PRC LAWS AND REGULATIONS OVERVIEW

This section outlines major PRC laws, rules and regulations relating to our business.

Regulatory Departments

The regulators of medical industry in China include the National Medical Products Administration (NMPA), the National Health Commission (NHC), and the National Healthcare Security Administration (NHSA).

LAWS AND REGULATIONS RELATING TO NEW DRUGS

Application for New Drug Registration

Drug registration is a process for the NMPA to review the safety, efficacy, quality controllability and other aspects of applying drug according to the application submitted by the applicant, and determine whether to approve or not. Under the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) issued by the SAMR on January 22, 2020, effective from July 1, 2020, the Administrative Measures for Drug Registration (2020) is applicable to drug development, registration and supervision carried out in China for the purpose of drug marketing. According to the Administrative Measures for Drug Registration (2020), drug registration is a series of activities, for example, the applicant files an application for drug clinical trial, drug marketing permit, re-registration and others pursuant to legal procedures and related requirements, while the regulator reviews the safety, efficacy and quality controllability of the applying drug based on laws, regulations and existing science, and determines whether to approve or not. The drug registration certificate is valid for 5 years, during which the holder shall continuously ensure the safety, efficacy and quality controllability of the marketed drug, and apply for its re-registration at least 6 months before expiry.

Non-clinical Study and Animal Testing

The non-clinical safety evaluation for drug marketing application shall be conducted under the Good Laboratory Practice (《藥物非臨床研究質量管理規範》) issued by the China Food and Drug Administration ("CFDA") in August 2003, newly revised by the CFDA in July 2017 and effective from September 1, 2017. The Administrative Measures for Good Laboratory Practice Certification (《藥物非臨床研究質量管理規範認證管理辦法》) issued by the CFDA in April 2007 clarify the provisions for organizations applying for Good Laboratory Practice (GLP) certification. On January 19, 2023, the NMPA revised the Administrative Measures for GLP Certification, effective from July 1, 2023.

According to the Regulations on the Administration of Laboratory Animals (《實驗動物管理條例》) issued by State Science and Technology Commission (SSTC) in November 1988 and latest revised by State Council in March 2017, the Measures for the Quality Control of Laboratory Animals (《實驗動物質量管理辦法》) jointly issued by the SSTC and the State Bureau of Quality and Technical Supervision in December 1997, and the Measures for the Administration of Laboratory Animal Licenses (Trial) (《實驗動物許可證管理辦法(試行)》) issued by the Ministry of Science and Technology and other regulatory departments in December 2001 and effective from January 2002, in order to use laboratory animal or related products, one should obtain the license for laboratory animal use. The license will be valid for 5 years, and the holder shall apply for renewal within 6 months before expiry. The license is subject to annual inspection by local department/commission/bureau of science and technology.

Clinical Trial Application

After preclinical study, applicant shall carry out drug clinical trial with the approval of the NMPA, before a new drug clinical trial. According to the Decision on Adjusting the Approval Procedures for Administrative Examination and Approval Items of Certain Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) issued by CFDA on March 17, 2017 and effective from May 1, 2017. Since May 1, 2017, drug clinical trial approval shall be made by the Center for Drug Evaluation (CDE) in the name of CFDA. Under the Drug Administration Law of the People's Republic of China ("Drug Administration Law"), in order to conduct drug clinical trial, one should submit relevant new drug R&D materials required by State Council drug regulator, including development methods, quality indicators, pharmacological and toxicological test results and other related data, information and samples, to the State Council drug regulator for approval.

State Council drug regulator shall decide whether to approve the application or not within sixty (60) working days after receiving the clinical trial application, and notify the applicant of its decision. Failure to notify will be deemed as approval. Among them, any bioequivalence test shall be reported to State Council drug regulator for filing.

Before clinical trial, applicant shall submit a series of detailed documents to the NMPA. According to the Announcement on the Drug Clinical Trial Information Platform (《關於藥物臨床試驗信息平台的公告》) effective from September 2013 and the Regulatory Specifications for Drug Clinical Trials Registration and Information Disclosure (Trial) (《藥物臨床試驗登記與信息公示管理規範(試行)》) effective from July 2020, any applicant who has obtained the NMPA approval to conduct clinical trial in China shall complete the clinical trial registration and information disclosure on the drug clinical trial information platform. Applicant shall complete the trial pre-registration within 1 month from approval, to obtain the trial exclusive registration number; complete subsequent information registration before the first subject enters in the group, and shall submit for publicizing for the first time.

With clinical trial approval, applicant shall select an eligible institution to conduct clinical trial. According to the Regulations for the Administration of Drug Clinical Trial Institutions (《藥物臨床試驗機構管理規定》) effective from December 2019, a drug developer in order to conduct drug clinical trial in China with NMPA approval, including bio-equivalence test after archiving, shall conduct so in a drug clinical trial institution. Drug clinical trial institutions shall be shall be subject to filing administration. Institutions that only engage in analysis of biological samples related to drug clinical trials shall not be subject to filing. The NMPA is responsible for setting up a filing management information platform for drug clinical trial institutions for registration, filing and operation management of drug clinical trial institutions, as well as the entry, sharing and disclosure of information on supervision and inspection of the drug regulatory authority and competent healthcare authority.

Implementation of Clinical Trial

According to the Administrative Measures for Drug Registration (《藥品註冊管理辦法》), a clinical trial includes phase I, phase II, phase III, phase IV and bio-equivalence trials:

To conduct drug clinical trial, applicant shall obtain the consent of ethics committee. The drug used in clinical trial shall be managed at the requirements of Good Clinical Practice (GCP) (《藥物臨床試驗質量管理規範》). Before conducting subsequent phased drug clinical trials, the approved applicant shall develop drug clinical trial plans, subject to consent of ethics committee, and shall submit relevant drug clinical trial plans and supporting materials to the website of CDE.

New drug applying for registration shall be subject to clinical trial pursuant to the GCP issued by NMPA and NHC and effective from July 1, 2020.

The GCP, by reference to internationally recognized principles, specifies the standards for the entire clinical trial procedure, including preclinical trial preparation and necessary conditions, protection of subject rights and interests, trial protocol, duties of investigators, duties of applicants, duties of inspectors, trial records and reports, data management and statistical analysis, trial drug management, quality assurance, and multi-center trials.

According to the NMPA Announcement on Adjusting Drug Clinical Trial Review and Approval Procedures (《國家藥品監督管理局關於調整藥物臨床試驗審評審批程序的公告》), with approval for new drug clinical trial, applicant shall file an application for communication and exchange meeting with the CDE after phase I and phase II clinical trials and before Phase III clinical trial, to discuss with the CDE on critical technical issues including the phase III clinical trial design. Applicant may also file communication application at different stages of clinical trials, in respect of critical technical issues.

According to the Administrative Measures for Drug Registration, applicant may communicate with the CDE concerning important issues, before drug clinical trial application, during drug clinical trial and before drug marketing permit application or other critical stages. According to the Administrative Measures for Communication of Drug R&D and Technical Review (《藥物研發與技術審評溝通交流管理辦法》) issued by CDE on December 10, 2020, applicant may propose communication meeting with the CDE during drug R&D and registration application. There are 3 categories of communication meetings: Category I meeting, to be held for important safety

problems found in drug clinical trial or important technical problems found in breakthrough therapeutic drug R&D; Category II meeting, to be held at critical stage of drug R&D, mainly including the meeting before new drug clinical trial application, the meeting before initiating phase III clinical trial but after phase II clinical trial, the meeting before new drug marketing permit application, and the meeting for new drug risk assessment and control; Category III meeting, other than Category I and Category II.

New Drug Application

According to the Administrative Measures for Drug Registration, applicant shall, after completing the pharmaceutical, pharmacological, toxicological and drug clinical trial studies supporting drug marketing registration, determining quality standards, completing commercial-scale production process verification, and preparing for drug registration verification and inspection, file the application for drug marketing permit, and submit related study materials as required by the application materials. After formal review of application materials, the conforming application will be received. For generic drugs, *in vitro* diagnostic reagents under drug management, and other eligible events, if the applicant assesses that drug clinical trials are unnecessary or impracticable, and meet the conditions for drug clinical trial exemption, the applicant may directly file an application for drug marketing permit. The technical guidance and specific requirements for drug clinical trial exemption shall be developed and published by the CDE.

The CDE shall organize pharmaceutical, medical and other technical personnel to review the received drug marketing permit applications as required. After comprehensive evaluation, if the result is passed, the drug marketing will be approved, and the drug registration certificate will be issued. If the result is failed, it will be rejected. The drug registration certificate contains drug approval document number, holder, manufacturer and other information.

Drug registration verification refers to the verification on development site and manufacturing site to verify the integrity, consistency of application materials and the commercial production conditions for drug marketing, as well as additional verification (if necessary) on the manufacturers, suppliers or other entrusted institutions of chemical APIs, excipients and packaging materials and containers that are in direct contact with drugs involved in drug registration applications.

CDE will decide whether to carry out on-site verification of drug registration and development based on risks according to the degree of drug innovation and the previous verification of drug research institutions.

