

『オンライン診療から電子処方箋発行に至るまでの法的担保』
ーアジア各国の法整備事情ー

株式会社 先端総合開発研究所
代表取締役・研究主幹 坂部 望

2023/8/19

1

「ASEAN デジタル・マスタープラン 2025」

- 2005年以降、世界保健機関(WHO)により医療サービスにおけるデジタル化を推進強化。
- ASEANはデジタル・ヘルス事業の強化を公共サービスの主要な優先事項として指定。
- デジタル・ヘルス事業は、ASEAN 諸国が既存の医療システムの課題を解決し、医療サービスを向上させることが期待されている。

- ASEANとは？
- 1967年の「バコップ協定」によって結ばれた東南アジア10国による地域同盟。
- 加盟国はインドネシア、マレーシア、タイ、フィリピン、シンガポール、ブルネイ。
- 協定の加盟国は10国（「10国連合」）。
- 別名「ASEAN」。

2023/8/19

2

デジタル・ヘルス事業への期待

(ASEANの特徴)

- シンガポールは医療サービスと医療技術研究の地域拠点として発展。
- 加盟国の社会経済発展に関する多様性。
- 多くの ASEAN 諸国における健康格差は顕著。
- ブルネイ、シンガポール、マレーシアなどの先進国を除き、それ以外は一人当たりの医師数が世界平均を下回る。
- 多くのASEAN 加盟国は、病床数が世界平均よりも低い。

2023/8/19

3

人口1000人当たりの医師数

Number of Physicians per 1,000 Population
ASEAN vs World

Country	Number of Physicians per 1,000 Population
Singapore	1.61
Brunei	0.47
Indonesia	0.39
Malaysia	0.37
Laos	0.74
Thailand	0.60
Philippines	0.81
Vietnam	0.83
World average	1.07

Source: World Bank DataBank, latest data from different countries were applied (from 2014 to 2018), world average figure is of 2017.

2023/8/19

4

人口1000人当たりの病床数

Number of Hospital Beds per 1,000 Population
ASEAN vs World

Country	Number of Hospital Beds per 1,000 Population
Singapore	2.85
Brunei	0.80
Indonesia	1.04
Malaysia	1.04
Laos	0.98
Thailand	2.48
Philippines	2.50
Vietnam	1.50
World average	2.82

Source: World Bank DataBank, latest data from different countries were applied (from 2014 to 2018), world average figure is of 2017.

2023/8/19

5

アジアのデジタル・ヘルス事情予測

- 今後デジタル・ヘルス事業は、特にインドネシアやフィリピンのような島嶼諸国や医療インフラやサービスを利用しにくい農村地域において、患者からの医療アクセスを改善することが期待される。
- 現在のアジアにおけるデジタル・ヘルス市場は、中国とインドがこの市場の大部分を占めると考えられるが、インドネシア、マレーシア、ベトナムなどの ASEAN 諸国も拡大の一途といつてよい。

2023/8/19

6

出典: 東南アジア、中国、インドの経済見通し、OECD、Leaology(ライについて)、KPMG(ベトナムについて)、およびさまざまな国の情報源によって補足

法規制(その2)

シンガポール	2019年、保健サービス、病気の予防並びに医療機関として規制される遠隔医療サービスに関する「デジタルヘルス」を施行しました。遠隔医療は、病気の予防、診断、治療、治療などの医療目的を目的としたハードウェアデバイス、ソフトウェアおよびモバイルアプリケーションを含みます。遠隔医療サービスと関連し、2022年までにこの分野が規制される予定です。	遠隔医療提供者は、特にデータが書き取られアクセスされた場合に個人の権利が侵害されるリスクを軽減するために、個人データを保護するために、より厳格なセキュリティ体制を構築する必要があります。
タイ	2020年7月、タイ医療評議会が、遠隔医療サービスの範囲を定義し、その実施を奨励するために、遠隔医療およびオンライン診療に関するガイドラインを承認しました(2020年12月20日)を発行しました。	遠隔医療に関する特定のデータ保護はありませんが、2022年には期待される2019年個人データ保護法(遠隔医療サービス)を別表としています。
ベトナム	ポリシーのリストは遠隔医療を定義し、期間の枠組みを形成します。2017年の第16号令は、デジタルヘルス規制の範囲がドキュメントを定めています。2017年の第16号令は、遠隔医療(遠隔医療)のライセンスと技術要件が定められています。2019年の法律46号令は、スマートヘルスケアにおけるデータの適用をさらに進めます。	遠隔医療に関する特定のデータ保護はありませんが、2016年に行われたネットワーク保護を強化するガイドライン(ドキュメント)のデータ保護規定は、オンラインサービス上のデータ保護を保護する企業の義務を規定しています。

