

# Telemedicine and Telehealth Legal Framework Overview



## Introduction

Radical technological change and innovation is transforming the delivery of healthcare across the globe, affecting the legal and regulatory landscape in healthcare technology. This rapid digitization has led to new players in telemedicine, online pharmacies and other forms of the digital delivery of healthcare.

Our Telemedicine and Telehealth Legal Framework Overview addresses the recent developments and future outlook across both the telemedicine and telehealth sectors; providing high level considerations pertaining to specific topics such as drug distribution and operation of e-pharma.

We hope you find this material useful and pertinent, as you navigate the legal complexities of this rapidly evolving industry. We have also included links to some of our other complimentary Healthcare & Life Sciences resources, along with our team's contact information, should you wish to discuss any of the topics raised in more detail.

This document has been prepared for the general information of clients and professional associates of Baker McKenzie and the content is current as of April 2022. It is not legal advice and should not be regarded as a substitute for legal advice.

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	<b>Australia</b>		<b>Malaysia</b>		<b>Taiwan</b>
	<b>China</b>		<b>Philippines</b>		<b>Thailand</b>
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## Asia Pacific

Jurisdiction	1. Is it possible for pharmacies to dispense drugs by means other than over-the-counter (or equivalent)? If yes, what are the relevant legal requirements?	2. Is it possible for healthcare professionals and pharmacies to deliver drugs directly to a patient's residence? If yes, what kind of drugs can be delivered, and what law allows such activity?	3. Are there any specific license(s) required for the operation of e-pharmacies?	4. Is it possible for healthcare professionals to treat and/or diagnose patients via a telemedicine platform (i.e., from a distance)? If yes, is there a need to have prior patient-doctor relationship?	5. Please advise on the recent developments and future outlook in the telemedicine and telehealth sector (i.e., if the COVID-19 pandemic has had any impact on the adoption of telemedicine, e-pharmacies or the issuance of any regulatory guidance.)
<p><b>Australia</b></p> 	<p>Yes, it is possible to dispense drugs through online pharmacies.</p> <p>While the Australian Pharmacy Board views the indirect supply of medicines through Internet and mail-order dispensing to be 'less than optimal', its guidelines permit dispensing of drugs through these methods.<sup>1</sup> Pharmacists are instructed to ensure compliance with state and national laws, the guidelines and established practice standards, including the Code of conduct for pharmacists.</p> <p>Breach of the guidelines can be used in disciplinary proceedings under section 41 of the Health Practitioner Regulation National Law.</p>	<p>Many pharmacies in Australia offer home delivery upon receipt of a valid prescription.</p> <p>For prescription medicines, online pharmacies will typically require the patient to post their physical prescription to the store or the doctor to send the prescription for the patient to the pharmacy before the pharmacist can dispense and supply the medicine to the patient (this is to cover the circumstance where the doctor has seen the patient via telehealth and the doctor cannot physically give the prescription to the patient). Alternatively, patients or the prescribing doctor may provide pharmacies with electronic prescriptions. Additionally, OTC medicines and general sales medicines can also be generally supplied online, but there may be exceptions depending on ingredients in the product.</p>	<p>There is no national license required for the operation of e-pharmacy businesses. Individual pharmacists must be registered with the Pharmacy Board to practice in Australia.<sup>2</sup> Pharmacists are also required to obtain approval from the Australian Community Pharmacy Authority before supplying medications subsidised by the government under the Pharmaceutical Benefits Scheme.</p> <p>State or Territory licences are required to operate pharmacies, including e-pharmacies, in Australia.<sup>3</sup> Pharmacies that have an online operation are generally required to be connected to an existing, registered pharmacy business operating out of approved premises.<sup>4</sup> Additionally, most States/Territories require registration of the pharmacy premises.</p>	<p>It is accepted practice for healthcare professionals to treat and diagnose patients via a telemedicine platform ('telehealth'). Telehealth appointments are governed by the same standards as face-to-face consultations,<sup>5</sup> and require doctors ensure "effective communication" as the standard of practice when working with patients.<sup>6</sup> The Medical Board of Australia released guidelines on technology-based patient consultations in 2012, as a complement to the primary code of professional medical standards in Australia.<sup>7</sup></p> <p>Eligibility for General Practitioner ("GP") telehealth services require most patients to have had a face-to-face consultation with their telehealth provider, or another provider at the same practice, in the 12-months before the telehealth service. There are currently some limited exceptions to this requirement for patients who are subject to COVID-19 Public Health Orders and for some specific types of GP services.</p>	<p>The COVID-19 pandemic has had a positive impact on the availability of telemedicine and telehealth services in Australia.</p> <p>In March 2020, the Australian government launched the 'Home Medicines Service' for free home delivery of prescription medications to eligible persons during the COVID-19 pandemic.<sup>8</sup> The program has been extended in 6-month increments, with the most recent extension ending on 30 June 2022.</p> <p>Telehealth services were added to Australia's Medicare Benefits Schedule in March 2020,<sup>9</sup> making it clear that telehealth appointments are able to be reimbursed under Australia's medical benefits system.</p> <p>In November 2020, the Federal Health Minister announced that Australia had surpassed 40 million telehealth consultations since the beginning of the pandemic and the telehealth Medicare scheme will become permanent.<sup>10</sup> The Minister also announced \$4 million is being put towards COVID digital health delivery, including a project that integrates remote monitoring technology into Australia's digital health infrastructure. On 13 December 2021, the Australian Government announced it is providing \$106 million</p>

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<sup>1</sup> Pharmacy Board of Australia, 'Guidelines for Dispensing of Medicines' (2015) guideline 5 <https://www.pharmacyboard.gov.au/codes-guidelines.aspx>

<sup>2</sup> Pharmacy Board of Australia, 'Registration' (2017) <https://www.pharmacyboard.gov.au/Registration.aspx>

<sup>3</sup> See, e.g., Pharmacy Regulation Act 2010 (Vic), Pharmacy Business Ownership Act 2001 (Qld), Health Practitioner Regulation National Law (NSW) (2009) (NSW) Schedule 5F.

