compound
shall be indicated per daily dose. However, in the case of tablet
capsules, the contents of each raw material shall be indicated in
unit.
5. Labeling on capsule shells:
(1) Soft capsules: A description of the full formula of soft caps
provided.
(2) Hard capsules: The outer colors of the cap and body of hard c
as the size number shall be indicated.
6. If any cold and cough preparations contain tea leaves, the max
tea leaves per day shall be 3.75 grams.

Article 79 Information filled in the “efficacy” or “indications” field on the application form for Chinese medicine registration shall comply with the following regulations:
1. For those using a standard formula announced by the central health competent authority as the formulation basis, the information shall be identical to the standard formula.
2. For those using a well-established publication as the formulation basis, the information shall be consistent with the contents of said publication.
3. For those using a formula listed in the drug license of another drug company as the formulation basis, the information shall be consistent with that in the drug license.
4. If clinical trials have been conducted, the information shall be consistent with the clinical trial reports that have been submitted for recording.

Article 80 Information given in the “dosage and administration” field on the application form for Chinese medicine registration shall comply with the following regulations:
1. The dosage shall be proportional to the content of the original formula.
2. After conversion, the daily dose of Chinese medicine in concentrated form or liquid form (for internal use) shall be equivalent to that of Chinese medicine drinks; in principle, the daily dose is divided into 2-3 doses for administration.
3. Dosages for children: In principle, the dose for children between the ages of 8 and 15 is two-thirds of the dose for adults; the dose for children between the ages of 5 and 7 is half of the dose for adults; the dose for children between the ages of 2 and 4 is one-third of the dose for adults; or there shall be a label specifying that the dosage for children decreases with age.

Medication for infants under the age of 2 shall be decided by phy diagnosis and treatment. The label on OTC drugs shall not indicat administration for infants under the age of 2.

Article 81 The information contained on labels, package inserts, or packaging for Chinese medicine is subject to Article 75 of the Act. The contents and presentation shall comply with the following regulations, and the fonts shall be easy to read:

1. Package inserts shall contain information on drug category, packaging, storage conditions and other necessary information.
2. The information contained on package inserts is limited to the extent of the efficacy or indications. For compound preparations, the information is limited to the extent of the main pharmacological effects of their mixed active ingredients. Exaggerated terms and wordings are not allowed.
3. A detailed description of contraindications, warnings, side effects, and precautions shall be provided on the package inserts, and shall be printed in red or in bold with a different font or, when necessary, with a red frame.
4. For any Chinese medicine preparation that uses a merchandise name, the original formula name derived from a pharmacopeia shall be listed after the product name in the package inserts, or on the labels or outer boxes if no package inserts are provided.
5. Unless otherwise provided, the Chinese fonts printed on package inserts shall not be smaller than DFKai-SB font size seven.
6. Labels, package inserts, and packaging materials shall not include indecent or offensive images or wording or exaggerated descriptions of the efficacy and indications.
7. If a distributor’s name is printed on the labels, package inserts, or packaging materials, the distributor shall have obtained a business license, and the font size of the distributor’s name shall not be larger than that of the name of the manufacturer (license holder).
8. The font size of the Chinese product name shall not be smaller than that of any foreign letters. The font size of the Chinese product name shall not be lower than that of any foreign letters.
9. For the font size of the product name, no character is allowed to be less than half of the size of any other characters. However, the font size of the manufacturer’s name, merchandise name, and dosage form will not be compared with each other.
10. For OTC drugs, “OTC Drug” or “Class B OTC Drug” shall be printed in a significantly larger font on labels and packaging materials according to their categories. In the case of