CDE will decide whether to initiate on-site verification of drug registration based on risks according to factors such as the variety, process, facilities, and past verification status of the applying registration. For innovative drugs, improved new drugs, and biological products, CDE will verify the manufacturing site and inspect the Good Manufacturing Practice (GMP) before marketing. For generic drugs etc., considering whether the applicant has obtained the drug manufacturing license with corresponding scope and whether the same dosage product has been marketed, CDE will verify the manufacturing site and inspect the GMP before marketing based on risks.

After receiving the drug registration application, CDE shall make initial review within forty (40) working days, and if manufacturing site verification is required, CDE shall notify the Center for Food and Drug Inspection of NMPA ("CFDI") for inspection, provide relevant materials required for inspection, and meanwhile notify the applicant and the local drug regulators of the province, region or municipality where the applicant or its manufacturer is located. In principle, the CFDI shall complete the inspection forty (40) working days before expiry of the review period, and report the verification status, results and other related materials to CDE.

Drug registration inspection includes standard review and sample inspection. Standard review is laboratory evaluation on the scientificity of the specific item in the applicant's drug standards, the feasibility of inspection methods, the rationality of quality control indicators and others. Sample inspection is laboratory inspection on the samples according to the applicant's or the CDE verified drug quality standards.

Drug Review and Approval System Reform

State Council published the Opinions on Reforming the Review and Approval System for Drugs and Medical Devices (《關於改革藥品醫療器械審評審批制度的意見》) ("Reform Opinions") in August 2015, providing a framework for reforming drug review and approval system, and clarifying the missions to increase the drug registration approval standards and expedite the innovative drug review and approval procedure.

CFDA published the Announcement on Several Policies for Drug Registration Review and Approval (《關於藥品註冊審評審批若干政策的公告》) ("Announcement on Several Policies") in November 2015, further explaining the methods and policies to simplify and expedite approval process on the basis of Reform Opinions.

According to the Decision on Adjusting the Approval Procedures for Administrative Examination and Approval Items of Certain Drugs (《關於調整部分藥品行政審批事項審批程序的決定》) issued by CFDA in March 2017 and effective from May 2017, CDE will directly make drug clinical trial approval decision (including homemade and imported drugs), drug additional application approval decision (including homemade and imported drugs) and imported drug re-registration approval decision.

The Breakthrough Therapeutical Drug Review Procedures (Trial) (《突破性治療藥物審評工作程序(試行)》), the Review and Approval Procedures for Conditional Approval of Drug Marketing Applications (Trial) (《藥品附條件批准上市申請審評審批工作程序(試行)》), and the Drug Marketing Permit Preferred Review and Approval Procedures (Trial) (《藥品上市許可優先審評審批工作程序(試行)》) issued by the NMPA in July 2020 and effective from July 2020 shall replace the Opinions on Preferred Review and Approval to Encourage Drug Innovation (《關於鼓勵藥品創新實行優先審評審批的意見》) published by CFDA in December 2017 and effective from December 2017, to further clearly expedite the drug registration procedure.

New Drug Administrative Protection and Monitoring Period

According to the Regulations for Implementation of the Drug Administration Law of the People's Republic of China (《中華人民共和國藥品管理法實施條例》) published on December 6, 2024 and operable from January 20, 2025, and the Work Plan for the Reform of Chemical Drug Registration and Classification (《化學藥品註冊分類改革工作方案》) published on March 4, 2016, the NMPA may monitor the Category 1 new drugs approved for the sake of public health protection, for a period of 5 years starting from the date of approval, to continuously monitor the safety of new drugs. During the new drug monitoring period, the NMPA shall not approve the application from other enterprise to manufacture or import such drug.

Regulations on International Multi-center Clinical Trials and Acceptance of Overseas Clinical Trial Data

According to the Notice on Publishing International Multi-center Drug Clinical Trials Guidance (Trial) (《關於發布國際多中心藥物臨床試驗指南(試行)的通告》) ("Multi-center Clinical Trials Guidance") issued by the CFDA on January 30, 2015 and effective from March 1, 2015, for international multi-center drug clinical trials, applicant may conduct clinical trials according to the same clinical trial program at different centers at the same time. When planning and conducting international multi-center drug clinical trials in China, the applicant shall comply with the Drug Administration Law (《藥品管理法》), the Regulations for the Implementation of the Drug Administration Law of the PRC (《中華人民共和國藥品管理法實施條例》), the Administrative Measures for Drug Registration (《藥品註冊管理辦法》) and other laws, regulations and requirements, and perform Chinese Good Clinical Practice (GCP) (《藥物臨床試驗質量管理規範》), refer to ICH and other international principles, and meanwhile satisfy the legal and regulatory requirements of other countries involved in the international multi-center drug clinical trials. If the applicant plans to use the international multi-center drug clinical trial data in drug registration in China, then this may at least involve two countries including China, and shall comply with the Multi-Center Clinical Trials Guidance (《多中心臨床試驗指南》) and other provisions relating to clinical trials in relating laws and regulations.

According to the Opinions on Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices (《關於深化審評審批制度改革鼓勵藥品醫療器械創新的意見》) published on October 8, 2017 and operable from then, the clinical trial data obtained from overseas multi-centers, if meeting the requirements of drug or medical device registration in China, may be used for registration application in China.

According to the Technical Guidelines for Receiving Drug Overseas Clinical Trial Data (《接受藥品境外臨床試驗數據的技術指導原則》) published by the NMPA on July 6, 2018, the basic principles for receiving overseas clinical trial data are: (i) applicant shall ensure the authenticity, completeness, accuracy, and traceability of overseas clinical trial data; (ii) the production process of overseas clinical trial data shall meet the ICH-GCP requirements; (iii) applicant shall ensure the overseas clinical trial design is scientific, the clinical trial quality management system meets the requirements, and the data statistical analysis is accurate and complete; and (iv) in order to ensure that the clinical trial design and statistical analysis are scientific and reasonable, for drugs that are developed simultaneously at home and abroad and will be tested in China, the applicant can communicate with the CDE before implementing the registered clinical trial to ensure that the design of the registered clinical trial meets the basic technical requirements of drug registration in China.

HGR Gathering, Collection and Archiving

Interim Measures for the Administration of Human Genetic Resources (HGR) (《人類遺傳資源管理暫行辦法》) provide for the effective protection and rational utilization of China's human genetic resources. According to the Administrative Licensing Matters Service Guide for HGR Gathering, Collection, Trading, Export and Departure (《人類遺傳資源採集、收集、買賣、出口、出境審批行政許可事項服務指南》) published by the MOST in July 2015 and the Notice of Implementation of Administrative Licensing for HGR Gathering, Collection, Trading, Export and Departure (《關於實施人類遺傳資源採集、收集、買賣、出口、出境審批行政許可的通知》) published by the MOST in August 2015, foreign invested applicant in order to gather or collect human genetic resources through clinical trials shall file to China Human Genetic Resources Management Office through online system. The Notice to Optimize HGR Administrative Approval Procedure (《關於優化人類遺傳資源行政審批流程的通知》) published by the MOST in October 2017 (effective from December 2017) simplifies the HGR gathering and collection approval procedure required for marketing in China. The Notice to Update HRG Administrative Licensing Matters Service Guide, Archiving and Early Reporting Scope and Procedure (《關於更新人類遺傳資源行政許可事項服務指南、備案以及事先報告範圍和程序的通知》) issued by the MOST on July 14, 2023 (effective from July 14, 2023) further streamlines the approval procedure for HGR gathering and collection required for drug marketing in China.

According to the Administrative Regulations on Human Genetic Resources of the People's Republic of China (《中華人民共和國人類遺傳資源管理條例》) issued by State Council in May 2019, revised in March 2024 and effective from May 1, 2024, China supports rational utilization of human genetic resources to conduct scientific research, develop biomedical industry, increase diagnostic and therapeutic skills, increase China's biosecurity ability, and increase people's health security level. A foreign entity or individual person or the organization established or actually controlled by it shall not gather or store Chinese human genetic resources in China, or provide Chinese human genetic resources to outside of China. In addition, the gathering, storage, utilization and outbound provision of Chinese human genetic resources shall: (i) comply with ethical principles, and have ethic review at national requirements; (ii) respect the privacy of HGR provider, obtain its prior knowing consent, and protect is legitimate rights and benefits; and (iii) perform the technical specifications prepared by State Council health regulator.

The Standing Committee of the National People's Congress issued the Biosecurity Law of the PRC on October 17, 2020, which was newly revised and came into effect on April 26, 2024. It establishes a comprehensive legal framework for existing laws and regulations in the fields of: epidemic prevention and control of infectious diseases in humans, animals and plants; research, development and application of biotechnology; biosecurity management of pathogenic microorganism laboratories; safety management of human genetic and biological resources; response to microbial resistance; and the prevention of bio-terrorist attacks and the threat of biological weapons. According to the Biosecurity Law, high-risk and medium-risk biotechnology R&D activities shall be carried out by legal entities established in China at law, and shall be approved or archived at law. The establishment of pathogenic microorganism laboratories shall be approved or archived at law. In addition, (i) the gathering human genetic resources of China's important genetic families, human genetic resources in specific regions, or human genetic resources of the types and quantities specified by State Council health regulator, (ii) the storage of China's human genetic resources, (iii) the utilization of China's human genetic resources to carry out international scientific research cooperation, or (iv) the transportation, mailing, and carrying of China's human genetic resources materials shall be approved by the health regulator.