<sup>4</sup> See Victorian Pharmacy Authority, 'Frequently asked questions' page 6-7 [https://pharmacy.vic.gov.au/cms\\_files/Application%20FAQs.pdf](https://pharmacy.vic.gov.au/cms_files/Application%20FAQs.pdf); Pharmacy Council of New South Wales 'The Guide: Explanatory Notes and Guidelines' (2020) Note 23 [https://downloads.pharmacycouncil.nsw.gov.au/s3fs-public/the\\_guide\\_-\\_final\\_30\\_march\\_2020\\_1.pdf](https://downloads.pharmacycouncil.nsw.gov.au/s3fs-public/the_guide_-_final_30_march_2020_1.pdf)

<sup>5</sup> Medical Board of Australia, 'Good medical practice: a code of conduct for doctors in Australia' (2020) section 1.2 <https://www.medicalboard.gov.au/codes-guidelines-policies/code-of-conduct.aspx>

<sup>6</sup> Medical Board of Australia, 'Good medical practice: a code of conduct for doctors in Australia' (2020) section 4.3 <https://www.medicalboard.gov.au/codes-guidelines-policies/code-of-conduct.aspx>

<sup>7</sup> Medical Board of Australia, 'Guidelines for technology-based patient consultations' (2012) <https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Technology-based-consultation-guidelines.aspx>

<sup>8</sup> Australian Government Department of Health, 'COVID-19 National Health Plan - Home Medicines Services Information for consumers' (2020) <https://www.health.gov.au/sites/default/files/documents/2020/03/covid-19-national-health-plan-home-medicines-services-information-for-consumers.pdf>

<sup>9</sup> Australian Government Department of Health, 'COVID-19 Temporary MBS Telehealth Services' (2020) <http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/Factsheet-TempBB>

<sup>10</sup> Australian Department of Health, 'Doorstep interview on 27 November 2020' (2020) <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/doorstop-interview-on-27-november-2020>

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					over four years to support continuing telehealth services. <sup>11</sup>
<b>China</b> 	<p>Yes. Online drug sale is permitted in China under the <i>Tentative Measures for Internet-Based Drug Trading Services</i> (2005) issued by the China FDA (now known as the National Medical Products Administration, "NMPA"). The pharmacy must be a retail pharmacy chain with suitable drug supply permit.</p>	<p>Yes for pharmacies, under the <i>Tentative Measures for Internet-Based Drug Trading Services</i> (2005). Online sales of prescription drugs are now allowed at a policy level by PRC State Council, provided that (i) the authenticity of the electronic prescriptions can be verified, and (ii) the drugs are not among those subject to special regulations, e.g., anaesthetics, psychotropic drugs, etc. Detailed regulations remain to be enacted but pilot cities such as Shanghai, Shenzhen and Hainan are taking lead in local implementation.</p> <p>No for healthcare professionals.</p>	<p>The pharmacy must be a retail pharmacy chain with suitable drug supply permit. In addition, an internet-based drug information service permit is also required as the online provision of drug-related information is generally inevitable for e-pharmacy.</p>	<p>Yes, but first-time diagnosis is not allowed.</p>	<p>As a response to COVID-19, the use of electronic prescriptions and online pharmacy received an incentive: the National Healthcare Security Administration confirmed that the use of electronic prescriptions for certain common chronic diseases (e.g., diabetes, hypertension) would be covered under China's public health insurance during the pandemic. This has now been extended to other diseases nationwide, subject to the establishment of necessary IT infrastructure in local areas.</p>
<b>Indonesia</b> 	<p>In accordance with the regulations issued by the Drugs and Food Monitoring Agency ("BPOM"), the online distribution of drugs, traditional drugs, health supplements, cosmetics and processed foods is permitted.</p> <p>All products that are sold through online channels must be registered at BPOM and equipped with marketing authorization.</p> <p>Additionally, pharmacies can sell drugs online, by using their own electronic system or cooperating with a third party pharmacy electronic system operator.</p>	<p>No, healthcare professionals are not allowed to deliver drugs remotely to a patient's residence. BPOM Regulation 8/2020<sup>12</sup> only allows brick-and-mortar or physical pharmacies to deliver drugs directly to a patient's residence.</p> <p>Delivery of drugs that are sold online by these physical pharmacies may be arranged through their own electronic systems or an electronic system provided by a third party pharmacy electronic system operator (i.e., e-Commerce platforms (e.g., Shoppe, Tokopedia, Lazada, etc.).</p> <p>Drugs can be surrendered directly at the concerned physical pharmacies or sent to the patient. In case of the latter, the delivery can be arranged by the</p>	<p>In addition to i) a pharmacy license ii) general licenses required for web portal platform (i.e., Electronic System Operator (ESO) Registration Certificate and Electronic System Trading Business Licenses (<i>Surat Izin Usaha Perdagangan melalui Sistem Elektronik</i> or SIUPMSE) and iii) a marketing authorization for the products; for e-pharmacies, a pharmaceutical electronic system operator ("PSEF") would need to hold a PSEF registration as one of its technical licenses under the OSS system. OSS is an integrated electronic system under the prevailing licensing regime in Indonesia. However, a party would not need to hold a PSEF registration and adopt the line of business as a PSEF if it only relays the promotional material or 'ads' to the users,</p>	<p>In accordance with COVID-19 interim regulations issued by the MOH,<sup>16</sup> Indonesia Honorary Board of Medical Ethics<sup>17</sup> and Indonesian Medical Council,<sup>18</sup> doctors and dentists can provide healthcare services through electronic system platforms (i.e., in the form of writing, voice, and/or video) to diagnose, treat and cure patients.</p> <p>Below is the scope of medical practices that doctors and dentists could provide remotely using online telemedicine platform during the state of national health emergency COVID-19:</p> <p>(a) performing anamnesis</p> <p>(b) performing physical examinations through audio-visual media</p>	<p>Regarding the telemedicine and the telehealth sectors, during COVID-19, the MOH along with Indonesia Honorary Board of Medical Ethics and Indonesia Medical Council has issued COVID-19 interim regulations that allow doctors and dentists to provide full diagnosis and also provide scope of medical practices that doctors and dentists could provide through an online platform to patients during the COVID-19 situations. However, there <b>is no certainty</b> that the Government will allow this exemption to continue after COVID-19.</p> <p>Therefore, it remains to be seen whether the current online doctor consultation and medical services features may need or not need to be adjusted after COVID-19 national health emergency status is officially ended.</p>