preparations for external use, “For External Use” shall be printe
bold with a different font or, when necessary, with a red frame.
11. The labeling of the smallest unit for single use, which is gi
its original package with the outer box remaining intact, should
labeled indicating Chinese product name, manufacturer’s name, and
on the circumstances of the immediate package does not have enoug
include all required information.
12. For drugs packed in aluminum blister foils, the Chinese produ
manufacturer’s name, and license number shall be printed on each
The same rule also applies to aluminum foil packets for refills u
institutions.
13. Labels, packaging, or aluminum foil packets for refills used
institutions shall contain information in any of the following fo
(1) Batch number, manufacturing date, and effective period;
(2) Batch number and expiry date; or
(3) Batch number, manufacturing date and expiry date.
14. The manufacturing date or expiry date, as required in the pre
paragraph, shall be printed in year-month-day format. The manufac
effective period, and expiry date shall be printed in a manner un
consumers.
15. In the case of imported drugs, such information as the import
address, license number, Chinese product name, and category may b
sticker.
16. The process of labeling or attaching stickers is subject to t
regulations. For imported drugs, labels or stickers shall be prop
the original manufacturers. Alternatively, a GMP certified manufa
certified medical product distribution center in Taiwan might be
accordance with the Regulations for Medicament Contract Manufactu
to carry out the packaging and labeling or sticker attaching proc
drugs are imported into Taiwan. However, labels indicating the fo
manufacturer’s name and address shall be properly attached by the
manufacturer.
The package inserts, labels, stickers, outer boxes, aluminum blis
other printed materials or drafts indicating the materials used,
the regulations set forth in all subparagraphs of the preceding p
be properly attached to the forms for sticking outer boxes, packa
labels, as specified in Paragraph 2 of Article 3. However, the pa
not required for any Chinese medicated patches with contents to b
the preceding paragraph package insert fully indicated on the lab

Article 82 The application for Chinese medicine registration shall pick up the drug license and proceed with drug testing as notified by the central health competent authority; the application for post-approval changes of Chinese medicine registration shall pick up the drug license or proceed with drug testing as notified by the central health competent authority.
Upon receipt of the aforesaid notice for picking up the drug

license, the applicant shall, within three months, pay the fees a
the following steps:
1. Two copies each of the forms for sticking outer boxes, package
labels that are printed properly shall be provided. For new drugs
each shall be provided.
2. The originally approved copies of the forms for sticking outer
inserts, and labels shall be returned.
3. A photocopy of the drug license that was attached to the appli
returned.
If the applicant is required to correct any mistakes contained on
package inserts, packaging, or other related materials submitted
of picking up the license within a specified deadline, the applic
the license only after having made corrections within the deadlin
the central health competent authority.
If the applicant applies for any other change after receipt of a
picking up the license, the fee for post-approval changes shall b
In the review of a drug license, the competent central health com
shall add a supplementary clause, stating that the medicine canno
the market until it receives the notice of passed the tests; afte
license has been picked up, the applicant does not follow the reg
proceed with drug testing, or the sample test results are not con
contents of the application or are disqualified for other reasons
central health competent authority shall revoke the drug license
applicant to return the drug license within a specified deadline.

Article 83 After an applicant receives a drug testing notice as set forth in the first paragraph of the preceding article, the applicant shall pay the fees and submit three portions of raw materials and a drug sample test form before the deadline. The deadline for drug testing shall be within 30 days for domestic Chinese medicines and within three months for imported Chinese medicines.

When necessary, the central competent health authority may order the applicant to provide three portions of drug samples or an appropriate quantity of reference standards.

The three portions mentioned in the preceding two paragraphs shall refer to a quantity sufficient for carrying out three tests.

If the central competent health authority deems it necessary to re-test a tested Chinese medicine product, the applicant shall pay the fees again.

Article 29 shall apply mutatis mutandis to the matters that the applicant shall comply with when proceeding with drug testing.

Article 84 If an applicant for the registration of imported Chinese medicines is required to apply for Chinese medicine samples before proceeding with drug testing in accordance with the

preceding article, the applicant shall carry out customs clearanc
the quantity of the Chinese medicine samples, raw materials, and
standards stated on the drug testing notice set forth in Paragrap
82 in addition to proceeding with drug testing in accordance with
article. However, to ensure that the packaging remains intact, th
request the customs office to release the medicines in a single c
if the quantity of a single package of imported medicines exceeds
required for testing.
The regulations of the preceding paragraph shall apply mutatis mu
samples, their quantity, and the customs clearance procedures for
required for the application for post-approval changes of importe
medicines.

Article 85 In the event that an applicant fails to pay the fees, fill out and submit an application form, prepare all required materials, or meet the other requirements set forth in the Regulations and, subsequently, has to take corrective actions, the central health competent authority shall notify the applicant to make the corrections within three months.
If the applicant is not able to make corrections within the deadline, a written statement specifying the reasons shall be submitted before the expiration of the correction period to apply for an extension. The extended period is one month after the day following the expiration of the original correction period. Only one extension will be allowed. If the applicant fails to make corrections within the deadline, then the central health competent authority may reject the application based on the current materials available.