2023/8/19

13

遠隔医療と電子薬局の双方の分野にわたる法規制 - ASEAN最近の動向 -

- ここでは、アジアにおける遠隔医療と電子薬局の分野にわたる最近の法規制の動向について説明する。医薬品の流通に電子薬局の導入は、世界の多くの国で進んでいる。電子薬局に関連する法的要件について説明するため、各国への質問の内容を下記の5項目に限定している(詳細の質問は本報告書の別添付資料を参照してください)。

- 薬局が店頭販売(または同等のもの)以外の手段で薬を調剤することは可能か? 「はい」の場合、関連する法的要件は何ですか?
- 医療従事者や患者が自身の住居に直接薬を届けたい場合は可能か? 「はい」の場合、どのような種類の薬物を配達できますか? また、そのための配送と処方箋を保持していますか?
- 電子薬局の運営に必要な特定のライセンスはありますか?
- 医療専門家が遠隔医療プラットフォームを通じて(口頭または電子)患者の診断や診断を行うことは可能か? 「はい」の場合、事前に患者と医師の顔見合(事前の面談)が必須ですか?
- 遠隔医療および遠隔医療分野の最近の動向と将来の見通し。

2023/8/19

14

薬局が店頭販売(または同等のもの)以外の手段で薬を調剤することは可能ですか? 「はい」の場合、関連する法的要件は何ですか?

(その1)

Indonesia	In accordance with the regulations issued by the Drugs and Food Monitoring Agency (BPOM), the online distribution of drugs, medical devices, health supplements, cosmetics and processed foods is permitted. All products that are sold through online channels must be registered and approved with marketing authorization. Additionally, pharmacies can sell drugs online, by using their own information system or cooperating with a third-party pharmacy electronic system operator.
Philippines	Yes, it is possible to dispense drugs through licensed online pharmacies. Based on Food and Drug Administration (FDA) Advisory No. 2019-14, the online sale of pharmaceutical products is generally prohibited. By way of exception, a sale with an existing License to Operate (LTO) as a drugstore, pharmacy, or clinic with a physical address and where LTO covers the additional sale of selling drug online, may engage in online sale of drugs.
Malaysia	As a rule, prescription drugs may not be sold online, unless the producer presents a valid prescription. (PMA Circular No. 2020-07) (Reference to the Guidelines on the Implementation of the Sale of Medicines: Manual of Prescription for Drugs for the Benefit of Individuals) Whereas in COVID-19 (E-Pharmacy Guidelines) allows pharmacy to issue electronic prescriptions and authorize dispensing to recipient.
Thailand	The Ministry of Health has issued a notification regarding the standards and methods of the provision of telepharmacy on 3 June 2021. The notification stipulates online, which pharmacies will be allowed to provide pharmaceutical care without a face-to-face meeting with patients, including the delivery of drugs.
タイ	The notification requires that the provision of telepharmacy must be done by a pharmacist and must meet the following requirements: (1) having a patient registration system, (2) having a secure data recording system during the provision of telepharmacy, (3) having pharmaceutical user system, (4) prescription analysis, and (5) having appropriate delivery system/standards.
	The main telepharmacy process includes verification of the patient information for enrollment, consulting the patient and making a schedule for delivery of the drug, identification of the patient upon providing the telepharmacy service, providing care/consultation on the use of the drug, keeping a medical record, and following up on the result of the drug use.

2023/8/19

15

薬局が店頭販売(または同等のもの)以外の手段で薬を調剤することは可能ですか? 「はい」の場合、関連する法的要件は何ですか?

(その2)

Malaysia	Yes, it is possible for pharmacies to dispense drugs by means other than over-the-counter, for examples, through delivery service and online sale.
マレーシア	For drugs that contain any scheduled poison under the Poisons Act 1952/19, pharmacies, through their licensed pharmacist, may provide delivery service on their own, or appoint a licensed/contract company to do so. The regulatory requirements are set out in the Guidelines on Medicine Delivery Service by Licensed Pharmacies to Patients and the Guidelines on the Online Sale/Supply of Medicines Containing Poisons by Licensed Pharmacies (Type A Retail Licence Holders)21, some of which include: <ul style="list-style-type: none"> Preparing a comprehensive and complete standard operating procedure to address request for supply, preparation, safe delivery and acceptance of drugs by patients. Obtaining recording prior consent/notification of patients to hand over the drugs via delivery service. For prescription drugs, ask/signify may only be made with original prescription. Electronic prescription must digital signature that complies with the Digital Signature Act 1997. 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 Guidelines on the Online Sale of Non-Poison Pharmaceutical Product22, some of which include: <ul style="list-style-type: none"> Using local domain with local hosting and server. Not containing any other product in the page displaying the sale of non-poison pharmaceutical products. Not containing any link to social media - sale via social media is prohibited. Displaying the mandatory information on the website where the product is displayed i.e., business name, business registration number, full contact address (or P.O. box), contactable phone number, email address, product registration number, advertisement approval number (if required) and a prescribed cautionary statement.