<sup>11</sup> Australian Department of Health, 'Permanent telehealth to strengthen universal Medicare' (2021) <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/permanent-telehealth-to-strengthen-universal-medicare>

<sup>12</sup> BPOM Regulation No. 8 of 2020 on the Supervision of Online Circulation of Food and Drugs, as amended by BPOM Regulation No. 32 of 2020 ("**BPOM Regulation 8/2020**")

<sup>16</sup> MOH Circular Letter No. HK.02.01/MENKES/303/2020 on the Implementation of Healthcare Services through the Utilisation of Information Technology and Communication in order to prevent the Spread of COVID-19

<sup>17</sup> Indonesian Honorary Board of Medical Ethics (*Majelis Kehormatan Etika Kedokteran* or "MKEK") Decree No. 017/PB/K.MKEK/05/2020

<sup>18</sup> Indonesian Medical Council (*Konsil Kedokteran Indonesia*) ("KKI") Regulation No. 74 of 2020 on Clinical Authorities and Medical Treatment through Telemedicine during the COVID-19 Pandemic in Indonesia

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		<p>pharmacies themselves or through cooperation with a third party legal entity.</p> <p>The drug delivered remotely may be in a form of over-the-counter (OTC) drugs, limited OTC drugs<sup>13</sup> and potent/ethical drugs. Potent/ethical drugs can only be issued based on prescriptions issued by doctors. Therefore, upon placing order of potent/ethical drugs through the online platform, users must attach the e-prescription (if electronic) or upload the image of physical prescription into the system.<sup>14</sup></p> <p>BPOM Regulation 8/2020 specifically prohibits physical pharmacies from selling the following drugs through online channels:<sup>15</sup></p> <ul style="list-style-type: none"> <li>• drugs that contain pharmaceutical precursors</li> <li>• injections, except insulin for self-administration</li> <li>• implants</li> <li>• narcotics and psychotropic</li> <li>• certain ethical drugs that are specifically prohibited from being sold through online channels</li> </ul>	<p>as long as the online drug transaction is not done through its platform.</p> <p>For context, PSEF is defined as legal entities that provide, manage and/or operate electronic systems for their own and/or other parties' purposes. The definition is very broad and covers anyone who runs or provides an electronic system for the purpose of online sale of drugs and other commodities.</p> <p>E-pharmacy businesses can only assist conventional pharmacy stores or drug wholesalers by providing e-pharmacy IT solutions to pharmacy businesses. Additionally, a PSEF would also need to have a dedicated pharmacist, considering the required documents that must be submitted to obtain a PSEF registration based on Minister of Health Regulation No. 14 of 2021 (e.g., pharmacist registration certificate (<i>Surat Tanda Registrasi Apoteker</i> or "<b>STRA</b>") and pharmacist practice license).</p>	<ul style="list-style-type: none"> <li>(c) providing advice based on physical and/or supporting examination</li> <li>(d) establishing diagnoses</li> <li>(e) performing medical treatment</li> <li>(f) issuing prescriptions</li> <li>(g) issuing referral letters for further physical examination or medical action at healthcare facilities and/or laboratories based on the results of</li> <li>(h) other supporting examination services in the form of laboratory, radio imaging, therapy</li> <li>(i) issuing letter of illness to their patients, i.e., but are restricted from</li> </ul> <p>Doctors and dentists who intend to provide medical treatment through telemedicine services are required to have a registration letter and practice permit at their healthcare facility. In other words, independent practitioners are not allowed to provide teleconsultations.</p> <p>There is no need to have a prior patient-doctor relationship. There are also currently no laws mandating an initial face-to-face meeting before the first teleconsultation meeting between the doctor and the patient.</p> <p>However, note that such regulations will only remain in effect until the Indonesian government officially declares the end of the COVID-19 state of public health emergency.</p>	<p>Regarding the e-pharmacy, on 30 December 2020, BPOM issued BPOM Regulation No. 32 of 2020 as the amendment of BPOM Regulation No. 8 of 2020 on Supervision of Drugs and Food Online Distribution ("<b>BPOM Regulation 32</b>").</p> <p>This BPOM Regulation 32 introduces Quasi-Drugs as one of the types of drugs that can be sold through online channels. Quasi-Drugs are defined as preparations (or substances) that contain active ingredients with non-systemic or local pharmacology effects, with the purpose of overcoming minor complaints.</p>
<p><b>Malaysia</b></p> 	<p>Yes, it is possible for pharmacies to dispense drugs by means other than over-the-counter, for examples, through delivery service and online sale.</p>	<p>Yes, licensed pharmacists in community pharmacies and hospitals may deliver drugs directly to a patient's residence without appointing a licensed courier company to do so.</p>	<p>The concept of e-pharmacies is not officially recognised in Malaysia.</p> <p>For drugs that contain any scheduled poison under the Poisons Act 1952, the <i>Guidelines on Medicine Delivery Service</i></p>	<p>Yes, healthcare professionals may treat and/or diagnose patients via a telemedicine platform.</p> <p>Pursuant to the <i>Advisory on Virtual Consultation</i> issued by the Malaysian</p>	<p>The COVID-19 pandemic has had a positive impact on the telemedicine and telehealth sector in Malaysia.</p> <p>Existing players have seen a significant surge in their users, while several private</p>

<sup>13</sup> Limited OTC drugs, also known as list W drugs (*W: Waarschuwing* = warning/alert) are potent drugs that can be purchased without a doctor's prescription, but users must pay attention to the drug information on the packaging.