Article 86 The review criteria for concentrated Chinese medicine preparations are as follows:
1. In principle, compounds shall be decocted in combination. Those whose original formula involves traditional pills or powders may be decocted separately. Donkey-hide gelatin, mirabilite, maltose, and others not suitable for adding into decocting shall not be decocted in combination with others.
2. Extracts of decocted medicines may be prepared with lactose or starch, as listed in the Chinese Pharmacopoeia, or with excipients that do not affect efficacy. If the original formulation basis involves traditional pills, non-boiled traditional powders, or other medicines approved by the central health competent authority, the extract may be prepared with Chinese medicine base powders.
3. The levels of microorganisms, heavy metals, and pesticide residues in concentrated Chinese medicine preparations shall be within the limits announced by the central health competent authority.

4. The ratio of extracts to excipients should be 1:1 in principle
limit of 1:3.
5. The ratio of crude drugs actually produced to extracts shall b
or less than the figure specified in the application.
The quantitative method, specifications, and required materials f
ingredients of concentrated Chinese medicine preparations shall b
with the regulations announced by the central health competent au

Article 87 If a Chinese medicine product contains any protected species listed in Appendix 2 of the Convention on International Trade in Endangered Species of Wild Fauna and Flora, the source of these ingredients shall be indicated.

Article 88 The Assurance Statements (A) and (B), Assurance Statement for Export Only (C), and Affidavit of Loss (D), as stipulated in the Regulations, shall include the name and address of the company or firm signing such statements or affidavits, the name of the person in charge, and the date of signature, and shall be affixed with the signet or stamp that is the same as those on the application form. In the case of outsourced manufacturing, assurance statements or affidavits shall be signed by both parties.

Article 89 For the purpose of applying for Chinese medicine registration or post-approval changes, the clinical trials conducted in Taiwan shall conform to the following regulations:
1. A manufacturer shall conduct clinical trials in Taiwan in accordance with the Regulations for Good Clinical Practice and other regulations announced by the central health competent authority.
2. Before conducting a clinical trial, a manufacturer shall submit an application form for drug clinical trials, a protocol, a summary, and the technical data announced by the central health competent authority for reviews by the said authority.
3. After an application is reviewed and approved by the central health competent authority, the manufacturer shall conduct a clinical trial based on the comments given. After completion of the clinical trial, the clinical trial report and results shall be submitted for recording. Any necessary changes in the clinical trial protocol may be done only after such changes have been approved.
4. Before the central health competent authority reviews the clinical trial report and results, grants its approval, and issues a letter regarding the recording of the report, no applications for registration or post-approval changes will be approved.

Article 90

Unless otherwise provided in this Chapter, the authorization letter, FSC from the country of origin, batch record and manufacturing and controls standards, form for sticking changed licenses and certificates, references and research reports, the applicant field on the application form, and outsourced manufacturing and inspection shall be subject to Article 5, Article 6, Article 11, Article 12, Article 13, Paragraphs 1 and 3 of Article 16, and Article 23, respectively.
If any of the following conditions occurs, applications concerning Chinese medicine shall be rejected:
1. Any of the conditions listed in Article 25 occurs.
2. Another application is submitted for products with the same dosage form on the same formulation basis. However, this provision is not applicable to those made into different sizes of pills, tablets, or capsules, as well as excipients made of different aromatics, coloring agents or flavors.

Section 2 Chinese Medicine Review and Registration

Article 91 When applying for Chinese medicine registration, the applicant shall provide photocopies of documents to justify that the hardware, software, and relevant dosage form equipment of the manufacturers have complied with the Good Manufacturing Practice for Medicinal Products. For toll-manufactured products, the manufacturers shall include those commissioned to engage in any and all of the manufacturing processes outsourced in different stages.

