IN-DEPTH

Pharmaceutical Intellectual Property And Competition

TAIWAN

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In-Depth: Pharmaceutical Intellectual Property and Competition (formerly The Pharmaceutical Intellectual Property and Competition Law Review) provides a practical overview of pharmaceutical intellectual property issues, including patent linkage and exclusivities, and related competition concerns. With a focus on recent developments, it is a useful tool for managing global risks in this area – analysing the key elements of the relevant legal and regulatory regimes across major jurisdictions worldwide.

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Taiwan

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Summary

Introduction

Taiwan's pharmaceutical industry is primarily engaged in the manufacturing of pharmaceutical products, including active pharmaceutical ingredients, Western medicine, oriental medicine and biologics. Generic Western medicinal products make up the largest portion and are also the category that receives the most registration applications.[1] However, government policy has been promoting originator activity in Taiwan with products being sold domestically and abroad, as well as licensing foreign pharmaceutical entities to operate in Taiwan. Furthermore, the race for vaccine development during the covid-19 pandemic has also jump-started new interest in biologics.

'Year in review' describes the most significant pharmaceutical policy developments in Taiwan in the past year. 'Legislative and Regulatory framework' covers the legal framework for Western medicinal products in Taiwan. 'New drugs and biologics – approval, incentives and rights' provides an overview of the registration and inspection process for new drugs, generics, biologics and biosimilars, and 'Patent linkage' describes the patent linkage regime. Competition law-related matters are covered in 'Competition enforcers' onward, including how merger filings are handled and recent key cases. 'Special considerations' introduces two bills related to regenerative therapy and the exemptions to the drug registration process.

Year in review

The National Health Insurance Administration (NHIA) announced a new parallel review system for new drugs effective January 2024 that would allow the new manufacturer of a new drug to simultaneously apply to the NHIA for reimbursement recommendations during the new drug registration process, thereby reducing the permit review and NHIA payment approval time. The NHIA has also established the 'Center for Health Policy and Technology Assessment' that is dedicated to the assessment of medical technologies in accelerating the review process of including new drugs in the National Health Insurance (NHI) package.[2]

The Taiwan Food and Drug Administration (TFDA) has initiated a three-year pilot programme for 'Combined Registration and Review of Rare Disease Drugs Approved in Advanced Countries' [3] to accelerate the market launch of rare disease drugs. Currently, the preliminary review by the TFDA's Review Committee for Rare Disease and Orphan Drugs-Drug Subcommittee may be completed in as few as 240 days.

On 28 June 2023, the Taiwan Fair Trade Commission (TFTC) announced an amendment on the types of mergers that no longer require a merger filing.[4] It is no longer necessary for foreign enterprises setting up or operating a joint venture outside of Taiwan to make a merger filing in Taiwan if such joint venture does not engage in any economic activity within Taiwan.

Legislative and regulatory framework

The competent authority for the pharmaceutical industry in Taiwan is the Ministry of Health and Welfare (MoHW), and various departments of the MoHW are responsible for specific aspects of the industry as it relates to public health. For example, the TFDA is responsible for the registration, approval and inspection of pharmaceutical products, and the NHIA is responsible for the mandatory national health insurance policy.

In terms of primary legislation, pharmaceutical products in Taiwan are governed by the Pharmaceutical Affairs Act (PAA) and other statutes and regulations promulgated pursuant to its authority. The PAA regulates the registration, inspection, sales, manufacturing, advertisement and administration of pharmaceutical products as well as the patent linkage regime for Western medicine.

Taiwan's Patent Act is the primary statute regarding the patent duration of pharmaceuticals. While pharmaceuticals receive the same 20-year duration for an invention patent under the Patent Act, the applicant may obtain a one-time, five-year extension[5] in recognition of the inability to make use of the patent during the drug registration approval process, and the testing and use of the invention for registration approval purposes are generally not regarded as infringing the patent.[6]

Due to their close relationship with national health insurance and public health, rules relating to the public purchasing of pharmaceuticals, such as the National Health Insurance Pharmaceutical Benefits and Reimbursement Schedule and the Regulations on Price Adjustments for National Health Insurance Reimbursed Drugs are promulgated by the NHIA pursuant to the National Health Insurance Act. In general, once the NHIA approves the inclusion of a drug under the national health insurance programme for the first time, the former is used to set the pricing, and subsequent price adjustments are made according to the latter in consideration of the prevailing market price and other factors.