<sup>14</sup> Article 8 (1) of BPOM Regulation 8/2020.

<sup>15</sup> Article 27 of BPOM Regulation 8/2020.

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	<p>For drugs that contain any scheduled poison under the Poisons Act 1952<sup>19</sup>, pharmacies, through their licensed pharmacists, may provide delivery service on their own, or appoint a licensed courier company to do so. The regulatory requirements are set out in the <i>Guidelines on Medicine Delivery Service by Licensed Pharmacists to Patients</i><sup>20</sup> and the <i>Guidelines on the Online Sale / Supply of Medicines containing Poison by Licensed Pharmacists (Type A Retail Licence Holders)</i><sup>21</sup>, some of which include:</p> <ul style="list-style-type: none"> <li>• Preparing a comprehensive and complete standard operating procedure to address request for supply, preparation, sale, delivery and acceptance of drugs by patients.</li> <li>• Obtaining and recording prior consent/application of patients to hand over the drugs via delivery service.</li> <li>• For prescription drugs, sale/supply may only be made with original prescription. Electronic prescription must use digital signature that complies with the Digital Signature Act 1997.</li> </ul> <p>For drugs that do not contain any scheduled poison under the Poisons Act 1952, pharmacies may dispense them through online sale. The regulatory requirements are set out in the <i>Guidelines on the Online Sale of Non-</i></p>	<p>Generally, all drugs may be so delivered save for:</p> <ul style="list-style-type: none"> <li>• dangerous drugs (as listed in the First Schedule of the Dangerous Drugs Act 1952); and</li> <li>• psychotropic substances (as listed in the Third Schedule of the Poisons Act 1952).</li> </ul> <p>Such delivery of drugs is not prohibited by law, but the legal requirements on prescribed drugs and dispensed medicine as provided under the Poisons Act 1952 must be complied with. The regulatory requirements are further set out in the <i>Guidelines on Medicine Delivery Service by Licensed Pharmacists to Patients</i>.</p>	<p><i>by Licensed Pharmacists to Patients</i> provides that:</p> <ul style="list-style-type: none"> <li>• the sale/supply must be made at the premises as stated in the Type A Licence issued to the pharmacists; and</li> <li>• the delivery must be made from such premises.</li> </ul> <p>Other requirements include the following:</p> <ul style="list-style-type: none"> <li>• Licensed pharmacists who use telecommunications technology to communicate with the patients in the process of selling/supplying such drugs must establish a mechanism to ensure that the sale is valid and complies with the law.</li> <li>• Drug counselling must be done prior to the delivery and may be done using effective telecommunications technology to ensure that the patients receive and clearly understand the message delivered.</li> <li>• Licensed pharmacists must be satisfied that the patients have knowledge and understanding regarding the indication, the route of administration and the storage condition for the drugs purchased.</li> </ul>	<p>Medical Council, doctors may only have virtual consultation with a person who is already their patient and are prohibited from conducting teleconsultations with patients with cognitive disorders, intoxication or cognitive barriers.</p>	<p>hospitals have also rolled out teleconsultation services to reduce the risk of virus transmission.<sup>23</sup></p> <p>The regulators have also responded by issuing relevant guidelines such as the <i>Guidelines on Medicine Delivery Service by Licensed Pharmacists to Patients</i>, the <i>Guidelines on the Online Sale / Supply of Medicines containing Poison by Licensed Pharmacists (Type A Retail Licence Holders)</i> and the <i>Guidelines on the Online Sale of Non-Poison Pharmaceutical Products</i> to set out further guidance and requirements in this regard.</p> <p>The Poisons (Amendment) Bill 2022 ("<b>Bill</b>") was recently tabled in the Malaysian Parliament and seeks to, among others, regulate the use of electronic documents relating to the dispensation of drugs. If it comes into effect, electronic prescriptions will be formally recognised as an acceptable form of prescription subject to newly prescribed statutory requirements such as that it must be signed by the prescriber with a digital signature in accordance with the Digital Signature Act 1997. Electronic signatures in accordance with the Electronic Commerce Act 2006 may also be used where the Poisons Act 1952 requires a signature of a person on a document (except for a prescription). Further, the Bill proposes to allow retail sale of drugs containing scheduled poisons not only <b>on</b> the physical premises specified in the pharmacy licence, but also <b>from</b> the premises. It is unclear whether and when the Bill will become law.</p>

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<sup>19</sup> In Malaysia, all registered drugs will carry a registration number beginning with "MAL" followed by 8-digit numbers, and an alphabet (which will indicate their registration category), and may also contain further administrative code(s). A product registration number which indicates "A" immediately after the 8-digit numbers means that the drug contains scheduled poison.

<sup>20</sup> This was published by the Pharmacy Enforcement Division of the Ministry of Health on 10 February 2021 and is only available in Malay language.

<sup>21</sup> This was published by the Pharmaceutical Services Programme of the Ministry of Health on 16 March 2022 and is only available in Malay language.