Article 92 The application form and following documents and data are required for applications for the registration of domestically manufactured Chinese medicine:
1. Assurance Statements (A) and (B); Assurance Statement for Export Only (C) is also required if an application is simultaneously submitted for the name used for export only;
2. Two copies each of the forms for sticking outer boxes, package inserts, and labels;
3. Form for sticking licenses and certificates;
4. Photocopy of the formulation basis;
5. Photocopy of batch records;
6. Two copies each of the forms for testing specifications for finished products, testing methods for finished products, records of general inspection for finished products, testing report for finished products, and identification test results (including chromatographic maps or other documents sufficient for confirmations); the testing items and specifications shall comply with Appendix 13 and the announcements made by the central health competent authority;
7. The standard operating procedures for stability testing, and reports of stability tests, furthermore, of all the stability tests should comply with The standards for stability tests of Chinese medicine products announced by the central health

competent authority;
8. For formulas not approved by the central health competent auth
included in the well-established publications, testing methods, s
and graph spectra of the content of one marker ingredient are req
case of single ingredient preparations; those of two or more mark
are required in the case of compound preparations. However, those
central health competent authority as having difficulties in sati
requirements may be exempted;
9. For applications for any formula listed in the drug license of
company as the formulation basis, testing or inspection data iden
submitted when the drug concerned is approved shall also be provi
The application form and following documents and data are require
applications for the registration of Chinese medicine for export
1.The documents and data required in Subparagraphs 1 to 5 of the
paragraph and the standard operating procedures for stability tes
forth in subparagraph 7.
2.Testing specifications for finished products, testing methods f
products, records of general inspection for finished products, an
for finished products. Except for the identification test, the te
specifications shall comply with Appendix 13 and the announcement
central health competent authority, otherwise in accordance with
of the country of destination.
The Chinese medicine for export only stated in the preceding para
conduct the stability testing and have a written report which is
pharmaceutical factory for future inspection. The stability test
with The standards for stability tests of Chinese medicine produc
the central health competent authority.
Appendix 13.pdf

Article 92-1 Any person submitting the application specified in Paragraph 1 of the preceding article may remove any Chinese medicine materials or ingredients banned by the importing country from the formula listed in the license held for a domestically manufactured Chinese medicine and may use the revised formula as the formulation basis set forth in Subparagraph 4 of Paragraph 1 of the preceding article when applying for registration of the Chinese medicine, without being subject to the restrictions set forth in Paragraphs 1 and 2 of Article 75.
The manufacturer listed in the drug license issued upon the registration specified in the preceding paragraph is limited to the one listed in the license for the domestically manufactured Chinese medicine specified in the preceding paragraph. However, this does not apply in the event of a change of the manufacturer in accordance with Paragraph 1 of Article 106 or Article 107.
For applications for registration in accordance with Paragraph 1, the batch records required in Subparagraph 5 of Paragraph 1 of the preceding article may be replaced by the Manufacturing

and Control Standard. Moreover, submission of the records of gene for finished products, testing report for finished products, and identification test results (including chromatographic maps or ot sufficient for confirmations), as set forth in Subparagraph 6 of the preceding article, as well as the reports of stability tests, Subparagraph 7, is not required.

Article 93 The following documents and data are required for applications for the registration of imported Chinese medicines:

1. Original copy of the authorization letter;
2. Original copy of the FSC from the country of origin and a copy of the Chinese translation;
3. Application form for drug review and registration;
4. Assurance Statements (A) and (B);
5. Two copies each of the forms for sticking outer boxes, package inserts, and labels;
6. Form for sticking licenses and certificates;
7. Photocopy of the formulation basis;
8. Photocopies of batch records for the same lot as the testing samples;
9. Two copies of documents specifying the testing specifications and methods for raw materials and finished products in Chinese or in English; the following regulations shall also be observed:
(1) Each ingredient (including main ingredients and excipients) of the formula shall be indicated; if the ingredients used are based on a pharmacopoeia, a photocopy of the description of such ingredients in the pharmacopoeia shall also be provided;
(2) The testing items and specifications for finished products shall comply with Appendix 13 and the announcements made by the central health competent authority
10. Two copies of the testing reports on raw materials and finished products; the following regulations shall also be observed:
(1) The batch number, testing date, product names, and signatures of the persons in charge of testing and supervision shall be provided;
(2) The batch number indicated on the testing report on each ingredient (including main ingredients and excipients) of the formula shall be the same as that of the raw materials used for the finished products. The raw materials and finished products shall be tested for each specification criterion.
11. Documentation procedures and reports of stability tests;
12. For formulas not approved by the central health competent authority to be included in the well-established publications, testing methods, specifications, and a graph spectra of the content of one marker ingredient are required in the case of single ingredient preparations; those of two or more marker

ingredients are required in the case of compound preparations. Ho
deemed by the central health competent authority as having diffic
satisfying such requirements may be exempted;
13. For applications for any formula listed in the drug license o
company as the formulation basis, testing or inspection data iden
submitted when the drug concerned is approved shall also be provi