For competition law, the main statute is the Taiwan Fair Trade Act (TFTA), which covers both restriction of competition conduct, such as abuse of a dominant market position and concerted action, as well as unfair competition conduct such as false advertising and counterfeit products. As described later in this chapter, outside of certain exceptions, the TFTA applies to all competition-related conduct among pharmaceutical entities.

New drugs and biologics – approval, incentives and rights

Drugs

New drug application and approval process

An application for a new drug (new chemical entity, NCE), new therapeutic compound or new method of administration), new dosage form, or new unit-dose requires the submission of the application materials pursuant to the Regulations for Registration of Medicinal Products (RRMP) to the TFDA, which will assemble a committee of experts to review the application.[7] If the data presented for review can sufficiently support the safety,

efficacy and quality of the new drug, then it may enter the Taiwan market. The review process takes on average just under one year to complete.

The TFDA has announced several reforms to increase the efficiency of the new drug review process in recent years. In addition to the general process, there are also several specialised review tracks and mechanisms:

1. A 'priority review mechanism': this track shortens the review process to 240 days for pharmaceutical products vital to maintaining the life and health of the people.
2. A 'simplified review process': this is for NCE drugs that have already been approved by the US Food and Drug Administration, the European Union European Medicines Agency or the Ministry of Health, Labour and Welfare of Japan. The review process may be shortened to 180 days or 120 days depending on the documentation from the approved jurisdiction.
3. An 'accelerated review process': this is to allow certain drugs to shorten the R&D period and enter the market more quickly via the use of substitute efficacy benchmarks and with proper scientific evidence support. The review process for such drugs may be shortened to 240 days per the 'priority review mechanism'.
4. 'Paediatric or rare severe disease': this also allows drugs targeting paediatric care or certain rare severe diseases to enter the market more quickly. The review process for such drugs may be shortened to 240 days per the 'priority review mechanism'.
5. 'Breakthrough in treatment': this is for drugs targeting rare or severe diseases that show a key breakthrough in preliminary clinical trials compared to current treatment methods. The review process for such drugs may be shortened to 240 days per the 'priority review mechanism'.[8]

For orphan drugs, there is an 'orphan drug determination' mechanism established under the Rare Disease and Orphan Drug Act (RDODA),[9] under which the candidate drug is submitted for review by the TFDA and the Review Committee for Rare Disease and Orphan Drugs. Once the drug passes the review, even if it has not yet completed the registration process, it is possible to apply for permission to import or manufacture the drug as long as certain conditions are met;[10] and if it has already been registered, it may be included under the national health insurance system upon application.[11] Other incentive programmes to promote the registration of orphan drugs include giving orphan drugs a 10-year permit during which the competent authority will not register any other orphan drug of the same type,[12] simplifying the documents needed to register an orphan drug,[13] and reducing the registration fee to about one-third of other ordinary drugs (see below).[14]

The new drug registration fees are codified in the Standards of Review Fees for the Registration of Western Medicines. For NCE drugs, the fee is NT$1.5 million; for new therapeutic compounds, the fee is NT$500,000, and for new dosage form or unit-dose drugs, the fee is NT$250,000.[15]

In addition, the TFDA is promoting a new parallel review system for five major categories of drugs to accelerate the review process and the NHIA reimbursement approval, which may now be applied concurrently with the review process.[16] The types of drugs eligible for the parallel review system include but are not limited to those that have undergone TFDA inspection and registration review and have been identified as meeting the criteria for the

aforementioned 'prioritised review', 'accelerated approval', 'paediatric drug or drug for rare severe disease' or 'breakthrough in treatment drugs'; and those that are not yet marketed internationally at the time of application for inspection and registration in Taiwan.