The Implementing Rules for the Regulation on Human Genetic Resources Administration ("Implementing Rules") (《人類遺傳資源管理條例實施細則》) ("《實施細則》") were published by the MOST on May 26, 2023 and effective from July 1, 2023. Implementing Rules further provide for China's HGR management in details below: (a) clarify HGR information scope, including human genes, genome data and other information materials generated by HGR materials, excluding clinical data, imaging data, protein data and metabolic data. (b) clarify the criteria for overseas organizations, for example, (i) any overseas entity or person that directly or indirectly holds over 50% shares, equities, voting rights, property shares or other similar rights and benefits of an institution; (ii) any overseas entity or person that directly or indirectly holds less than 50% shares, equities, voting rights, property shares or other similar rights and benefits of an institution, but enjoys the voting rights or other rights and benefits sufficient to manipulate or exert great influence on the institution's decision, management and other behaviors; (iii) any overseas entity or person sufficient to manipulate or exert great influence on the institution's decision, management or other behaviors through investment relations, agreements or other arrangements; and (iv) other events according to laws, regulations or statutes. (c) list events that may require security review, including: (i) HGR information of significant genetic families; (ii) HGR information in specific regions; (iii) Exome sequencing and genome sequencing information resources with more than 500 cases; and (iv) other events that may affect China's public health, national security, and social public interests.

GCP Certification and GCP Compliance

To improve clinical trial quality, the NMPA and the NHC jointly published the Good Clinical Practice (GCP) in April 2020 (effective from July 1, 2020), for the purpose of ensuring the drug clinical trial process is standard, the results are scientific and reliable, and protecting the benefits and safety of subjects. According to the Opinions on Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices published by the General Office of the CPC Central Committee and the State Council in October 2017, the clinical trial institution's qualification will be archived. Clinical trial shall comply with GCP and the scheme approved by the ethics committee of every research center.

LAWS AND REGULATIONS CONCERNING DRUG OPERATION

Under the Drug Administration Law, one without drug operating permit shall not operate drugs, including drug distribution and retailing. The drug operating permit shall specify the effective period and business scope, and shall be reissued upon expiry after review.

Under the Measures for the Supervision and Administration of Drug Quality in Operation and Usage (《藥品經營和使用質量監督管理辦法》) effective from January 1, 2024, the drug operating permit is effective for 5 years. The holder of drug operating permit shall apply for renewal 6 to 2 months before expiry.

Good Supply Practice ("GSP Rules") was updated on July 13, 2016 and became effective since then. GSP Rules are the basic standards for drug supply management, applicable to drug operators in China, which requires strict control over the drugs operated by drug suppliers, covering staff qualification, business place, warehouse, testing equipment and facilities, management and quality control among other standards. Under the Drug Administration Law, drug supplies no longer need GSP certification, but they shall still comply with GSP Rules.

LAWS AND REGULATIONS CONCERNING INTELLECTUAL PROPERTIES

Patents

Chinese patents are mainly protected by the Patent Law of the People's Republic of China published by the Standing Committee of the National People's Congress on March 12, 1984, latest revised on October 17, 2020 and effective from June 1, 2021, and the Implementing Regulations of Patent Law of the People's Republic of China ("Implementing Regulations") published by State Council on June 15, 2001, latest revised on December 11, 2023 and effective from January 20, 2024. The Patent Law and its Implementing Regulations provide for 3 kinds of patents, namely: "invention", "utility model", and "design". "Invention" means a new technical program proposed to product, method or improvement; "utility model" means a practicable new technical program proposed to product form, structure or their combination; "design" means beautiful and industrial new design for product form, pattern or their combination or the combination of color, form and pattern. The patent of "invention" may be effective for twenty (20) years, the patent of "utility

model" may be effective for ten (10) years, and the patent of "design" may be effective for fifteen (15) years, all starting from the date of application. Under the Patent Law of the PRC, for the purpose of public health, State Council patent administrator may grant a mandatory permit to any patented drug, which allows it to be manufactured and exported to any country or region under related international treaty where the PRC is a party.

The latest revised Patent Law of the PRC introduces patent extension for new drug marketed in China, and provides that in order to compensate for the time occupied by new drug marketing review and approval, the State Council patent administrator shall on demand of patent holder grant patent period compensation to the invention patent related to the new drug permitted to market in China.

The compensatory period shall not be more than five (5) years. And the total effective patent period of a new drug marketed with approval shall not be more than fourteen (14) years. Such newly adopted patent period extension is favorable to the Company, because it provides longer protection period for the patents applied for or registered in China and the patents related to our product in research. During the patent period compensation, the protection scope of new drug is limited to the technical program related to such new drug and its approved indications; within the protection scope, patent holder enjoys the same rights and undertakes the same obligations as before the patent period compensation.

Trademarks

Chinese registered trademarks are mainly protected by the Trademark Law of the People's Republic of China published by the Standing Committee of the National People's Congress on August 23, 1982, latest revised on April 23, 2019 and effective from November 1, 2019, and the Implementing Regulations of the Trademark Law of the People's Republic of China published by State Council on August 3, 2002, latest revised on April 29, 2014 and effective from May 1, 2014. Trademark Office takes charge of national trademark registration and management, and a registered trademark will be effective for ten (10) years. Upon expiry, for continuing use, trademark registrant shall proceed with renewal within twelve (12) months before expiry as required. Failing so, the registrant may enjoy an extended period of 6 months. Every extended registration will be effective for ten (10) years, starting from the next day upon expiry of previous trademark. If the registrant fails to proceed with extension upon expiry, its registered trademark will be canceled.

Domain Name

Domain name is governed by the Measures for the Administration of Internet Domain Names (《互聯網域名管理辦法》) published by the MIIT on August 24, 2017 and effective from November 1, 2017. The MIIT is a major regulator of Internet domain names in China. Domain names are registered with domain name services established at relevant requirements, while the registrants will become domain name holders after registration.

Trade Secrets

Under the Anti-Unfair Competition Law of the People's Republic of China published by the Standing Committee of the National People's Congress, revised on June 27, 2025 and to be effective from October 15, 2025, "Trade Secrets" mean the technical information and operational information unknown to public, practicable, able to bring about commercial interest or profit for legal owner or holder and kept confidential by the legal owner or holder. Under the Anti-Unfair Competition Law of the People's Republic of China, an operator shall not commit any of the following infringements on trade secrets: (i) obtaining right holder's trade secrets by theft, bribery, fraud, coercion, electronic intrusion or other improper means; (ii) disclosing, using, or permitting others to use a rights holder's trade secrets obtained by the means described in item (i); (iii) disclosing, using or allowing others to use trade secrets in hands, in breach of confidentiality obligation or in breach of right holder's requirements for trade secrets; (iv) soliciting, attracting, or procuring others to break the confidentiality obligation or break the right holder's requirements for trade secrets, and thereby obtaining, disclosing, using or allowing others to use the right holder's trade secrets. If a third party knowing or who is conceived to know the foregoing infringements obtains, uses or discloses other's trade secrets, such behavior shall be deemed as infringement on other's trade secrets. The infringed party may request administrative remedy, while the regulator shall order to stop such infringement and penalize the infringing party.

Company Law and Relevant Regulations

The Company Law of the People's Republic of China revised by the Standing Committee of the National People's Congress on December 29, 2023 and effective from July 1, 2024 provides for company establishment, organizational structure and corporate management, which also applies to foreign invested enterprises in China.

LAWS AND REGULATIONS ON FOREIGN DIRECT INVESTMENT

Since January 1, 2020, the Foreign Investment Law of the People's Republic of China ("Foreign Investment Law") published by the National People's Congress of the People's Republic of China ("NPC") came into force. Simultaneously, the Law of the People's Republic of China on Sino-Foreign Equity Joint Ventures (《中華人民共和國中外合資經營企業法》), the Law of the People's Republic of China on Foreign-Capital Enterprises (《中華人民共和國外資企業法》) and the Law of the People's Republic of China on Chinese-Foreign Contractual Joint Ventures (《中華人民共和國中外合作經營企業法》) were repealed. Since then, the Foreign Investment Law becomes the fundamental law to regulate all or part of the foreign invested enterprises in China. However, the organizational form, organizational structure and behaving principles of foreign invested enterprises are still subject to the Company Law. The Chinese government has implemented a pre-entry national treatment and negative list management system for foreign investments, and canceled the original approval and archiving management system for the establishment and change of foreign-invested enterprises. The pre-entry national treatment is the treatment to foreign investors and their investments in the entry stage, in the conditions not less than the treatment to domestic investors and their investments. The negative list is a special administrative measure on entry of foreign investments in special fields at national requirements. China offers national treatment to foreign investments out of the negative list. The prevailing negative list is the Special Administrative Measures for Foreign Investment Access (Negative List) (2024 Edition) (《外商投資准入特別管理措施(負面清單)(2024年版)) issued by the NDRC and MOFCOM on September 6, 2024 and effective from November 1, 2024, which lists special administrative measures for foreign investment entry like equity requirements, officer requirements etc. in respect of the industries subject to the negative list. The Foreign Investment Law strengthening investment promotion and protection further regulates foreign investment management, proposes establishment of foreign investment information reporting system, to replace the original MOFCOM approval and archiving system for foreign invested enterprises.