<sup>23</sup> <https://codeblue.galencentre.org/2020/06/08/malaysia-telehealth-grows-in-contactless-world/>

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	<p><i>Poison Pharmaceutical Products</i><sup>22</sup>, some of which include:</p> <ul style="list-style-type: none"> <li>Using local domain with local hosting and server.</li> <li>Not containing any other product in the page displaying the sale of non-poison pharmaceutical products.</li> <li>Not containing any link to social media - sale via social media is prohibited.</li> <li>Displaying the mandatory information on the website where the product is displayed i.e., business name, business registration number, full premises address (not P.O. box), contactable phone number, email address, product registration number, advertisement approval number (if required) and a prescribed cautionary statement.</li> </ul>				<p>While the Malaysian Parliament has passed the Telemedicine Act 1997, it is still not yet in force and it remains to be observed whether there will be any other legislative development which will impact the telemedicine and telehealth sector.</p>
<p><b>Philippines</b></p> 	<p>Yes, it is possible to dispense drugs through licensed online pharmacies.</p> <p>Based on Food and Drug Administration (FDA) Advisory No. 2019-154, the online sale of pharmaceutical products is generally prohibited.</p> <p>By way of exception, a seller with an existing License to Operate (LTO) as a drugstore, pharmacy, or botica with a physical address and whose LTO covers the additional activity of selling drugs online, may engage in online sale of drugs.</p> <p>As a rule, prescription drugs may not be sold online, unless the purchaser presents a valid prescription.</p> <p>FDA Circular No. 2020-037 (Reissuance of the Guidelines on the Implementation</p>	<p>Yes, under current practice, certain duly licensed drugstores, pharmacies or botica whose LTO includes the specific authority to engage in online sale of drugs, also provides delivery services.</p> <p>Prescription drugs may not be sold online by licensed online drugstores and pharmacies, unless the purchaser presents a valid prescription that is issued according to the requirements of the E-Prescription Guidelines.</p> <p>HCPs are not authorized to engage in online sale and delivery of drugs.</p>	<p>Yes. An e-pharmacy must have an LTO as a pharmacy, drugstore or botica, with a physical address and whose LTO covers the additional activity of selling drugs online.</p>	<p>Yes. To address the needs of patients during the COVID-19 pandemic, while also ensuring their protection, the Philippine government has issued various guidelines to regulate telemedicine.</p> <p>Under Joint Administrative Order No. 2021-0001 issued by the Department of Health (DOH), Department of Interior and Local Government ("DILG") and Philippine Health Insurance Corporation ("PHIC") or the Guidelines on Implementation and Delivery of Individual-Based Health Services ("Implementation Guidelines"), telemedicine refers to the delivery of healthcare services, where distance is a critical factor, by all healthcare professionals, using information and communications technologies for the exchange of valid information for diagnosis, treatment and</p>	<p>The COVID-19 pandemic has accelerated the development of telemedicine and telehealth in the Philippines.</p> <p>The pandemic has seen a rise in telemedicine platforms in the Philippines, as both physicians and patients resort to virtual consultations to avoid physical consultations during the pandemic. Despite decreasing COVID-19 cases in recent months, government policies and public demand indicate that the use of telemedicine and telehealth will continue to form part of the "new normal" in the country. To complement telemedicine consultations, the FDA issued the E-Prescription Guidelines to authorize physicians to issue prescriptions, and e-pharmacies to rely on such e-</p>

<sup>22</sup> This was published by the Pharmacy Enforcement Division of the Ministry of Health on 24 December 2021 and is only available in Malay language.

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	<p>of the Use of Electronic Means of Prescription for Drugs for the Benefit of Individuals Vulnerable to COVID-19) (<b>E-Prescription Guidelines</b>) allows physicians to issue electronic prescriptions and authorizes drugstores to recognize electronic prescriptions.</p>			<p>prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interest of advancing the health of individuals and their communities .</p> <p>The Implementation Guidelines do not expressly require a prior patient-doctor relationship to qualify for telemedicine consultation.</p> <p>Nonetheless, the Implementation Guidelines provide that <u>first-time consultations</u>, emergency and serious conditions where emergency care is needed, or anytime that face-to-face assessment and physical contact are warranted, should not be managed using telemedicine.</p> <p>Also, licensed physicians must exercise their professional judgment to decide whether telemedicine consultation is appropriate in a given situation and the specific conditions of the individual patient.</p> <p>The following principles and requirements shall also apply:</p> <ul style="list-style-type: none"> <li>• telemedicine shall follow the standards of practice of medicine under the Medical Act, its implementing rules and regulations, the Philippine Medical Association Code of Ethics and other applicable policies and guidelines, taking into account the absence of physical contact;</li> <li>• telemedicine consultation should not be anonymous and both the patient and the licensed physician should be able to know, verify, and confirm each other's identity at the start of the consultation;</li> <li>• physicians practicing telemedicine shall uphold the same standards of</li> </ul>	<p>prescriptions, in prescribing and dispensing prescription drugs to patients.</p> <p>Regulations on telemedicine and telehealth are still evolving in the Philippines and current guidelines indicate that the government may be looking into issuing specific regulations on the following:</p> <ul style="list-style-type: none"> <li>• details on the implementation and maintenance of an integrated health information system;</li> <li>• Code of Ethics and Clinical Practice Guidelines for telemedicine;</li> <li>• certification program on good clinical practice ("GCP") of telemedicine;</li> <li>• verification of license and credentials of healthcare providers;</li> <li>• details on evaluation mechanism of third-party telemedicine providers; and</li> <li>• telemedicine scorecard.</li> </ul> <p>The DOH also has the power to issue regulations regarding licensing of telemedicine platforms.</p>