2023/8/19

16

薬局が店頭販売(または同等のもの)以外の手段で薬を調剤することは可能ですか? 「はい」の場合、関連する法的要件は何ですか?

(その3)

Singapore	Yes, it is possible to dispense registered prescription only medicines ("POM") and pharmacy only medicines ("P") 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.
シンガポール	E-pharmacy services can only be provided by Singapore-registered companies, and on a Singapore business name. The e-pharmacy provider must: <ol style="list-style-type: none"> Hold a pharmacy licence issued by the Health Sciences Authority (HSA). Obtain prior approval from the HSA to provide telepharmacy and home delivery services; and Comply with the conditions which may be imposed by the HSA when it grants its approval. 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 pharmacy services adequately (based on personnel) to provide the services, and written procedures on how the services are to be provided. The provider must also appoint a competent qualified pharmacist registered under the Pharmacy Regulation Act as the pharmacist-in-charge to be responsible for the pharmacy operations, including proper storage and supply of the registered therapeutic products.

2023/8/19

17

薬局が店頭販売(または同等のもの)以外の手段で薬を調剤することは可能ですか? 「はい」の場合、関連する法的要件は何ですか?

(その4)

Vietnam	Drugs for distribution in Vietnam are divided into two categories: prescription drugs and non-prescription drugs.
ベトナム	Under the Pharmacy Law, prescription drugs can only be sold/dispensed outwards when there is a prescription. However, it remains debatable as to how the word "sell" 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 understanding is that prescription drugs may only be sold at physical pharmacies with physically presented prescriptions.
	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.

2023/8/19

18

医療従事者や薬局が患者の住居に直接薬を届けることは可能ですか？ 「はい」の場合、どのような種類の薬物を配送できますか？ また、そのような活動はどのような法律で許可されていますか？ (その1)	
Indonesia インドネシア	<p>No. Healthcare professionals are not allowed to deliver drugs (mainly to a patient's residence). BPFM Regulation 9/20102 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 (an electronic system provided by a third party pharmacy electronic system operator (i.e., e-Commerce platform (e.g., Shopee, 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 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 and potential drugs. Potential drugs can only be issued based on prescription, issued by doctor. Therefore, upon picking order of potential drugs through the online platform, users must attach the prescription (if electronic) or upload the image of physical prescription into the system.</p> <p>BPFM Regulation 9/2010 specifically prohibits physical pharmacies from selling the following drugs through online channels:</p> <ul style="list-style-type: none"> • drugs that contain pharmaceutical precursor • injections, except insulin for self-administration • tablets • narcotics and psychotropic <p>• certain critical drugs that are specifically prohibited from being sold through online channels.</p>

2023/8/19

19

医療従事者や薬局が患者の住居に直接薬を届けることは可能ですか？ 「はい」の場合、どのような種類の薬物を配送できますか？ また、そのような活動はどのような法律で許可されていますか？ (その2)	
Philippines フィリピン	<p>Yes, under current practice, certain duly licensed dispensers, pharmacies or botica whose LTO includes the specific authority to engage in online sale of drugs, also provide delivery service.</p> <p>Prescription drugs may not be sold online by licensed online dispensers and pharmacies, unless the purchaser presents a valid prescription that is issued according to the requirements of the Dispensing Guidelines.</p> <p>HCOs are not authorized to engage in online sale and delivery of drugs.</p>
Thailand タイ	<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>