Foreign investment information report is subject to the Measures for Reporting Foreign Investment Information (《外商投資信息報告辦法》) jointly developed by MOFCOM and SAMR, effective from January 1, 2020, under which, the MOFCOM is responsible for centralize and direct nationwide foreign investment information reporting. County and above level local commercial authorities and corresponding authorities in free-trade pilot zones and national level economic and technological development zones are responsible for foreign investment information reporting within their own jurisdiction. A foreign investor to directly or indirectly invest in China shall report its investment information to local commercial authority through corporate registration system and National Enterprise Credit Information Publicity System, by means of initial reporting, change reporting, de-registration reporting, annual reporting etc. A foreign investor to set up foreign invested enterprise in China or merge/acquire the equities of non-foreign-invested enterprise in China shall submit initial report through corporate registration system, at the time of establishment registration or at the time of change registration (filing) for such merger/acquisition. If not involving change registration (filing), a foreign invested enterprise shall file the change report through corporate registration system within twenty (20) working days from such change event.

The Measures for the Security Review of Foreign Investment (《外商投資安全審查辦法》) jointly published by NDRC and MOFCOM on December 19, 2020 and effective from January 18, 2021 provide for the foreign investment security review mechanism, covering applicable foreign investment types, review scope, review procedures etc.

REGULATIONS ON ENVIRONMENTAL PROTECTION

Enterprises engaged in industrial, construction, catering, medical and other activities that discharge sewage into urban drainage facilities shall apply to the relevant urban drainage authorities for a permit for sewage discharge into drainage network in accordance with relevant laws and regulations. These laws and regulations include the Regulations on Urban Drainage and Sewage Treatment (《城鎮排水與污水處理條例》) promulgated on October 2, 2013 and effective on

January 1, 2014, and the Administrative Measures on Permit for Urban Sewage Discharge into Drainage Network (《城鎮污水排入排水管網許可管理辦法》) promulgated on January 22, 2015 and last revised on December 1, 2022 and effective on February 1, 2023. Drainage households within the coverage of urban drainage facilities shall discharge sewage into urban drainage facilities in accordance with national regulations. Drainage households discharging sewage into urban drainage facilities shall, in accordance with the provisions of these Measures, apply for a drainage permit. Drainage households shall not discharge sewage to urban drainage facilities without obtaining drainage permits.

According to the Administrative Measures on the Pollution Discharge Permit (《排污許可管理辦法》) issued by the Ministry of Ecology and Environment on April 1, 2024, and effective on July 1, 2024, enterprises, public institutions, and other producers/operators subject to pollution discharge permit management shall apply for and obtain a pollution discharge permit, and discharge pollutants in accordance with the provisions of such permits; no entity may discharge pollutants without obtaining the permit. Pursuant to the Fixed Pollution Source Classification Management List (2019 Edition) (《固定污染源排污許可分類管理名錄(2019年版)》), the manufacturing of biological pharmaceutical products falls within the scope of pollution discharge permit management for fixed pollution sources.

REGULATIONS ON EMPLOYMENT AND SOCIAL SECURITY

Pursuant to the Labor Law of the People's Republic of China (《中華人民共和國勞動法》), promulgated by the Standing Committee of the National People's Congress on July 5, 1994, and last revised on December 29, 2018, and the Labor Contract Law of the People's Republic of China (《中華人民共和國勞動合同法》), promulgated by the Standing Committee of the National People's Congress on June 29, 2007, last revised on December 28, 2012, and effective on July 1, 2013, Employers shall enter into written labor contracts with full-time employees. Employers shall comply with the local minimum wage standards. Employers shall establish and improve management systems to protect the rights of workers, including establishing occupational health and safety systems and providing occupational training to workers to prevent occupational hazards. When hiring workers, employers shall truthfully inform them of the job content, working conditions, work location, occupational hazards, safety production status, remuneration, and other relevant information.

According to the Social Insurance Law of the People's Republic of China (《中華人民共和國社會保險法》), which was promulgated on October 28, 2010, and revised on December 29, 2018, employers shall pay social insurance premiums for their employees, including basic endowment insurance, basic medical insurance, unemployment insurance, maternity insurance, and work-related injury insurance. If an employer fails to make full and timely social insurance contributions, the social insurance contribution collection authority shall order it to pay or make up the arrears within a specified time limit and impose a late fee of 0.05% per day from the date of the default. If the entity still fails to make the payment after the deadline, the relevant administrative department shall impose a fine of not less than one time but not more than three times the amount in arrears.

According to the Plan for Deepening the Reform of the State Taxation and Local Taxation Administration System (《深化國稅、地稅徵管體制改革方案》) issued and implemented on December 24, 2015, various social insurance premiums, including basic pension insurance premiums, basic medical insurance premiums, unemployment insurance premiums, work-related injury insurance premiums, and maternity insurance premiums, will be collected uniformly by the tax authorities. According to the Notice on Steadily and Orderly Carrying Out Work Related to the Collection and Administration of Social Insurance Premiums (《關於穩妥有序做好社會保險費徵管有關工作的通知》) issued by the General Office of the State Taxation Administration on September 13, 2018, and the Urgent Notice on Implementing the Spirit of the State Council Executive Meeting and Effectively Carrying Out Work to Stabilize the Collection of Social Insurance Premiums (《關於貫徹落實國務院常務會議精神切實做好穩定社保費徵收工作的緊急通知》) issued by the General Office of the Ministry of Human Resources and Social Security on September 21, 2018, all local authorities responsible for collecting social insurance premiums are strictly prohibited from conducting centralized collection of historical arrears from enterprises on their own initiative. The Notice on the Implementation of Several Measures to Further Support and Serve the Development of the Private Economy (《關於實施進一步支持和服務民營經濟發展若干措施的通知》) issued by the State Taxation Administration on November 16, 2018 reiterates that tax authorities at all levels shall not independently organize and carry out centralized collection of arrears from payers, including private enterprises, for previous years. The Notice of the General Office of the State

Council on Issuing the Comprehensive Plan for Reducing Social Insurance Rates (《國務院辦公廳關於印發降低社會保險費率綜合方案的通知》) issued on April 1, 2019, requires the steady advancement of reforms to the social insurance contribution collection system. Contributions for basic endowment insurance and other insurance schemes for enterprise employees shall, in principle, continue to be collected under the current collection system, maintaining stable contribution methods. It also emphasizes that historical arrears of enterprises shall be properly addressed, and during the reform of the collection system, no centralized enforcement of historical arrears shall be carried out arbitrarily, nor shall any measures be taken that would increase the actual payment burden on small and micro enterprises, so as to avoid causing operational difficulties for businesses.

According to the Housing Provident Fund Administration Regulations (《住房公積金管理條例》) promulgated on April 3, 1999, and latest revised on March 24, 2019, employers shall make contributions to the housing provident fund for their employees. If an employer fails to make contributions or make contributions less than required, the Housing Provident Fund Management Center shall order it to make contributions within a specified time limit. If the employer still fails to make contributions after the deadline, the Housing Provident Fund Management Center may apply to the People's Court for compulsory enforcement.

The Interpretation of the Supreme People's Court on Legal Issues Concerning the Adjudication of Labor Dispute Cases (II) (《最高人民法院關於審理勞動爭議案件適用法律問題的解釋(二)》), which was released on August 1, 2025, and took effect on September 1, 2025, includes the following key points: firstly, it strengthens the stability of labor contracts by clarifying specific circumstances for entering into two consecutive fixed-term labor contracts; secondly, it balances the rights and interests of both parties by reasonably defining the liability for damages for an employee's breach of contract, requiring courts to determine the amount of compensation based on factors such as actual losses, degree of fault, and the term already fulfilled; thirdly, for new business models and complex employment relationships, it establishes a "penetrating recognition" rule. This rule clarifies that contractors, and those who allow their licenses to be used, who subcontract their business to unqualified entities or allow affiliation, shall bear direct responsibility for the employees' labor remuneration and work-related injury insurance benefits. In cases of mixed employment, courts will determine the attribution of the employment relationship based on a comprehensive assessment of employment management behaviors, payment of remuneration, and social insurance contributions; fourthly, it reinforces the social insurance bottom line by clarifying that agreements between employers and employees to not pay social insurance are invalid. If an employee terminates the labor contract on this basis and claims economic compensation, the court should support it. After the employer pays the outstanding social insurance contributions, they can require the employee to return any social insurance compensation that was already paid.

REGULATIONS ON INFORMATION SECURITY AND DATA PRIVACY

Data Security and Data Export

The Standing Committee of the National People's Congress promulgated the Data Security Law of the People's Republic of China (《中華人民共和國數據安全法》) on June 10, 2021 (effective from September 1, 2021), for the establishment of a data classification and grading protection system to conduct classified and hierarchical protection of data. Entities engaged in data processing activities shall, in accordance with laws and regulations, establish a sound full-process data security management system, organize data security education and training, and take corresponding technical measures and other necessary measures to ensure data security.