Article 94 The following documents and data are required for applications for the registration of new Chinese medicine:
1. The registration application form and other documents;
2. Domestic clinical trial reports;
3. Technical data required by the central health competent authority as listed in official announcements.
In the event that the clinical trial report is difficult to conduct by local clinical trials, supporting data applicable to the Taiwanese people may be otherwise submitted for the application of adoption of foreign clinical trial data, which may be recognized only upon the approval by the competent central health competent authority.

Article 95 Licenses for drugs in the same dosage form but of different doses shall be applied for separately.

Article 96 A manufacturer may, in one month, submit two applications for the registration of compound preparations, or six applications for single ingredient preparations, or one application for compound preparations plus three applications for single ingredient preparations, unless the manufacturer has applied to the central health competent authority for special approval by giving reasons and providing relevant data.
The relevant data set forth in the preceding paragraph shall include information on the equipment and technical professionals of the drug manufacturing and quality control departments and other relevant information. When necessary, the central health competent authority may assign personnel to conduct on-site inspections of the quality control, production records, sample manufacturing processes and on-site supervision.
Each application for special approval, as set forth in Paragraph 1, shall involve up to 24 cases.

Section 3 Post-Approval Changes of Chinese Medicine

Article 97 In the case of outsourced manufacturing, the application form for post-approval changes of Chinese medicine shall be signed by both parties.

Article 98 The following documents and data are required for applications for registration of changes in the Chinese or English name of a Chinese medicine product:

1. 1. Application form for post-approval changes;
2. Original copy of the drug license;
3. Assurance Statement (A); if a trademark is used, a photocopy o
registration certificate or approval letter shall be submitted;
4. Two copies each of the originally approved outer boxes, packag
labels and the forms for sticking the outer boxes, package insert
be used instead;
5. 5. In the case of imported Chinese medicines, a letter of noti
post-approval changes issued by the original manufacturer and the
from the country of origin are also required;

Article 99 The changes in dosage forms of Chinese medicine products are limited to the changes from concentrated powders to concentrated granules, or vice versa, of standard formulas announced by the central health competent authority. Other changes in dosage forms shall be processed by filing a new application.
An applicant of registration of changes in dosage forms of Chinese medicine products shall have samples tested and the following documents and data submitted:
1. Application form for post-approval changes;
2. Original copy of the drug license;
3. Application form for drug review and registration;
4. Assurance Statement (A);
5. Two copies each of the originally approved outer boxes, package inserts, and labels and the forms for sticking the outer boxes, package inserts, and labels to be used instead;
6. Form for sticking licenses and certificates;
7. Photocopy of batch records;
8. Two copies each of the following documents: testing specifications for finished products, testing methods for finished products, records of general inspection for finished products, testing report on finished products, and the identification test results (including chromatographic maps or other documents sufficient for confirmations); the testing items and specifications shall comply with Appendix 13 and the announcements made by the central health competent authority;
9. Documentation procedures and reports of stability tests;
10. In the case of imported Chinese medicine, a letter of notification of post-approval changes issued by the original manufacturer and the original FSC from the country of origin are also required.

Article 100 An applicant of registration of changes in excipients of Chinese medicine products shall have samples tested and the following documents and data submitted:
1. Application form for post-approval changes;
2. Original copy of the drug license;

3. Two copies each of the originally approved outer boxes, packag
labels and the forms for sticking the outer boxes, package insert
be used instead;
4. Photocopy of batch records;
5. Two copies each of the following documents: testing specificat
finished products, testing methods for finished products, records
inspection for finished products, testing report on finished prod
identification test results (including chromatographic maps or ot
sufficient for confirmations); the testing items and specificatio
with Appendix 13 and the announcements made by the central health
authority;
6. Documentation procedures and reports of stability tests;
7. Testing specifications, methods, and reports of new excipients
In the event that the application set forth above only involves c
or capsule shell changes, without any impact on the characteristi
pharmacological effects, quality and safety of the original medic
following documents and data shall be submitted, and drug testing
1. Documents and data set forth in Subparagraphs 1 to 3 of the pr
paragraph.
2. Manufacturing and Control Standard.
3. Testing specifications and methods for finished products.
For an imported Chinese medicine under the change registration ap
preceding two paragraphs, a letter of notification of post-approv
issued by the original manufacturer and the original FSC from the
origin are also required.