2023/8/19

20

医療従事者や薬局が患者の住居に直接薬を届けることは可能ですか？ 「はい」の場合、どのような種類の薬物を配送できますか？ また、そのような活動はどのような法律で許可されていますか？ (その3)	
Malaysia マレーシア	<p>Yes, licensed pharmacist 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>Generally, all drugs may be self-delivered save for:</p> <ul style="list-style-type: none"> • dangerous drugs (as listed in the First Schedule of the Dangerous Drugs Act 1952); and • psychotropic substances (as listed in the Third Schedule of the Poisons Act 1952). <p>Such delivery of drugs is not prohibited by law, but the legal requirements on prescribed drugs and dispensed medicines as provided under the Poisons Act 1952 must be complied with. The regulatory requirements are further set out in the Guidelines on Medicine Delivery Service by Licensed Pharmacies to Patients.</p>
Singapore シンガポール	<p>Yes, provided these services are performed under a licensed e-pharmacy service provider (see preceding column).</p> <p>Only registered therapeutic products (i.e. POM or P) can be supplied by the pharmacy. These must also have been obtained through manufacturer or dealer licensed by the HSA.</p>

2023/8/19

21

医療従事者や薬局が患者の住居に直接薬を届けることは可能ですか？ 「はい」の場合、どのような種類の薬物を配送できますか？ また、そのような活動はどのような法律で許可されていますか？ (その4)	
Vietnam ベトナム	<p>The Law on Medical Examination and Treatment prohibits medical practitioners (i.e., doctors, physicians) from selling drugs to patients in any form.</p> <p>Pharmacists 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>

2023/8/19

22

電子薬局の運営に必要な特定のライセンスはあるか？ (その1)	
Indonesia インドネシア	<p>In addition to 1) a pharmacy license 2) general licenses required for web portal platform (i.e., Electronic System Operator (ESQ) Registration Certificate and Electronic System Trading Business License (Sistem Toko Online Perdagangan melalui Sistem Elektronik or STU/PMSSE) and 3) a marketing authorization for the products, for e-pharmacies, a pharmaceutical electronic system operator (PESOP) would need to hold a PSEP 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 PSEP registration and adopt the line of business as a PSEP if it only engages the promotional material or ads to the users.</p>
Philippines フィリピン	<p>Yes. Any pharmacy must have an LTO as a pharmacy, drugstore or botica, with a physical address and whose LTO cover the additional activity of selling drug online.</p>
Thailand タイ	<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>

2023/8/19

23

電子薬局の運営に必要な特定のライセンスはあるか？ (その2)	
Malaysia マレーシア	<p>The concept of e-pharmacies is not officially recognised in Malaysia. For drugs that contain any scheduled poison under the Poisons Act 1952, the Guidelines on Medicine Delivery Service by Licensed Pharmacist to Patients provides that:</p> <ul style="list-style-type: none"> • the sale/supply must be made at the premises as stated in the Type A Licence issued to the pharmacist; and • the delivery must be made from such premises. Other requirements include the following: <ul style="list-style-type: none"> • Licensed pharmacists who use telecommunication 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. • Drug counselling must be done prior to the delivery and may be done using effective telecommunication technology to ensure that the patient's receive and clearly understand the message delivered. • 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.

2023/8/19

24

電子薬局の運営に必要な特定のライセンスはあるか？
(その3)

Singapore シンガポール	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.
Vietnam ヴェトナム	There is no specific licence required for the operation of e-pharmacies. Key requirements to operate an e-pharmacy must at least include those applicable to a conventional drug retail outlet: <ul style="list-style-type: none"> • Good Pharmacy Practice (GPP) Certificate from the provincial Department of Health; • Pharmaceutical Practice Certificate is issued to the outlet owner; • Certificate of Eligibility for Pharmaceutical Business. The website or electronic application of the e-pharmacy business must also notify the Ministry of Industry and Trade as an e-commerce sales website

2023/8/19

25

まとめ

- ASEAN諸国では、デジタル・ヘルス事業を円滑に実施するために、共通の技術的基盤(デジタル・ヘルス・プラットフォーム)を構築し、そこへ適合する法的対応(法令の整備)をおこなっている。
- 技術的基盤は民間主導であり、競争が導入されており、今後加盟国間で互換性が進んでいくものと思われる。
- その結果、最終的にはデジタル・ヘルス(遠隔医療や電子薬局等)に関する法令は整合性がとれていくのではないかと(私見)

2023/8/19

26

ご清聴ありがとうございました

◎ 弊社ではASEAN諸国の法令、政策等につきましては情報提供サービス、コンサルティング等も実施しておりますので、お気軽にお問い合わせください。

株式会社 先端総合開発研究所
Advanced Research Challenger Inc./ARC
代表取締役(研究主幹) 坂部 望
〒065-0811
札幌市南区北11条東1丁目1-40 SAKURA-N11
E-mail: sakaba@sensoken.jp
Web: <https://sensoken.jp/>

2023/8/19

27