On December 28, 2021, the Cyberspace Administration of China (the "CAC") and other twelve PRC regulatory authorities jointly revised and promulgated the Measures for Cybersecurity Review (《網絡安全審查辦法》) (the "Cyber Review Measures"), which came into effect on February 15, 2022. The Cyber Review Measures stipulate that, among others, (i) when the purchase of network products and services by a critical information infrastructure operator (the "CIIO") (關鍵信息基礎設施運營者) or the data processing activities conducted by a network platform operator (網絡平臺運營者) affect or may affect national security, a cybersecurity review shall be conducted pursuant to the Cyber Review Measures; (ii) an application for cybersecurity review shall be made by an issuer who is a network platform operator holding personal information of more than one million users before such issuer applies to list its securities abroad; and (iii) the relevant PRC governmental authorities may initiate a cybersecurity review if such governmental authorities determine that the issuer's network products or services, or data processing activities affect or may affect national security.

According to the Measures for Security Assessment of Data Exports (《數據出境安全評估辦法》) issued by the Cyberspace Administration of the People's Republic of China on July 7, 2022, and effective from September 1, 2022, data processors that provide data overseas shall declare a security assessment for data exports to the national cyberspace administration via the provincial-level cyberspace administration where they are located under any of the following circumstances: (i) where a data processor transfers important data overseas; (ii) where a critical information infrastructure operator, or a data processor processing the personal information of more than one million individuals, who, in either case, transfers personal information overseas; (iii) where a data processor who has, since January 1 of the previous year cumulatively transferred overseas the personal information of more than 100,000 individuals, or the sensitive personal information of more than 10,000 individuals; or (iv) other circumstances under which security assessment of data cross-border transfer is required as prescribed by the national cyberspace administration.

According to the Regulations on Improving and Regulating the Cross-Border Transfer of Data (《促進和規範數據跨境流動規定》) issued and implemented by the Cyberspace Administration of the People's Republic of China on March 22, 2024, data processors other than the critical information infrastructure operators are exempt from declaring data export security assessments, entering into standard contracts for personal information export, or obtaining personal information protection certification if the cumulative amount of non-sensitive personal information provided overseas since January 1 of that year does not exceed 100,000 individuals.

Personal Information Protection

According to the Civil Code of the People's Republic of China (《中華人民共和國民法典》), personal information of natural persons is protected by law. If any organization or individual needs to obtain other people's personal information, it should obtain it in accordance with the law and ensure the security of the information. It shall not illegally collect, use, process, or transmit other people's personal information, and shall not illegally buy, sell, provide, or disclose the information. The Personal Information Protection Law of the People's Republic of China (《中華人民共和國個人信息保護法》) promulgated by the Standing Committee of the National People's Congress on August 20, 2021 and implemented on November 1, 2021, further emphasizes the obligations and responsibilities of processors for the protection of personal information, and requests higher level of protective measures on the processing of sensitive personal information.

According to the Cybersecurity Law of the People's Republic of China (《中華人民共和國網絡安全法》) promulgated by the Standing Committee of the National People's Congress on November 7, 2016 and effective on June 1, 2017, network operators shall follow the principles of legality, legitimacy and necessity when collecting and using personal information, and publicly disclose the rules for collection and use, clearly state the purpose, method and scope of collecting and using information, and obtain the consent of the person whose data is being collected. Network operators shall not collect personal information unrelated to the services they provide. Network operators are not allowed to leak, tamper with, or damage the personal information they collect; they are not allowed to provide personal information to others without the consent of the person whose data is being collected. However, this does not apply to cases where a specific individual cannot be identified and the identity cannot be recovered after processing. Network operators should take technical measures and other necessary measures to ensure the security of the personal information they collect and prevent leakage, damage and loss of information.

REGULATIONS ON TAXATION

For more details, please refer to "Appendix III — Taxation" in this document.

REGULATIONS ON FOREIGN EXCHANGE

Foreign Exchange Regulation

On January 29, 1996, the State Council promulgated the Administrative Regulations on Foreign Exchange of the People's Republic of China (《中華人民共和國外匯管理條例》) which became effective on April 1, 1996 and was amended on January 14, 1997 and August 5, 2008. Foreign exchange payments under current account items shall, pursuant to the administrative provisions of the foreign exchange control department of the State Council on payments of foreign currencies and purchase of foreign currencies, be made using self-owned foreign currency or foreign currency purchased from financial institutions engaging in conversion and sale of foreign

currencies by presenting the valid document. Domestic entities and domestic individuals making overseas direct investments or engaging in issuance and trading of overseas securities and derivatives shall process registration formalities pursuant to the provisions of the foreign exchange control department of the State Council.

According to the Notice on Relevant Issues Concerning the Administration of Foreign Exchange for Overseas Listing (《關於境外上市外匯管理有關問題的通知》) issued by the SAFE on December 26, 2014, the domestic companies shall register the overseas listing with the foreign exchange control bureau located at its registered address within 15 working days after completion of the overseas listing and issuance. The funds raised by the domestic companies through overseas listing may be repatriated to China or deposited overseas, provided that the intended use of the fund shall be consistent with the contents of the document and other public disclosure documents.

According to the Notice of the State Administration of Foreign Exchange on Reforming the Management Mode of Foreign Exchange Capital Settlement of Foreign Investment Enterprises (《國家外匯管理局關於改革外商投資企業外匯資本金結匯管理方式的通知》), or the SAFE Circular 19, promulgated on March 30, 2015, coming effective on June 1, 2015 and partially abolished on December 30, 2019 and March 23, 2023, foreign-invested enterprises could settle their foreign exchange capital on a discretionary basis according to the actual needs of their business operations. Whilst, foreign-invested enterprises are prohibited to use the foreign exchange capital settled in RMB (a) for any expenditures beyond the business scope of the foreign-invested enterprises or forbidden by laws and regulations; (b) for direct or indirect securities investment; (c) to provide entrusted loans (unless permitted in the business scope), repay loans between enterprises (including advances by third parties) or repay RMB bank loans that have been on-lent to a third party; and (d) to purchase real estates not for self-use purposes (save for real estate enterprises).

On October 23, 2019, SAFE promulgated the Notice on Further Facilitating Cross-Board Trade and Investment (《國家外匯管理局關於進一步促進跨境貿易投資便利化的通知》), which became effective on the same date (except for Article 8.2, which became effective on January 1, 2020), and partially amended on December 4, 2023 and effective since then. The notice canceled restrictions on domestic equity investments made with capital funds by non-investing foreign-funded enterprises. In addition, restrictions on the use of funds for foreign exchange settlement of domestic accounts for the realization of assets have been removed and restrictions on the use and foreign exchange settlement of foreign investors' security deposits have been relaxed. Eligible enterprises in the pilot area are also allowed to use revenues under capital accounts, such as capital funds, foreign debts and overseas listing revenues for domestic payments without providing materials to the bank in advance for authenticity verification on an item by item basis, while the use of funds should be true, in compliance with applicable rules and conforming to the current capital revenue management regulations.

According to the Circular on Optimizing Administration of Foreign Exchange to Support the Development of Foreign-related Business (《關於優化外匯管理支持涉外業務發展的通知》) issued by the SAFE on April 10, 2020, eligible enterprises are allowed to use revenues under capital accounts, such as capital funds, foreign debts and overseas listing revenues for domestic payments without providing materials to the bank in advance for authenticity verification on an item by item basis, provided that the use of funds should be true, in compliance with applicable rules and conforming to the current capital revenue management regulations. The bank in charge shall conduct post spot checking in accordance with the relevant requirements.

Regulations in Relation to Overseas Securities Offering and Listing by Domestic Companies

According to the Overseas Listing Trial Measures issued by the CSRC on February 17, 2023 and effective on March 31, 2023, where a domestic company seeks overseas securities issuance and listing, the issuer shall file with the CSRC in accordance with the Overseas Listing Trial Measures. If an issuer procures an overseas initial public offering or listing, it shall file with the CSRC within three (3) business days after submitting application documents for overseas securities issuance and listing.

According to the Provisions on Strengthening Confidentiality and Archives Administration of Overseas Securities Offering and Listing by Domestic Companies (《關於加強境內企業境外發行證券和上市相關保密和檔案管理工作的規定》) jointly issued by the CSRC and other departments on February 24, 2023 and effective on March 31, 2023, in the overseas offering and listing activities of domestic enterprises, domestic enterprises, and securities companies and securities service

institutions that provide corresponding services shall strictly comply with the applicable laws and regulations of the People's Republic of China and satisfy the requirements of these provisions, enhance the legal awareness of safeguarding state secrets and strengthening archives administration, establish and improve the confidentiality and archives work system, and take necessary measures to fulfill the confidentiality and archives administration obligations, and shall not divulge state secrets or work secrets of state organs, or harm the interests of the state or the public. A domestic enterprise that, either directly or through its overseas listed entity, publicly discloses or provides to relevant securities companies, securities service institutions, overseas regulators, and other entities and individuals, any documents and materials that involve state secrets or work secrets of state organs, shall obtain approval from the competent department with the power of examination and approval according to the law, and report to the administrative department of confidentiality at the same level for filing. A domestic enterprise that, either directly or through its overseas listed entity, publicly discloses or provides to relevant securities companies, securities service institutions, overseas regulators, and other entities and individuals, other documents and materials whose divulgence will have adverse impact on national security or public interest, shall strictly undergo the relevant procedures in accordance with the relevant regulations of the state.