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				<p>care as in a face-to-face consultation but within the intrinsic limits of telemedicine;</p> <ul style="list-style-type: none"> <li>the patient-physician relationship shall be based on full knowledge of the patient's medical history and a physical examination given the circumstances of a lack of physical contact (i.e., by virtual physical exam only);</li> <li>physicians shall use their professional discretion to gather the type and extent of patient information required to be able to exercise proper clinical judgment; and</li> <li>if physical examination is critical information for consultation, the physician should not proceed until a physical examination can be arranged through a face-to-face consultation.</li> </ul>	
<p><b>Singapore</b></p> 	<p>Yes, it is possible to dispense registered prescription only medicines ("<b>POM</b>") and pharmacy only medicines ("<b>P</b>") through online pharmacies. This is known as the provision of "e-pharmacy" or "telepharmacy" services where a qualified pharmacist processes valid prescriptions online through electronic means, and conducts professional counselling remotely, as needed. The drugs are then delivered directly to the patients without having to come down to a pharmacy outlet.</p> <p>E-pharmacy services can only be provided by Singapore-registered companies, and on a Singapore domain name. The e-pharmacy provider must:</p> <p>(a) Hold a pharmacy licence issued by the Health Sciences Authority ("<b>HSA</b>");</p>	<p>Yes, provided these services are performed under a licensed e-pharmacy service provider (see preceding column).</p> <p>Only registered therapeutic products (be it POMs or Ps) can be supplied by the e-pharmacy. These must also have been obtained through manufacturers or dealers licensed by the HSA.</p>	<p>Yes. As mentioned in the preceding columns, the e-pharmacy service provider must hold a pharmacy licence. If the provider is an existing pharmacy licence holder, it must make an amendment to its pharmacy licence to include the mode of e-pharmacy services in order to notify and obtain approval from the HSA.</p>	<p>Yes, it is possible to provide tele-consultation (including diagnosis) over a mobile platform in Singapore. Such telemedicine services, which are not premise-based, are not currently regulated under any legislation in Singapore. Instead, the Ministry of Health has only published the <i>National Telemedicine Guidelines</i> to set out certain guidelines on good practices relating to the provision of telemedicine services.</p> <p>There is no requirement for a prior doctor-patient relationship.</p>	<p>The Healthcare Services Act ("<b>HCSA</b>") came into operation on 3 January 2022 and expands the licensing regime for healthcare services.</p> <p>The new regulatory regime introduces a services-based licensing regime where healthcare service providers would need to obtain a licence based on the type of service they provide. This is a marked change from the premises-based licensing regime previously used, where licences were obtained based on the brick-and-mortar premises of healthcare providers.</p> <p>The new licensing regime is expected to be implemented in 3 phases. The timelines have been shifting due to the COVID-19 developments. However, based on the latest update by the Ministry of Health, telemedicine services are expected to be regulated by end 2023, under Phase 3 of the implementation.</p>

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	<p>(b) Obtain prior approval from the HSA to provide telepharmacy and home delivery services; and</p> <p>(c) Comply with the conditions which may be imposed by the HSA when it granted its approval.</p> <p>When deciding whether to grant approval, the HSA will consider factors such as whether the provider has the necessary technological set-up and capability to deliver the e-pharmacy services, adequately trained personnel to provide the services, and written procedures on how the services are to be provided.</p> <p>The provider must also appoint a competent qualified pharmacist registered under the <i>Pharmacists Registration Act</i> as the pharmacist-in-charge to be responsible for the pharmacy operations, including proper storage and supply of the registered therapeutic products.</p>				
<p><b>Taiwan</b></p> 	<p>In principle, E-pharmacy or online pharmacy are not allowed in Taiwan. i.e, dispensing drugs over-the-counter is required unless sales of Class B OTC (over-the-counter) drugs online or an exemption from over-the-counter dispensing requirement is approved by the Taiwan Food and Drug Administration (<b>TFDA</b>).</p> <p>OTC drugs in Taiwan are classified as Class A or Class B, and only Class B OTC drugs can be sold online by a pharmacy, grocery store or department store. The solutions prescribed for home dialysis patients can be exempt from over-the-counter dispensing requirement and be delivered by a wholesaler to the patients directly without dispensing by any pharmacy, according to a ruling TFDA ruling.</p>	<p>The pharmacist can deliver the drugs to the patients' residence directly provided that the following requirements are met: (1) the drugs must be delivered face-to-face by a licensed pharmacist; and (2) the licensed pharmacist can only deliver the drugs within the city/county where he/she makes his/her practice registration, according to a ruling issued by the TFDA.</p>	<p>E-pharmacy (or online pharmacy) is generally not allowed in Taiwan. As mentioned in our responses to Q1, the pharmacy may establish a website to sell Class B OTC drug or an online system for the patients to make schedule for receiving drugs. Supplying other drugs online or delivering the drugs by third party (any person other than licensed pharmacist) is not allowed unless there is an exemption approved by the TFDA.</p>	<p>Currently telemedicine in Taiwan is only allowed for very limited circumstances. According to Article 11 of the Physicians Act of Taiwan, a physician must provide medical diagnosis to patients <u>in person</u> and telemedicine services may only be provided by the physicians designated by authorities in the mountain areas, on outlying islands, in remote areas designated by the Ministry of Health and Welfare or under "special or urgent circumstances" as defined under the Rules of Medical Diagnosis and Treatment by Telecommunications ("<b>Telemedicine Rules</b>").</p> <p>The Telemedicine Rules do not expressly stipulate that a prior patient-doctor relationship is required for telemedicine. However, the types of "special circumstances" set forth thereunder include certain circumstances under</p>	<p>Since the outbreak of COVID-19, Taiwan has not promulgated any new law or regulation concerning telemedicine or telehealth. Nonetheless, flexibility is allowed for the enforcement of the existing laws and regulations.</p> <p>For example, Taiwan Centers for Disease Control ("<b>CDC</b>") issued guideline for the persons under quarantine or isolation due to COVID-19 to seek medical advice. The person under quarantine or isolation should inform the department of health of municipal government ("<b>Local DOH</b>") which will evaluate the necessity for going out to seek medical advice. If not necessary, the Local DOH can arrange telemedicine or home care for the person under quarantine or isolation. The CDC further announced a tentative flexible measure under which the telemedicine services can be provided by medical</p>