New drug pricing

The pricing of new drugs is determined pursuant to National Health Insurance Pharmaceutical Benefits and Reimbursement Schedule. Of particular note is the section added in 2018 by the MoHW on managed entry agreements (MEAs):[17] MEAs in Taiwan may be based on performance as well as finances to allow risk to be shared between the pharmaceutical firm or manufacturer and the NHIA in multiple ways so that the new drugs may reach the patients through the national health insurance programme as soon as possible. For example, in a performance-based MEA, the cost-sharing between the firm and the NHIA may be based on overall survival, median progression-free survival time, or the time efficacy of the treatment becoming measurable, while for a finance-based MEA, the firm may offer a fixed rebate, pay for the costs of the initial treatment period, or provide adjuvant medication.[18]

For orphan drugs, specialised drugs with no generic substitutes and other specialised drugs, the pricing rules are more flexible compared to those for other new drugs and in principle defer to the prevailing market price.[19]

Data exclusivity and market exclusivity protections

NCE drugs are entitled to a three-year data exclusivity period starting from the date the NCE permit is issued and a five-year market exclusivity period.[20] If the NCE drug has already been approved for launch in a foreign market, the registration of the NCE drug in Taiwan must be made within three years from the date it received market authorisation in the foreign market to enjoy the data exclusivity period in Taiwan.

For new indications, the data exclusivity period is two years from the time the TFDA approves the added or revised indication, and a market exclusivity period of three years;-[21] however, if the applicant is conducting clinical trials in Taiwan, the applicant would be entitled to five years of market exclusivity as a way to incentivise firms to conduct clinical trials in Taiwan. In addition, if the new indication has already been approved for market launch outside Taiwan, the registration of the new indication must be completed within two years of such foreign market authorisation to be entitled to the aforementioned data exclusivity period.

As mentioned, an approval for registration of an orphan drug comes with a term of 10 years, during which no other drug of the same type may be registered. After the 10-year period, an application can be submitted to the TFDA for an extension of up to five years, but the TFDA will start to accept applications to register other drugs of the same type.[22]

Generic and follow-on pharmaceuticals

The registration of generics in Taiwan follows the same general procedure as other drugs, with some minor differences, such as the documents to be submitted with the generics application, which depends on the type of generic in question (a 'drug under post-market

surveillance', 'ordinary generics' or 'medical gas').[23] The process typically takes about 180 days, but for drugs under post-market surveillance, the process will take about 210 days instead.[24] The fee is NT$140,000 for a drug under post-market surveillance, and NT$80,000 for other generic types.

The factors that affect the pricing of a 'BA/BE generic drug' or 'ordinary generics drug' include whether the national health insurance programme has already approved the corresponding branded drug, or another BA/BE or ordinary generic drug with the same specifications, as well as whether the patents of the branded drug are still in effect or whether the branded drug is still within the period of surveillance.[25]

As the generic applicant needs to submit a declaration[26] regarding the status of the patents of the corresponding branded drug, the applicant may declare that the patent rights of the branded drug should be invalidated, or that the generic drug does not infringe on such patent rights. The first generic applicant who makes the above declaration and can subsequently prevail in a patent infringement challenge action from the branded drug manufacturer or otherwise successfully work around the patent is entitled to a market exclusivity period of 12 months.[27] However, if the generic drug only differed from the branded drug due to skinny labelling, no such market exclusivity is granted.[28]

Biologics and biosimilars

Biologics

Registration of a biologic product is generally similar to that for new drugs. For NCE biologics, requesting a bridging study is mandatory unless credible clinical trials regarding its medical efficacy and safety for Taiwanese nationals have already been conducted, and data from pharmacokinetics (PK) studies of the product in relation to East Asian populations are available.[29] The information and documents needed by the TFDA for the registration review are stipulated in Article 41 of the RRMP.