OVERVIEW OF LAWS AND REGULATIONS IN THE UNITED STATES

This section summarizes the principal laws and regulations in the United States that are relevant to our business.

U.S. Government Regulation of Drug and Biological Products

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations, and the FDA regulates biologics under the FDCA and the Public Health Service Act (the "PHSA") and their respective implementing regulations. Both drugs and biologics also are subject to other federal, state, and local statutes and regulations, such as those related to competition. The process of obtaining regulatory approvals to manufacture or market drugs and biologics in the United States and the subsequent compliance with appropriate federal, state, local, and non-U.S. applicable statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or following approval may subject an applicant to administrative proceedings, administrative actions, government prosecution, judicial sanctions or any combination of them in the United States. These actions and sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, license revocation, a clinical hold, untitled or warning letters, voluntary or mandatory product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement and civil or criminal fines or penalties. Any administrative proceeding on action or any judicial enforcement action could have a material adverse effect on our business, financial condition and results of operations as well as the market's acceptance of our products and our reputation. Outside the United States, drugs and biologics are regulated under other statutory and regulatory systems with which we would need to comply if we were to manufacture or market drugs or biologics outside the United States, and failure to comply there could also subject us to administrative actions, government prosecution or judicial sanctions (or any combination of them).

Once a product candidate is identified for development, it enters preclinical testing, which includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. Preclinical testing is conducted in accordance with FDA's Good Laboratory Practice regulations. A sponsor of an Investigational New Drug application ("IND") must submit the results of the preclinical tests (such as animal tests), manufacturing information, analytical data, the clinical trial protocol, and any available clinical data or literature to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions and places the trial on a clinical hold within that 30-day period. FDA may also impose clinical holds or partial clinical holds at any time during clinical trials due to safety concerns or non-compliance. Although information a sponsor submits in an IND is confidential information, general clinical trial information such as the number of patients involved and the type of adverse events studied can be made public information and can be available for public review through publication on government websites such as **www.clinicaltrials.gov**.

All clinical trials, which involve the administration of the investigational product to humans, must be conducted under the supervision of one or more qualified investigators in accordance with Good Clinical Practice ("GCPs") and human subject protection regulations, including the requirement that all research subjects provide informed consent in writing before their participation in any clinical trial. Further, an Institutional Review Board ("IRB"), often under the auspices of a university and sometimes a private, independent organization, must review and approve the plan for any clinical trial before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. An IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB's requirements or human subject research regulations or if the product has been associated with unexpected serious harm to subjects and the IRB believes patients are at risk.

Clinical trials generally are conducted in three sequential phases, known as Phase I, Phase II and Phase III, and may overlap.

- Phase I clinical trials generally involve a small number of healthy volunteers or disease-affected patients who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the product candidate.

- Phase II clinical trials involve studies in disease-affected patients to evaluate proof of concept and/or determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetics and pharmacodynamics information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.

- Phase III clinical trials generally involve a large number of patients at multiple sites and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA before marketing approval is received. Safety reports must be submitted to the FDA and the investigators 15 calendar days after the trial sponsor determines that the information qualifies for reporting. The sponsor also must notify FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than 7 calendar days after the sponsor's initial receipt of the information. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information, which is publicly available at **www.clinicaltrials.gov**.

Concurrent with clinical trials, companies usually complete additional animal studies and must also finalize a process for manufacturing the product in commercial quantities in accordance with FDA's current Good Manufacturing Practices ("cGMP").

U.S. Review and Approval Processes

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the product, proposed labeling and other relevant information, are submitted to the FDA as part of a New Drug Application ("NDA"). Unless deferred or waived, NDAs, or supplements, must contain data adequate to assess the safety and efficacy of the product at the proposed commercial dosing regimen and administration for the claimed indications in all relevant populations, including any pediatric subpopulations. The submission of an NDA is subject to the payment of a user fee and an annual prescription drug product program fee to the FDA although in certain circumstances the FDA may waive the annual prescription drug product program fee if the drug qualifies for orphan drug designation.

Within 60 days of its receipt, the FDA reviews the NDA to ensure that it is sufficiently complete for substantive review before it accepts the NDA for filing. After accepting the NDA filing, the FDA begins an in-depth substantive review to determine, among other things, whether a

product is safe and effective for its intended use. The FDA also evaluates whether the product's manufacturing is cGMP-compliant to assure the product's identity, strength, quality and purity. Before approving the NDA, the FDA typically will inspect whether the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA to an advisory committee, generally consisting of a panel of experts, to review whether the application should be approved and under what conditions, and the FDA typically considers such recommendations when making decisions.

The FDA may refuse to approve the NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information. The FDA will issue a complete response letter describing all of the specific deficiencies that the FDA identified in the NDA that must be satisfactorily addressed before it can be approved. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. The applicant may withdraw the application and resubmit the NDA when all the data addressing all of the deficiencies identified in the letter is available, or the applicant may request an opportunity for a hearing.

The regulatory approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including phase IV clinical trials, to further assess a product's safety and effectiveness after NDA/BLA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

Expedited Development and Review Programs

The FDA has various programs that are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

Fast Track Designation

Fast Track is a process designed to facilitate the development, and expedite the review of, drugs to treat serious conditions and fill an unmet medical need. Fast Track designation must be requested by the drug company. The request can be initiated at any time during the drug development process. The FDA will review the request and make a decision within sixty days based on whether the drug fills an unmet medical need in a serious condition. Determining whether a disease is serious is a matter of judgment, but generally the FDA considers whether the proposed drug will affect factors such as survival, day-to-day functioning, and the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. To address an unmet medical need, the proposed drug may be developed as a treatment or preventative measure for a disease that does not have a current therapy. The type of information necessary to demonstrate unmet medical need varies with the stage of drug development: early in development, nonclinical data, mechanistic rationale, or pharmacologic data will suffice; later in development, clinical data should be utilized.

A sponsor may request Fast Track designation when the sponsor files a BLA application or any time thereafter prior to the receipt of marketing approval. If a new drug product meets the requisite criteria for Fast Track designation, the FDA should grant the application. However, the FDA may rescind Fast Track designation, if the FDA determines the criteria for Fast Track designation are no longer met. The FDA will notify the sponsor in writing of its intent to rescind the designation through a "Intent to Rescind Fast Track Designation" letter, which will include the criteria for making the determination and provide the sponsor with an opportunity to submit additional data and justification to support the continuing designation and request a meeting to discuss the designation for the product. The rescinding of a Fast Track designation does not necessarily mean the product is not promising or that the product may not receive marketing approval. It means that the criteria for Fast Track designation are no longer met. The sponsor may request the designation to be

rescinded/withdrawn. The impact of revocation is that the sponsor will lose all of the benefits of Fast Track designation, which include more frequent meetings and written communication with the FDA, rolling review, and eligibility for Accelerated Approval and priority review.

Priority Review

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months under the Prescription Drug User Fee Act (the "PDUFA") guidelines. These six- and ten-month review periods are measured from the "filing" date rather than the receipt date for NDAs for new molecular entities, which typically adds approximately two months to the timeline for review and decision from the date of submission. Most products that are eligible for fast track designation are also likely to be considered appropriate to receive a priority review.

Accelerated Approval

Under the FDA's accelerated approval regulations, the FDA may approve a drug or biologic candidate for a serious or life-threatening illness that provides meaningful therapeutic benefit to patients over existing treatments and demonstrates an effect on either a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality ("IMM"), that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the disease or condition and the availability or lack of alternative treatments. A product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm a clinical benefit during post-marketing studies, will allow the FDA to withdraw the product from the market on an expedited basis. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Breakthrough Designation

Another program potentially available for sponsors is the breakthrough therapy designation. A drug or biologic may be eligible for designation as a breakthrough therapy if the product is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request that a product be designated as a breakthrough therapy concurrently with, or at any time after, the submission of an IND, and according to FAQs published by the FDA (current as of February 3, 2022), the FDA must determine if the candidate qualifies for such designation within 60 days of receipt of the request. If so designated, the FDA shall act to expedite the development and review of the products marketing application, including by meeting with the sponsor throughout the products development, providing timely advice to the sponsor to ensure that the development program to gather preclinical and clinical data is as efficient as practicable.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs or biologic candidates intended to treat a rare disease or condition generally affecting fewer than 200,000 individuals in the United States. The first applicant to receive FDA approval for the disease or indication for which it has orphan drug designation is entitled to a seven-year exclusive marketing period. During the exclusivity period, the FDA may not approve any other applications to market the same product for the same disease or condition except in limited circumstances. The impacts on the clinical development and registration of drugs receiving Orphan Drug designation are: the sponsors may be provided with (1) a tax credit of 50 percent of the cost of conducting human clinical trials, and (2) federal research grants for clinical testing of new therapies to treat and/or diagnose rare diseases; (3) eligibility for seven-year marketing exclusivity and (4) a waiver of NDA PDUFA fees. The approval of an orphan drug designation request does not alter the standard regulatory requirements and processes for obtaining marketing approval. Sponsors must establish safety and efficacy of a compound to treat a rare disease through adequate and well-controlled studies.