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	<p>In current practice, some pharmacies establish an online system for the patients holding refillable prescriptions for chronic illnesses to make a schedule for receiving drugs. However, the patients should collect the drugs physically in pharmacy directly or the licensed pharmacist should deliver the drugs to the patient face-to-face directly (please refer to our responses to Q2). The drugs (except for Class B OTC drugs) may not be sold online or delivered by any third party (any person other than licensed pharmacist, eg, logistic company).</p>			<p>which telemedicine services are provided to patients or inpatient requiring follow up treatments after diagnosis or being discharged. In these cases, a prior patient-doctor relationship should be still necessary.</p>	<p>institutions designated by Local DOH to all outpatients, except for the patients who are not applicable to telemedicine based on the physician's assessment. These measures remain valid as of the date hereof but may be amended or cancelled based on COVID-19 situation in Taiwan.</p> <p>As mentioned, this is just a flexible measure as a response to COVID-19 rather than an amendment to the existing law or regulations concerning telemedicine or telehealth.</p>
<p><b>Thailand</b></p> 	<p>The Pharmacy Council has issued a notification regarding the standards and methods of the provision of telepharmacy on 2 June 2020. The notification is guidelines under which pharmacists will be allowed to provide pharmaceutical care without a face-to-face meeting with patients, including the delivery of drugs.</p> <p>The notification requires that the provisions of telepharmacy must be done by a pharmacist and must meet the following requirements: (i) having a patient registration system, (ii) having a voice or video recording system during the provision of telepharmacy, (iii) having pharmaceutical care system, e.g. prescription analysis, and (iv) having appropriate delivery system standards.</p> <p>The main telepharmacy processes includes verification of the patient's information (or enrollment), contacting the patient and making a schedule for delivery of the drug, identification of the patient upon providing the telepharmacy service, providing consultation on the use of the drug, keeping a medical record, and following up on the result of the drug use.</p>	<p>Yes, the notification of the Pharmacy Council permit delivery of drugs directly to patients.</p> <p>There are three types of telepharmacy under the notification, i.e. telepharmacy by health facilities, telepharmacy by drug stores in relation to prescription drugs, and telepharmacy by drug stores in relation to non-prescription drugs.</p> <p>Both prescription and non-prescription drugs can be delivered to the patients, subject to specific conditions of each drug, e.g. the prescription drug can be delivered only when the prescription is provided by the patient.</p>	<p>The key requirements are that the telepharmacy service provider must be a licensed pharmacist and must have a system for enrollment and a record of the patient's profile and telepharmacy received, as well as a system to record video or voice data when providing the service. The patient's consent must also be obtained.</p>	<p>On 2 February 2021, the Announcement of the Ministry of Public Health ("MOPH") with respect to "telemedicine" and "telehealth" became effective.</p> <p>The MOPH defined telemedicine to be the provision of medical and health services of health facilities to applicants by healthcare professionals through the telemedicine system for the purpose of exchanging information beneficial to the consultation, examination, diagnosis, treatment, nursing, prevention, health promotion, and physical rehabilitation, and for the benefit of continuing education of medical and public health personnel.</p> <p>In addition, digital infrastructure for telemedicine services is defined to be a system utilizing digitalization for the provision of medical and health services from a distance using visual and audio communications or any other means.</p> <p>A license to provide telemedicine is required from now on.</p>	<p>The guidelines of health facilities for telemedicine purposes has been issued by the MOPH and came into effect on 2 February 2021. Under such guidelines, amongst others, a medical facility wishing to provide the telemedicine service must ensure there is a sufficient number of professionals to provide the telemedicine service without disrupting the medical facility's main services. The medical facility must also have telecommunication plans and devices for the telemedicine service that allows for clear communication, with information security standards implemented. Additionally, medical facilities must implement a process to inform patients of the telemedicine service details before providing the telemedicine service, including service procedures, all aspects of the possible effects of the service, and risks associated with the service.</p> <p>Additionally, the Medical Council of Thailand approved the Telemedicine Guidelines that became effective on 20 October 2020, under this guideline, the provision of healthcare via the telemedicine healthcare system must be in accordance with the professional standards, competency criteria and guidelines of the Medical Council.</p>