On 16 October 2015, the TFDA announced that as long as the materials used and the manufacturing process and the quality control mechanisms are identical, an approval registration for a biological product (such as a vaccine) may list multiple manufacturers instead of one manufacturer per registration limit for other pharmaceutical products.[30]

The registration fee depends on the type of biological product: NT$1.5 million for blood serums, antitoxins or vaccines, or pharmaceutical products derived from genetic engineering; and NT$250,000 for previously reviewed biologics with different dosage units or different country of origin.[31]

Biologics that have been determined as suitable for therapeutic purposes and contain an NCE as defined in Article 7 of the PAA may be entitled to a three-year data exclusivity period as a new NCE drug.[32]

Biosimilars

To promote transparency in the registration process, the Biosimilar Registration Review Standards as promulgated by the MoHW stipulates the review standards and consideration factors by which the competent authority reviews an application to register

a biosimilar product. Pursuant to the TFDA's overview of the registration process on its website, the review period for a biosimilar product is 300 days.[33] In addition, the MoHW has also taken note of the unique features and potential therapeutic value of biosimilar monoclonal antibodies (mAbs) in recent years and published the Biosimilar Monoclonal Antibody Registration Review Standards to address the specialised scientific strategy and corresponding review standards applied in reviewing a biosimilar mAb registration application.

Since a biosimilar by definition is supposed to have no clinically meaningful difference from the reference pharmaceutical product, the approval process is focused on comparative testing and demonstrating such lack of clinically meaningful difference. The supporting materials therefore include physical, chemical and biological characteristics data as well as non-clinical and clinical therapeutic efficacy and safety testing data. The TFDA may also stipulate increased post-market launch supervision to make up for any deficiencies in the comparative testing data.[34]

The registration of a biosimilar in Taiwan will require the applicant to make a declaration regarding the status of the patents of the reference product. As is the case for generics, the first applicant of a biosimilar who manages to subsequently prevail in a patent infringement challenge action from the manufacturer of the reference product or otherwise successfully work around the patent is entitled to a market exclusivity period of 12 months.[35] Biosimilars that only differed from the reference product due to skinny labelling will not be entitled to this market exclusivity period.

Finally, the pricing for biosimilars is handled in the same way as generics, namely that it depends on whether the NHIA has already approved of biosimilars, branded biologics or reference products with the same composition.[36]

Patent linkage

The patent linkage regime for Western medicine in Taiwan was established pursuant to a Presidential Order amending Chapter IV-1 of the PAA on 31 January 2018. The MoHW then drafted the Regulations for the Notification of Drug Patent Linkage Agreements and the Regulations for the Patent Linkage of Drugs and also established online the Registration System for Patent Linkage of Drugs[37] to enable generics manufacturers to make drug patent inquiries, plan the market launch timing and make patent challenges. Branded drug manufacturers may also use the database to stay informed of how their patents are being used and take appropriate action to protect their patent rights.

When the TFDA is issuing a registration permit for a new drug, if the permit holder believes it is necessary to disclose information regarding the patents of the new drug, it shall visit the aforementioned Registration System for Patent Linkage of Drugs and upload the information within 45 days.[38] If the permit holder only obtained the patent after receiving the permit, the patent information may be uploaded within 45 days starting from the day after the date the patent for the new drug is published in the Patent Gazette.[39] The patents to be disclosed must be in relation to a patent for a substance, compound, formula or drug invention for therapeutic use.

As mentioned previously, when applying for registration of a generic drug, if the corresponding new branded drug involves a patent or patents for a substance, compound, formula or a drug invention for therapeutic use, the applicant for the generic drug is required to disclose to the TFDA the status of the patent rights between the generic drug and the new branded drug, which can take the following four forms:[40]

1. the branded drug has not disclosed any patent information (the P1 Declaration);
2. the patents of the branded drug have been extinguished (the P2 Declaration);
3. the patents of the branded drug are recognised, but the MoHW shall issue the permit for the generic drug once those patents have been extinguished (the P3 Declaration); or
4. the patents of the branded drug should be invalidated, or the generic drug is not infringing on those patents (the P4 Declaration).