FDA may revoke orphan-drug designation for any drug if the agency finds that:

- The request for designation contained an untrue statement of material fact; or
- The request for designation omitted required or material information; or
- FDA subsequently finds that the drug in fact had not been eligible for orphan-drug designation at the time of submission of the request.

For an approved drug, revocation of orphan-drug designation also suspends or withdraws the sponsor's exclusive marketing rights for the drug but not the approval of the drug's marketing application.

Where a drug has been designated as an orphan drug because the prevalence of a disease or condition (or, in the case of vaccines, diagnostic drugs, or preventive drugs, the target population) is under 200,000 in the United States at the time of designation, its designation will not be revoked on the ground that the prevalence of the disease or condition (or the target population) becomes more than 200,000 persons.

If FDA revokes an orphan-drug designation, FDA will publicize that the drug is no longer designated in accordance with 21 CFR 316.28. The sponsor may request the designation to be rescinded/withdrawn. The impact of revocation is that the sponsor will lose all the benefits of Orphan Drug designation.

Post-Marketing Requirements

Following approval of a new product, the manufacturer of the approved product is subject to continuing regulation by the FDA, including, among other things, monitoring and record-keeping activities, reporting of adverse events ("AEs") experiences, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe legally available products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies such as the Department of Justice actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including investigation by federal and state authorities as well as potential tort liability. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the drug or biologic, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA/BLA or NDA/BLA supplement, which may require the development of additional data or preclinical studies and clinical trials. The FDA may also place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy ("REMS"), to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA/BLA must submit a proposed REMS. The FDA will not approve the NDA/BLA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

FDA regulations require that products be manufactured in specific approved facilities according to approved manufacturing processes and in accordance with cGMP regulations. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. These manufacturers must comply with cGMP regulations that require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. The manufacturer is ultimately responsible for its products and the manufacturing practices of its contract manufacturers, therefore the manufacturer must take responsibility for the failure for the contract manufacturers to manufacture according to cGMPs.

Manufacturers and other entities involved in the manufacture and distribution of approved drugs or biologics are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP

regulations, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA/BLA, including recall, any of which could have a material adverse effect on our business, financial condition and results of operations.

Once an approval is granted, if compliance with regulatory requirements and standards is not maintained or if problems occur after the drug reaches the market, the FDA may take enforcement actions such as issuing Warning Letters or Untitled Letters, ordering removal of the product from the market until deficiencies are remedied, withdrawing the approval of the product, or imposing civil and criminal penalties. Corrective action in response to these enforcement activities could delay drug distribution and require significant time and financial expenditures. Later discovery of previously unknown problems with a drug, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences which could arise from such regulatory violations include, among other things:

- restrictions on the marketing or manufacturing of the drug, suspension of the approval, complete withdrawal of the drug from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of drug approvals; drug seizure or detention, or refusal to permit the import or export of drugs; and
- injunctions or the imposition of civil or criminal penalties.

Patient Protection and Affordable Health Care Act

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the "ACA"), became law in the United States in March 2010, and has driven healthcare reform in the United States by extending health insurance coverage and substantially changing the way healthcare is financed by both governmental and private insurers in the United States. With regard to pharmaceutical products specifically, the ACA expanded and increased industry rebates for drugs covered under Medicaid programs and made changes to the coverage requirements under the Medicare prescription drug benefit. Among other things, the ACA contains provisions that may reduce the profitability of drug products through increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, and mandatory discounts for certain Medicare Part D beneficiaries and annual fees based on the pharmaceutical companies' share of sales to federal health care programs.

Since its enactment, there have been judicial and congressional challenges to certain aspects of the ACA, and there may be additional challenges and amendments to the ACA in the future. Since January 2017, former President Trump has signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have passed. There may be other efforts to challenge, repeal or replace the ACA.

Patent Term Restoration and Marketing Exclusivity

After approval, owners of relevant drug or biological product patents may apply for up to a five-year patent extension to restore a portion of patent term lost during product development and FDA review of NDA/BLA if approval of the application is the first permitted commercial marketing or use of a biologic containing the active ingredient under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act. The allowable patent term extension is calculated as one-half of the product's testing phase, which is the time between IND and BLA submission, and all of the review phase, which is the time between NDA/BLA submission and approval, up to a maximum of five years. The time can be shortened if the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension

may not exceed more than 14 years from the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration, only those claims covering the approved product, a method for using it, or a method for manufacturing it may be extended, and the patent holder must apply for restoration within 60 days of approval. The USPTO, in consultation with the FDA, reviews and approves the application for patent term restoration. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug candidate covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug candidate for which a BLA has not been submitted.

OVERVIEW OF LAWS AND REGULATIONS IN AUSTRALIA

Drug Development and Manufacturing

Clinical trials conducted in Australia are regulated by the Therapeutic Goods Administration ("**TGA**"). Clinical trials must comply with a number of laws and regulations in Australia at the Commonwealth and State/Territory levels, including the Therapeutic Goods Act 1989 (Cth) and the Therapeutic Goods Regulations 1990 (Cth). Clinical trials must also comply with: the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guidelines for Good Clinical Practice, as adopted and annotated by the TGA (the "**ICH GCP Guidelines**"); and the National Statement on Ethical Conduct in Human Research (the "**National Statement**").

There are two schemes for the approval of clinical trials in Australia: the Clinical Trial Notification ("**CTN**") scheme; and the Clinical Trial Approval ("**CTA**") scheme. The CTN scheme involves the TGA being notified of the clinical trial, but not undertaking any evaluation of the clinical trial. The CTA scheme involves the TGA not only being notified of the clinical trial, but also conducting an evaluation and assessment of the clinical trial prior to its commencement. The CTN scheme is generally used for earlier phase studies when there is adequate preclinical information about the product, particularly in relation to safety. The CTA scheme is generally used for high-risk or new treatments, where there is little known or no knowledge about the safety of the goods. The decision regarding which scheme to follow is generally up to the sponsor of the trial and the applicable Human Research Ethics Committee ("**HREC**"), although the CTA scheme is mandatory for certain types of biological medicines. Clinical trials in Australia require the approval of the research institute that is conducting the trial, following a review by its HREC before the trial commences. HRECs are also responsible for overseeing clinical trials.

Clinical trials conducted in Australia must have a trial sponsor that is an Australian company. It is permissible for a foreign corporation to engage an Australian company to act as the sponsor of a clinical trial in Australia, often referred to as the Local Sponsor. In this situation, the foreign corporation does not, itself, need to obtain any licenses or authorizations in respect of the clinical trial. The Australian trial sponsor is responsible for the initiation, management and financing (or arranging the financing) for the clinical trial and is legally responsible for the conduct of the clinical trial, including obtaining the requisite licenses or authorizations. The trial sponsor does not need to be the manufacturer of the product being trialed. The product manufacturer may rely on the results the trial when seeking to have the product registered on the Australian Register of Therapeutic Goods.

Clinical trials in Australia must follow the ICH GCP Guidelines as annotated by the TGA. The TGA's annotations provide additional guidance regarding compliance with the National Statement, obtaining informed consent in special cases, responsibility for the conduct of the trial (including management, data handling and record keeping), the manufacturing, packaging, labelling and coding of investigational products, and reporting for adverse drug reactions. The approval of a clinical trial in Australia is conditional upon compliance with the ICH GCP Guidelines as annotated by the TGA.

Clinical trials in Australia must also comply with the National Statement. The National Statement sets out the Australian ethical standards against which all research involving humans, including clinical trials, are reviewed. The approval of a clinical trial in Australia is conditional upon compliance with the National Statement.

In relation to safety reporting requirements, clinical trials conducted in Australia must follow: the Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95), as annotated by the TGA; and the National Health and Medical Research Council ("**NHMRC**") Guidance: Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods.

Additionally, per the ICH GCP Guidelines as annotated by the TGA, products used in clinical trial must comply with the applicable good manufacturing practices ("**GMP**"). For investigational products manufactured in Australia, the relevant manufacturing standards are set out in the Therapeutic Goods (Manufacturing Principles) Determination 2020 (Cth). Generally, therapeutic goods (other than blood, blood components, haematopoietic progenitor cells and biologicals that do not comprise or contain live animal cells, tissues or organs) must be manufactured in accordance with the Guide to Good Manufacturing Practice for Medicinal Products (PE 009-16, 1 February 2022) published by PIC/S.

Under both the CTN and CTA schemes, the clinical trial sponsor for a trial involving medicines or biological products must provide to the TGA information about the proposed dosage form, route of administration, formulation, dosage, and frequency of administration of the product (amongst other information), prior to the commencement of the clinical trial. If a change to the dosage is proposed to be made following the completion of a phase I clinical trial, then that change must be either notified to the TGA (if the clinical trial falls under the CTN scheme), or approved by the TGA (if the clinical trial falls under the CTA scheme). The change would also require review and approval by the HREC overseeing the trial.