Article 101 If a change in the formula of a Chinese medicine product involves changes of active ingredients, then the applicant shall re-apply for drug registration. However, the regulation shall not apply to cases of removing cinnabar or protected medical materials, cases based on standard formulas, or cases of proportional changes of other ingredients of a formula if applications for post-approval changes in excipients may be submitted in accordance with Paragraph 1 or 3 of the preceding article.

Article 102 The following documents and data are required for post-approval changes in the indications, efficacy, administration, and dosage of a Chinese medicine product:
1. Application form for post-approval changes;
2. Original copy of the drug license; however, a photocopy is acceptable for applications for changes in administration and dosage;
3. Two copies each of the originally approved outer boxes, package inserts, and labels and the forms for sticking the outer boxes, package inserts, and labels to be used instead;
4. Photocopy of the references that support the change.

Article 103 The following documents and data are required for post-approval changes in the product or license category for a Chinese medicine product:

1. Application form for post-approval changes;
2. Original copy of the drug license;
3. Application form for drug review and registration;
4. Two copies each of the originally approved outer boxes, package inserts, and labels and the forms for sticking the outer boxes, package inserts, and labels to be used instead;
5. Photocopy of the references that support the change.

Article 104 In any of the following situations, manufacturers may, at their own discretion, change labels, package inserts, or packaging of domestically manufactured Chinese medicine preparations without any changes in the originally approved text:

1. Changing the graphic design or colors; however, the graphic design shall not be offensive, indecent, or misleading;
2. Proportionally resizing the originally approved graphic design or text, or repositioning the originally approved graphic design or text;
3. Changing the fonts; however, the font size of the English product name shall not be larger than that of the Chinese product name;
4. Adding or changing the symbol for the corporate identity system;
5. Printing labels on outer boxes instead of sticking labels on them;
6. Additionally providing outer boxes that display the same text and graphic design as those on the original labels.

In case of any of the following changes in the originally approved text without affecting drug quality or medication safety, manufacturers may, at their own discretion, change labels, package inserts, or packaging of domestically manufactured Chinese medicine preparations:

1. Adding or changing the barcode, NHI code, ID code, “GMP” wording, names of ingredients of the formula in foreign languages, copyright registration number, trademark registration certificate number, or patent certificate number;
2. Adding or changing the suggested retail price or the customer service hotline;
3. Changing the name or address of the drug company, or adding or changing the telephone number, fax number, and contacts;
4. Adding or changing the distributor’s name and address; the font size of the distributor’s name shall not be larger than that of the drug company’s name;
5. Adding or changing seal labels for outer boxes or price labels;

6. Adding “For use by XX Hospital or hospitals only; no resale is similar wordings on the originally approved packaging;
7. Changing the manufacturer’s name that was added to the English
8. Changing the measurement unit of formulas in order to comply w Herbal Pharmacopoeia; or
9. Changing the terms used in describing the storage methods with original storage methods; the terms shall be consistent with thos Taiwan Herbal Pharmacopoeia or Chinese Pharmacopoeia.

If any changes in the text involves the addition of directions fo to ensure drug quality and medication safety, manufacturers may, discretion, change labels, package inserts, or packaging of domes manufactured Chinese medicine preparations.

For domestically manufactured Chinese medicine preparations to be manufacturers may, at their own discretion, change the font of th font of the distributor’s name, or the terms for storage method, “export only” label, package insert, or packaging, without being restrictions set out in the provisos of Subparagraph 3 of Paragra Subparagraphs 4 and 9 of Paragraph 2.

The changes or addition of an “export only” label, package insert forth in the preceding four paragraphs shall conform to the Good Practices for Pharmaceuticals specified in the Pharmaceutical Goo Practice Regulations, and records shall be made and retained by t for recording purposes.