If the generic drug applicant makes a P1 or P2 Declaration, once the application is found to be in order, the TFDA may issue the registration permit.[41] In the case of a P3 Declaration, the MoHW will issue the permit once the patents for the new branded drug have been extinguished.[42]

For a P4 Declaration, the generic drug applicant shall, within 20 days after the MoHW has notified the applicant that the application materials are in order, issue a written notification (a P4 Notice) to the holder of the registration permit for the new branded drug, the holder of the patents, the exclusive licensees of the patents, and the MoHW asserting the contents of the aforementioned P4 Declaration.[43]

If the patent holder or the exclusive licensee believes the generic drug applicant is infringing, they must initiate a patent infringement action within 45 days of their receipt of the P4 Notice and notify the TFDA of such.[44] The TFDA will initiate a 12-month moratorium on the issuance of the registration permit for the generic drug, but the review continues in the meantime.

If the court, in rejecting the infringement complaint, notes that there is a basis to invalidate the patents asserted in the case or that the generic drug applicant did not infringe on the patents, the TFDA will issue the registration permit for the generic drug;[45] if the applicant is the first applicant to achieve the above for the generic drug, the applicant would also be entitled to a 12-month market exclusivity period for the generic drug.[46] The same result would occur if the patent holder or the exclusive licensee failed to exercise their rights (e.g., failing to initiate the patent infringement action in a timely manner, or failing to disclose the patents on the Registration System for Patent Linkage of Drugs before initiating the infringement action) or other stipulated conditions occur.[47] On the other hand, if the court agrees that the generic drug is infringing during the moratorium period, the TFDA will only issue the registration permit after those patents have been extinguished.[48]

Competition enforcers

The TFTC is the competent authority of the TFTA. There are seven commissioners, including one Chairperson and one Vice-Chairperson serving four-year terms but with

staggered start and end dates between three commissioners and the other four to ensure the competent authority's independence. The commissioners' primary fields of expertise are law and economics. Commissioner meetings are held regularly to discuss and vote on issues, which are passed with a simple majority of the commissioners. Dissenting commissioners may also present their dissenting opinions.

When a TFTA violation also involves the violation of other laws, such as the Government Procurement Act in a government procurement case, the TFTA takes precedence over the other statute regarding any competition-related conduct unless the other statute prescribes otherwise, and only if such other language does not conflict with the legislative reasoning of the TFTA.[49] In actual practice, the TFTC often consults with the competent authority for the other statutes involved to work out the respective jurisdictions and scope of work. Between the TFTC and the MoHW, the only past understanding between the two authorities was for the MoHW to take the lead in false advertising cases. Due to the lack of clear jurisdiction delineation, it is possible for the TFTC and the MoHW to (at least initially) both become involved in a competition law matter involving pharmaceutical product manufacturers.

Merger control

Mergers in the TFTA are defined[50] as (1) a merger between two enterprises; (2) one enterprise acquiring an equivalent of more than one-third of the total number of voting shares or total capital of another enterprise; (3) one enterprise is assigned by or leaves from another enterprise the whole or the major parts of the business or assets of such other enterprise; (4) one enterprise jointly operating with another enterprise on a regular business; or (5) one enterprise directly or indirectly controls the business operations or makes human resources decision of another enterprise. Merger filings to the TFTC are required if (1) the merged enterprise will attain one-third of the market share; (2) one of the merging enterprises has one-quarter of the market share; or (3) one merging enterprise's sales turnover for the preceding fiscal year exceeds a certain threshold amount as announced by the TFTC (e.g., NT$40 billion combined global sales turnover, and at least two enterprises each attained a sales turnover in Taiwan of over NT$2 billion).[51] A fine of up to NT$50 million may be imposed on merging parties who fail to make a merger filing despite meeting the above requirements.[52]

Overall, merger prohibitions by the TFTC have been extremely rare in recent years. According to the TFTC's own statistics, of the 389 mergers that came before the authority from 2018 to March 2024, the TFTC only blocked two merger cases compared to 150 approvals (the merger review process was suspended in the remainder of cases due to incomplete application materials or other reasons).[53] The approvals include the following pharmaceutical firm mergers:

1. GlaxoSmithKline and Pfizer, 2019: the two firms declared the creation of a joint venture by each of their non-prescription drug consumer health businesses. The TFTC sought the opinions of the competent authorities of the industry, competitors and downstream transaction partners, and concluded that because the merger would only result in a limited increase of market share, and consumers would still have plenty of alternatives due to the large number of domestic and foreign

competitors in the relevant market, as well as how the clients are typically large transnational firms with sufficient bargaining power, there was no apparent restriction of competition concerns from the proposed merger.[54]

2. AbbVie Inc,Venice Subsidiary LLC and Allergan plc, 2019: the three firms filed their merger plan under which AbbVie would acquire 100 per cent of the shares and sole control of Allergan through its subsidiary Venice.[55] The TFTC concluded that since AbbVie and Allergan were not horizontally competing with each other, and the merger would not significantly change the market, there were no apparent restriction of competition concerns from the proposed merger.
3. Upjohn and Mylan, 2020: Pfizer spun off its subsidiary Upjohn, which then merged with Netherlands firm Mylan NV. The TFTC found that the two enterprises' products had many competitors, and all of the two enterprises' products were drugs covered by the NHIA, so the pricing for the patients was protected by the national health insurance programme. Furthermore, most of their downstream entities were large hospitals with sufficient bargaining power, so there was no basis to oppose the merger.[56]

Anticompetitive behaviour

In May 2021, the TFTC penalised two pharmaceutical companies for engaging in concerted action to mutually restrict each other's business activities. Lotus Pharmaceutical Co, Ltd (Lotus) entered into an exclusive distributor agreement with TTY Biopharm Co, Ltd (TTY) in 2009 in which TTY would be the exclusive distributor for Lotus' colon cancer drugs in Taiwan. Despite the agreement, TTY has never sold Lotus' drugs but its own colon cancer drugs instead, and neither party has ever alleged a breach of the agreement by the other party over a 12-year period. The TFTC concluded that even though Lotus' product had more competitive pricing compared to TTY's, TTY's failure to ever place an order for Lotus' drugs made it clear that the exclusive distributor agreement was merely a pretext for TTY to pay Lotus to stay out of the Taiwan market. Due to the considerable market shares of TTY in the colon cancer drug market in Taiwan, the conduct of TTY and Lotus was extremely harmful to the market order and punishable pursuant to the 'serious violation' provisions of the TFTA. Lotus and TTY were thus fined NT$65 million and NT$220 million respectively.[57]

The PAA[58] has a rule that requires a drug registration permit holder or applicant, a drug patent holder or an exclusive licensee to disclose to the MoHW any patent linkage-related settlement agreements or agreements among them that involve the PAA provisions on manufacturing, sales and marketing exclusivity periods within 20 days of the execution of such agreements. In addition, if the agreements involve reverse payment interests, the parties shall also notify the TFTC. The MoHW may notify the TFTC if it suspects the aforementioned agreements are in violation of the TFTA. However, as of the publicly available information by the end of March 2024 , the TFTC has yet to reach a decision in which it found a reverse payment interest agreement by pharmaceutical firms to be anticompetitive.

Special considerations

On 4 June 2024, the Legislative Yuan passed the Regenerative Medicine Act[59] and the Regenerative Medicine Product Regulations.[60] The Regenerative Medicine Act will regulate the R&D and promotion of regenerative medicine, manage regenerative medicine technologies and cell sources, and impose heavier fines on non-medical institutions advertising or carrying out regenerative medical treatment. The Regenerative Medicine Product Regulations monitor the entire life cycle of the derivative product, with mechanisms on conditional approvals, post-launch safety monitoring and relief measures for regenerative medicine product hazards.

Outlook and conclusions

To encourage the biotech pharmaceutical industry to engage in innovation and production in Taiwan, improve the people's right to health and the quality of medical care, the government is continuously implementing optimisation measures for the new drug registration and approval process to accelerate its overall pace. One example is the TFDA's new parallel review system, which entered into effect on 1 January 2024 and would greatly decrease the time needed for a new drug to become covered under the NHI programme. Efforts to accelerate and simplify the process to get new drugs to patients are thus expected to continue as in recent years.