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					<p>Thereunder, the use of tools, programs, or artificial intelligence (AI) jointly with telemedicine must be in accordance with specific laws, such as the law on medical devices and drug laws. Telemedicine must be conducted under an information system that meets the international information standards and security and maintained in a condition ready for use and for audit. The verification of identity of a healthcare provider and a healthcare recipient must be provided by the system.</p> <p>Separately, the Pharmacy Council announced telepharmacy guidelines on 2 June 2020. The key requirements thereunder are that the service provider must be a licensed pharmacist and must have a system for enrollment and a record of the patient's profile and telepharmacy received, as well as a system to record video or voice data when providing the service. The patient's consent must also be obtained.</p>
<p><b>Vietnam</b></p> 	<p>Drugs for distribution in Vietnam are divided into two categories: prescription drugs and non-prescription drugs.</p> <p>Under the Pharmacy Law, prescription drugs can only be sold <u>at</u> drug retail outlets when there is a prescription.<sup>24</sup></p> <p>However, it remains debatable as to how the word "at" in this provision should be interpreted, i.e., whether prescription drugs can only be sold at physical pharmacies with physically presented prescriptions or they can be sold by pharmacies through their own online sales channels with electronically presented prescriptions. Until further clarification is given by relevant State agencies, the conservative and narrow</p>	<p>The Law on Medical Examination and Treatment prohibits medical practitioners (i.e., doctors, physicians) from selling drugs to patients in any form.<sup>25</sup></p> <p>Pharmacies can deliver non-prescription drugs directly to a patient's residence by themselves or through third party delivery service providers. As discussed in Q1, direct delivery of prescription drugs is not allowed.</p>	<p>There is no specific license required for the operation of e-pharmacies.</p> <p>Key requirements to operate an e-pharmacy must at least include those applicable to a conventional drug retail outlet:</p> <ul style="list-style-type: none"> <li>• a Good Pharmacy Practice (GPP) Certificate from the provincial Department of Health;</li> <li>• Pharmaceutical Practice Certificate issued to the outlet owner;</li> <li>• Certificate of Eligibility for Pharmaceutical Business.</li> </ul> <p>The website or electronic application of the e-pharmacy business must also notify</p>	<p>No.</p> <p>Vietnam does not have an equivalent term for "telemedicine". Vietnam legislation currently provides a general legislative frame for remote medical activities under Circular No. 49/2017/TT-BYT of the Ministry of Health (MOH) ("<b>Circular No. 49</b>").</p> <p>Under Circular No. 49, remote medical activity is defined as "the exchange of information related to a patient's health between such patient and a health care provider or among health care providers in distant areas through the use of information technology (IT) and telecommunication."<sup>26</sup></p>	<p>As a response to COVID-19, in 2020, the MOH issued several decisions regulating the pilot of remote medical examination and treatment and the scheme for remote medical examination and treatment to be adopted by State-owned hospitals. The issuance of such decisions mostly aims at providing medical practitioners working at lower-level hospitals with access to remote consultation and training offered by medical practitioners at higher-level hospitals. Remote healthcare advisory (tele-health) between doctors and patients is also a part of the pilot but there has been no official regulatory progress on this.</p> <p>In practice, in 2021, remote medical activities in the form of remote medical</p>

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<sup>24</sup> Article 42.2.p, Pharmacy Law.

<sup>25</sup> Article 6.5, Law on Medical Examination and Treatment.

<sup>26</sup> Article 2.1, Circular No. 49.

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	<p>understanding is that prescription drugs may only be sold at physical pharmacies with physically presented prescriptions. by relevant State agencies, the conservative and narrow understanding is that prescription drugs may only be sold at physical pharmacies with physically presented prescriptions.</p> <p>We note that there is no similar restriction imposed on non-prescription drugs. In practice, pharmacies can dispense non-prescription drugs online through their own sales websites or by cooperating with third party delivery service providers.</p>		<p>the Ministry of Industry and Trade as an e-commerce sales website.</p>	<p>Circular No. 49 categorizes remote medical activities as follows: (a) remote medical advisory; (b) remote medical examination and treatment consultation; (c) teleradiology consultation; (d) remote anatomy consultation; (e) remote surgery consultation; and (f) training in technology transfer for remote medical examination and treatment.<sup>27</sup></p> <p>It should be noted that "remote medical examination and treatment" is not included under the scope of Circular No. 49. In other words, applicable entities may carry out activities related to medical examination and treatment (e.g., consultation), but not engage in remote medical examination and treatment itself. As such, diagnosing, treating and prescribing drugs via telemedicine platforms are not specifically allowed at present.</p>	<p>examination and treatment consultation and remote surgery consultation were widely practiced by healthcare practitioners of both public and private hospitals due to Covid outbreaks and mass lockdowns across Vietnam. Note that the activities of medical examination and treatment, and prescription through electronic platforms/applications are yet to be allowed and regulated.</p>

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<sup>27</sup> Article 1.1, Circular No. 49.

## Contributors



### Australia



**Ben McLaughlin**  
Partner  
+ 61 2 8922 5342  
ben.mclaughlin  
@bakermckenzie.com



**Toby Patten**  
Partner  
+ 61 3 9617 4456  
toby.patten  
@bakermckenzie.com



### China



**Isabella Liu (Hong Kong)**  
Partner  
+ 852 2846 1689  
isabella.liu  
@bakermckenzie.com



**Yilan Yang**  
Counsel  
+ 86 10 6535 3906  
yilan.yang  
@bakermckenziefenxun.com



### Indonesia



**Cahyani Endahayu**  
Partner  
+ 62 21 2960 8515  
cahyani.endahayu  
@bakermckenzie.com



### Malaysia



**Kherk Ying Chew**  
Partner  
+ 60 3 2298 7933  
kherkying.chew  
@wongpartners.com



### Philippines



**Christina Macasaet-Acaban**  
Partner  
+ 63 2 8819 4947  
christina.macasaet-acaban  
@quisumbingtorres.com



### Singapore



**Ren Jun Lim**  
Principal  
+ 65 6434 2721  
ren.jun.lim  
@bakermckenzie.com



### Taiwan



**Kevin Wang**  
Partner  
+ 886 2 2715 7322  
kevin.wang  
@bakermckenzie.com



### Thailand



**Peerapan Tungsuan**  
Partner  
+ 66 2636 2000 X4334  
peerapan.tungsuan  
@bakermckenzie.com



### Vietnam



**Yee Chung Seck**  
Partner  
+ 84 28 3829 5585  
yeechung.seck  
@bakermckenzie.com



**Minh Ha Vu**  
Special Counsel  
+ 84 28 3520 2664  
minhha.vu  
@bakermckenzie.com

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