Article 104-1 Except for the situations mentioned in the preceding article, a domestically manufactured Chinese medicine demanded for exporting which of any its “export only” label, package insert, or packing may be allowed to be changed without prior application and approval in any of the following circumstances where the originally approved text is changed without affecting the drug quality or medication safety:

1.Changing or deleting the manufacturer’s name or designation of the dosage form included in the product name;
2.The name of the Chinese medicine is changed to the approved name for “export-only” by the central health competent authority;
3.Changing the labeling method of the formula or deleting the excipient without changing the original formula proportion;
4.Deleting the domestic drug license number or adding license number approved by the destination country for export;
5.Changing or deleting the administration and dosage, but the changed administration and dosage shall not exceed the originally approved ones;
6.Deleting or simplifying the efficacy and indications;
7.Translating into a foreign language for the destination country for export;
8.Adding the trademark;

9.Adding precautions, warnings, or other text for ensuring drug q
medication safety;
10.Other items as announced by the central health competent autho
The changes or addition of an “export only” label, package insert
forth in the preceding paragraph shall conform to the Good Manufa
Practices for Pharmaceuticals specified in the Pharmaceutical Goo
Practice Regulations, and records shall be made and retained by t
for future reference.

Article 105

Except for the situations mentioned in the preceding two articles, applications for registration of changes in the packaging of Chinese medicine preparations shall comply with the following regulations:
1. The following documents and information are required for applications for changes in the maximum packaging size, provided that there are no changes in the packaging materials:
(1) Application form for post-approval changes;
(2) Original copy of the drug license.
2. The following documents and information are required for changes in the packaging materials:
(1) Application form for post-approval changes;
(2) Original copy of the drug license;
(3) Documentation procedures and reports of stability tests;
(4) Photocopy of batch records.
If the changes in the packaging materials mentioned in the preceding paragraph involve changes in labels, package inserts, or packaging, two copies each of the originally approved outer boxes, package inserts, and labels and the forms for sticking the outer boxes, package inserts, and labels to be used instead shall also be submitted.
In case of imported Chinese medicine preparations, on top of the provisions in the two preceding paragraphs, a letter of notification of post-approval changes issued by the original manufacturer and the original FSC from the country of origin are also required.

Article 105-1

Except for the situations described in the preceding article, the following information shall be submitted for application for change registration where domestically manufactured Chinese medicine preparations are making “export only” changes or adding “export only” drug name, maximum package quantity, packaging materials, efficacy, indications, administration and dosage, label, package insert, or packaging:
1.Application form for post-approval changes;
2.Assurance Statement for Export Only (C);
3.For changes in the drug name, maximum package quantity, packaging materials, efficacy or indications, the original copy

of the drug license is required;
4.For changes in the administration and dosage, label, package in packaging, the photocopy of the drug license (front and back) are
5.For changes in the drug name, the Assurance Statement (A) is re
6.For changes in the packaging materials, photocopies of the docu procedures and reports of stability tests, as well as the batch r required;
7.For changes in the efficacy or indications of the drug, photoco references that support changes is required;
8.For changes of the label, package insert, or packaging, two cop forms for sticking outer box, package insert, and label are requi

Article 106 The Assurance Statement (A) is required for applications for registration of outsourced manufacturing of Chinese medicine products and for applications for registration of self-manufacturing of products retrieved after outsourced manufacturing. Article 64 and Article 65 shall also apply mutatis mutandis respectively.
Article 66 applies mutatis mutandis to the outsourced inspection of Chinese medicine products.

Article 107 Articles 47, 57, and 60 to 63 shall apply mutatis mutandis to post-approval changes in Chinese medicine licenses, including letters of notification of post-approval changes issued by the original manufacturer, changes in testing specifications and methods, changes in the name or address of the drug company (including the manufacturer), changes in labels, package inserts, outer boxes, and aluminum blister foils (packets), and the reissuance of the approved copies due to loss.

Section 4 Chinese Medicine License Transfer, Replacement, and Reissuance

Article 108 Articles 71 shall apply mutatis mutandis to the reissuance of lost licenses, and the replacement of damaged licenses.