While it may take some time for intended benefits (and/or issues) to manifest, the passage of the Regenerative Medicine Act and the Regenerative Medicine Product Regulations through the legislature in June 2024 is expected to provide a strong basis for biotech players involved in areas such as gene/cell therapy to start and grow their business in Taiwan.

Endnotes

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5 Article 53(1)–(3) of the Patent Act. Back to section

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9 Articles 15 and 16 of the RDODA. Back to section

10 Article 2 of the Regulations for Ad Hoc Application of Rare Disease and Orphan Drugs. Back to section

11 Article 15-1 of the RDODA. Back to section

12 id. Article 17(1). Back to section

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14 Article 2(1)(i) of the Standards of Review Fees for the Registration of Orphan Drugs. Back to section

15 Article 2(1) of the Standards of Review Fees for the Registration of Western Medicines. Back to section

16 Checklist for Qualification Data for Parallel Review Cases of Drug to Be Included in National Health Insurance Reimbursement (January 2024 Edition), https://www.nhi.gov.tw/ch/dl-65753-ca7b966ba28c4e9e9fb42fb0b97b3759-1.odt (last visited on 5 June 2024) Back to section

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18 id. Article 44-1. Back to section

19 id. Articles 34 and 35. Back to section

20 Article 40-2 of the PAA. Back to section

21 id. Article 40-3. Back to section

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23 Article 40 of the RRMP. Back to section

24 The TFDA's Pin-Zi-1091101119 Announcement dated 16 March 2020, also found on the following page on the TFDA's website outlining the process for registration of generics: https://www.fda.gov.tw/TC/site.aspx?sid=2961&r=1143465865 (last visited on 23 May 2024). Back to section

25 Articles 29 to 32 of the National Health Insurance Pharmaceutical Benefits and Reimbursement Schedule. Back to section

26 Further discussed in 'Biosimilars', below. Back to section

27 Article 48-16 of the PAA. Back to section

28 id. Article 48-20(2). Back to section

29 Article 22-1(1) of RRMP. Back to section

30 The TFDA's Yao-Zi-1041409729 Letter dated 16 October 2015. Back to section

31 Article 2(3) of the Standards of Review Fees for the Registration of Western Medicines. Back to section

32 Chuan-Feng Wu, 'An Analysis of Taiwan's Pharmaceutical Affairs Act Amendment Regarding Data Exclusivity of Pharmaceutical Products with Emphasis on Pharmaceutical New Indication',Intellectual Property Right Journal Issue 216 (December 2016), pp. 51–52. Back to section

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35 Article 48-16 of the PAA. Back to section

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37 https://plls.fda.gov.tw/ (last visited on 7 June 2024). Back to section

38 Article 48-3(1) of the PAA. Back to section

39 id. Article 48-5. Back to section

40 id. Article 48-9(1). Back to section

41 id. Article 48-10. Back to section

42 id. Article 48-11. Back to section

43 id. Article 48-12. Back to section

44 id. Article 48-13(1), 48-13(2). Back to section

45 id. Article 48-13(2). Back to section

46 id. Article 48-16(1). Back to section

47 id. Article 48-13(2). Back to section

48 id. Article 48-13(4). Back to section

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50 Article 10 of the TFTA. Back to section

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53 The TFTC's case statistics as of March 2024: https://www.ftc.gov.tw/upload/bc479c73-a629-46a2-bcef-8740a15dd126.pdf (last visited on 10 May 2024). Back to section

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57 The TFTC Gong-Cu-Zi-110032 Sanctions Decision. Back to section

58 Article 48-19. Back to section

59 The press release on the MoHW's website regarding the passage of the "Regenerative Medicine Act" at the Legislative Yuan, https://www.mohw.gov.tw/cp-16-78933-1.html (last visited on 4 June 2024). Back to section

60 The press release on the MoHW's website regarding the passage of the " Regenerative Medicine Product Regulations" at the Legislative Yuan, https://www.mohw.gov.tw/cp-6650-78936-1.html (last visited on 4 June 2024) Back to section

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