Each State and Territory in Australia has agreed to abide by a set of National Standard Operating Procedures for Clinical Trials (**"SOPs"**). These SOPs are based on the ICH GCP Guidelines. The SOPs set out in detail guidelines in relation to a number of aspects of clinical trial design and conduct, including:

- responsibilities of investigators (including patient recruitment, staffing levels, conflict of interest management, and obtaining HREC approvals);
- site staff qualifications, training and capability (including ensuring staff have appropriate registrations and training, maintaining appropriate documentation of qualifications, and ensuring sufficient resourcing, managing delegation of obligations);
- development of the research protocol and investigational brochure (including ensuring that protocol content reflects study risks, research phase, and other relevant aspects of the trial, setting out processes regarding participant consent and information, describing the study including the methodology and design of the trial, and setting out storage and handling requirements of relevant products);
- site initiation (including mutual agreement with the sponsor for the scheduled date, time and location for initiation, arranging visits to participating site to ensure preparation is adequate, and ensuring all staff associated are able to attend);
- maintaining the study master file (including the record is kept up to date and secure);
- managing participant informed consent processes (including obtaining all relevant forms, ensuring consent has been obtained in the correct manner, allowing potential participants adequate time to read and digest information, assessing potential participants understanding of the trial, and managing the withdrawal of consent); and
- safety data monitoring and reporting requirements (including review of trial safety data, assessment of the balance of risks and benefits, and reporting of significant safety issues).

Marketing and Commercialization

The manufacture, registration, supply, advertising and post-marketing surveillance of therapeutic goods in Australia is regulated under the *Therapeutic Goods Act 1989 (Cth)* and the *Therapeutic Goods Regulations 1990 (Cth)* (and the *Therapeutic Goods (Medical Devices) Regulations 2022* with respect to therapeutic goods that are medical devices). All prescription

medicines must be registered on the *Australian Register of Therapeutic Goods* ("**ARTG**") before being supplied, unless exempt. Registration of a medicine involves assessing the medicines quality, safety, and effectiveness. Exemptions may apply where, for example, a medicine is dispensed or extemporaneously compounded for a particular person. Some lower risk over-the-counter medicines may instead be 'listed' on the ARTG, a process which requires less stringent evaluation (to reflect the lower risk posed by the products).

A marketing authorization holder is required to comply with conditions specified by the TGA, maintain the product's safety, quality and efficacy records, and report any serious adverse events in accordance with TGA requirements, including as set out in relevant guidance published by the TGA. Advertising of therapeutic goods to the public must comply with the *Therapeutic Goods Advertising Code 2021* ("**Advertising Code**"), noting that some types of therapeutic goods (such as prescription medicines) are not permitted to be advertised to the general public and may only be advertised where such advertisement is directed exclusively to healthcare professionals. The Advertising Code ensures that therapeutic good advertisements to the public do not mislead or deceive consumers, support informed health care choices, and remain consistent with public health campaigns. The *Competition and Consumer Act 2010 (Cth)* will also apply to advertisements of therapeutic goods, and similarly restricts the making of misleading or deceptive representations in advertising.

Guidelines Relating to Targeted Indications

In addition to the general therapeutic product regulatory framework, clinical guidelines have been developed for the management and treatment of gout. These include treatment advice set out in the *Australian Therapeutic Guidelines – Rheumatology: Gout* and management recommendations set out in the *Australian Rheumatology Association Gout Treatment Algorithm* (which provides evidence-based recommendations for diagnosis, acute flare management, serum urate-lowering therapy, and long-term follow-up of patients with hyperuricemia and gout). Not-for-profit organisations such as Arthritis Australia also produce guidance and information regarding gout, as well as maintaining resources regarding the conduct of clinical trials regarding gout. Such guidelines serve as key reference standards for the design and conduct of clinical trials on gout and for ensuring that investigational therapies are developed in line with current clinical practice in Australia.

Data Protection

The Privacy Act 1988 (Cth) ("**Privacy Act**") and Australian Privacy Principles ("**APPs**") apply to APP entities. An APP entity includes 'organizations', which means businesses that have an annual turnover for the previous financial year AU$3 million or more.

The Privacy Act is the principal piece of Australian legislation protecting the handling of personal information about individuals. This includes the collection, use, storage and disclosure of personal information of Australian individuals.

There are 13 APPs and they govern standards, rights and obligations around:

- the collection, use and disclosure of personal information;
- an organization or agency's governance and accountability;
- integrity and correction of personal information; and
- the rights of individuals to access their personal information.

It is a requirement for an APP entity to have a privacy policy. APP 1.4 contains a non-exhaustive list of information that an APP entity must include in its APP Privacy Policy:

- the kinds of personal information collected and held by the entity (APP 1.4(a));
- how personal information is collected and held (APP 1.4(b));
- the purposes for which personal information is collected, held, used and disclosed (APP 1.4(c));

- how an individual may access their personal information and seek its correction (APP 1.4(d));
- how an individual may complain if the entity breaches the APPs or any registered binding APP code, and how the complaint will be handled (APP 1.4(e)); and
- whether the entity is likely to disclose personal information to overseas recipients (APP 1.4(f)), and if so, the countries in which such recipients are likely to be located if it is practicable to specify those countries in the policy (APP 1.4(g)).

Each state and territory have its own separate privacy legislation which is largely consistent with the Privacy Act requirements.

Cross-Border Disclosure Requirements

Patient data falls under the category of 'sensitive information' under the Privacy Act. Sensitive information attracts a higher level of protection under the Privacy Act than other types of personal information, and can only be disclosed (1) for the purpose for which it was collected, (2) for a directly related secondary purpose, or (3) where an exception applies (for example, with an individual's consent, where required by law, or where a permitted general situation exists). For this reason, prior to disclosing patient data overseas a disclosing entity should ensure that such disclosure is permitted under the Privacy Act.

In addition to the above general disclosure requirements, where personal information is disclosed outside Australia to an overseas recipient the disclosing entity must take reasonable steps to ensure that the overseas recipient does not breach the Privacy Act in respect of that information. The concept of 'reasonable steps' is not defined, but it is generally expected that the disclosing party will enter into an enforceable contractual arrangement with the overseas recipient that requires the recipient to handle personal information in accordance with the Privacy Act. It is likely that more rigorous steps will be required where the information to be disclosed is sensitive information (including patient data).

The disclosing entity also remains accountable for any acts or practices of the overseas recipient, and may be liable for any breaches of the Privacy Act by the overseas recipient even if the disclosing entity has taken reasonable steps to ensure the overseas entity complies with its legal requirements. An 'overseas recipient' includes a related body corporate located outside Australia, however does not include an overseas office of the disclosing entity.

Limited exceptions to the above requirements arise under the Privacy Act, including circumstances where:

- the overseas recipient is subject to a substantially similar law or binding scheme which individuals can access;
- the overseas recipient is subject to the laws of a country which is prescribed by Australia's privacy regulations (this exception has been newly introduced and to date there are no such prescribed countries);
- the individual has consented to the disclosure after being expressly informed that if the individual consents, the entity will not be accountable under the Privacy Act;
- the disclosure is required or authorised by law; or
- a permitted general situation exists (i.e. disclosure is necessary to lessen or prevent a serious threat to life, to locate a missing person, etc.).

Patient data may also be subject to additional Australian privacy laws, such as State-based health privacy laws.

State and Territory privacy laws apply to 'health service providers' and entities which collect, hold, or use health information. Legislation underpinning these laws is the Health Records and Information Privacy Act 2002 (NSW) in New South Wales, the Health Records (Privacy and Access) Act 1997 (ACT) in the Australian Capital Territory, and the Health Records Act 2000 (Vic) in Victoria. These laws impose similar limitations to the disclosure of patient data as the Privacy Act.

Green-Washing Laws

The practice of 'greenwashing' occurs where a business makes a false or misleading environmental claim, typically in an attempt to make their business appear more environmentally beneficial. Greenwashing statements may be considered 'false or misleading representations', which are prohibited under the Australian Consumer Law (ACL) (legislation in Australia which provides protections to consumers and small businesses). The Australian Consumer Law will apply to all businesses selling goods and service in Australia (even if the business itself is located overseas). The Australian Competition and Consumer Commission, Australia's consumer law regulator, has frequently taken action against companies for allegations of greenwashing.

To avoid allegations of 'greenwashing', companies should ensure that all claims made about the environmental impact of a product/service are true and accurate, and that they are not misleading to an "ordinary and reasonable" audience. Businesses should only make claims that represent the genuine environmental impact of a product/service, and should not exaggerate the benefits or level of scientific acceptance of an environmental claim. Businesses should also ensure they have clear evidence to back up all environmental claims made. Visual elements are also important — use of symbols or other elements which are intended to give the impression that a product is 'good for the environment' can be considered misleading if the impression given to a consumer based on those elements is false.

A breach of the ACL's prohibition on false or misleading representations can lead to significant penalties — for example, corporations can be subject to penalties the greater of (a) $50 million AUD; (b) three times the value of the benefit obtained from the breach; or (c) 30% of the corporation's adjusted turnover during the breach period.