Article 108-1 The application for transferring a domestic Chinese medicine licenses should be filed by both parties. The following documents should be provided:
1. Application form for post-approval changes signed by both parties;
2. Original copy of the drug license to be transferred;
3. A list of drug licenses to be transferred, therein recording the license number, formula, dose and dosage form. However, the foregoing documents is not required for the application for transfer of a single drug license;
4. The assurance statement made by the transferee to certify the responsibility. For the transfer of the license of locally

manufactured drugs, the assurance statement should also certify t
drugs of the same formula;
5. Photocopy of the transfer approvals issued by the health compe
of the local governments where the transferor and transferee are
6. An assurance statement (A);
7. A photocopy each of all changed certificates and licenses;
8. Manufacturing and Control Standard. This document can be exemp
manufacturers have no intention to initiate production at present
The application for transferring an imported drug distributor’s l
filed by both parties. The following documents should be provided
1. Documents and data set forth in Subparagraphs 1 to 4 of the pr
paragraph.
2. Photocopy of the transfer approvals issued by the health compe
of the local governments where the transferor and transferee are
3. Original copy of the transfer agreement with signets of both p
4. Original copy of the authorization letter issued by the origin
stating the termination of the distributing contract with the tra
exchange of new contract with the transferee, as well as the addr
parties and the drug items involved in the transfer. The authoriz
should be authenticated by the R.O.C. foreign affairs offices;
5. A statement certifies that the same manufacturer does not have
the same formulation as the transferred drug.
For a product not yet manufactured as set forth in Subparagraph 8
the central health competent authority shall add the words “Manuf
prohibited” on the Chinese medicine license; if the manufacturer
actually produce the medicine subsequently, it should provide req
and data under Subparagraph 1, 2 and 8 of paragraph 1 to approved
competent central health competent authority before manufacturing
When applying for domestic Chinese medicine licenses transfer, if
name on the old license includes a prefix of the trademark or tra
company name which is not authorized, then an application for a c
name should be filed at the same time.

Section 5 Chinese Medicine License Extension Registration

Article 109 Applications for a license extension shall be filed within six months prior to the expiration date.
If an application is not filed before the deadline set forth in the preceding paragraph, the applicant shall reapply for registration. However, if the applicant reapplies for registration within six months after the expiration of the original license, he/she may submit an original copy of the application form for registration and proceed in accordance with Article 109-1.
If an application for a license extension also involves post-approval changes, then a separate application shall be submitted.

Article 109-1 The following documents and data are required for the applications set forth in Paragraph 1 of the preceding article:
1. Application form for a drug license extension, otherwise which shall be applied by the drug license holder on the circumstances of contract manufacturing;
2. Original copy of the drug license;
3. If the “expiration date” field on the drug license is filled with extension stamps, the original copy of the application form for drug registration is also required;
4. If the drug concerned is among those announced by the central health competent authority after it has conducted an evaluation in accordance with Article 48 of the Act, the documents required in the announcement shall be submitted for applications for extension;
5. If the manufacturing of the drug concerned is outsourced to a domestic manufacturer, a manufacturing outsourcing agreement shall also be submitted;
6. In the case of imported Chinese medicine, the original FSC from the country of origin, the authorization letter issued by the original manufacturer, and a photocopy of documents proving that the foreign manufacturer of imported medicines complies with the Good Manufacturing Practice for Medicinal Products are also required; if the applicant is not the holder of the documents proving the compliance with the Good Manufacturing Practice for Medicinal Products, the applicant may submit the authorization letter issued by the original manufacturer or the authorization letter issued by the domestic manufacturer that holds such documents and indicate the approval number instead. For Chinese medicine listed in the Taiwan Herbal Pharmacopeia, the testing specifications and methods for finished products as well as a photocopy of the approval letter for the latest change of the Taiwan Herbal Pharmacopeia, shall be otherwise submitted. However, if the testing specifications meet or are better than the latest edition of the Taiwan Herbal Pharmacopeia, the testing specifications and methods for finished products may be adopted instead.
If any application for a license extension submitted involves concerns about the safety, efficacy, or indications of a product, the central health competent authority may request the applicant to submit relevant documents and data.

Chapter 4 Supplementary Provisions

Article 110 The Regulations take effect on the date of promulgation.
The provisions of Article 53, Article 39 related Appendix 2, and Article 40 related Appendix 4 amended on April 6th, 2016 in this Regulation shall come into force as of July 1st, 2017; The provision of Article 92 Paragraph 3 amended on July 31th, 2017

in this Regulation shall come into force as of January 1st, 2019;
of article 42 related Appendix 8, the photocopy of the API for Ex
compliance certificate dated within the past 2 years, amended on
2021 in this Regulation shall come into force as of January 1st,
provisions of Article 46, 56, 62, 64 and 70 amended on April 27th
Regulation shall come into force as of January 1st, 2024.
