

Healthcare Certification Application Checklist: Japan

Welcome to the LegitScript Healthcare Certification Application Checklist for Japan! We are thrilled to accompany you on your journey towards LegitScript Healthcare Certification. This application checklist is crafted to provide telemedicine/medical providers, pharmacies, and related affiliates operating in Japan with a clear understanding of the compliance review process. At LegitScript, we are committed to offering a certification program you can trust—one that reflects your dedication to upholding the highest standards in healthcare. As you navigate through the checklist, remember that we are here to help and support you. We highly encourage you to review our [Certification Standards](#), [Terms & Conditions](#), and program [FAQs](#) for a comprehensive understanding of our requirements.

If you have any questions about the certification process or need further assistance, our team is here to help. Please don't hesitate to reach out to us at Certification@LegitScript.com.

Thank you for choosing LegitScript—we look forward to partnering with you every step of the way on your path to certification!

Scope Considerations

- ☐ Are you a third party provider, such as an affiliate program (アフィリエイトプログラム) or affiliate marketer (アフィリエイト) who connects consumers to online pharmacies and/or telemedicine providers? If so, to be in scope for certification you must either:
 - ☐ Actively facilitate the sale of prescription medications via a financial/contractual agreement between promoted pharmacies or medical providers or;
 - ☐ Process CNP (card-not-present) transactions for prescription-only drugs.

Licensure and Registration

- ☐ Be sure to include your active National Tax Agency (国税庁) corporate number on the [Business Registration tab](#) of our licensure template.
- ☐ If you directly provide telemedicine or pharmacy services, are you prepared to provide [active license information](#)?
 - ☐ Please note, pharmacies must provide [active license information](#) for every prefecture you operate within.
- ☐ If you directly provide telemedicine services, please be prepared to provide an image/copy of your Medical Practice license information and medical practitioner's MHLW certificate of completion.
 - ☐ Please note, all physicians performing telemedicine must attend a training prescribed by the [MHLW](#) before they can provide telemedicine services.
- ☐ If you directly provide telehealth services, please fill out the "International Applicants" tab within our [telemedicine template](#).
- ☐ Do you prescribe or dispense narcotics, psychotropics, or stimulants? Please provide your drug handler license assigned by your prefecture.
- ☐ Are you a pharmacy that compounds medications? Please complete each applicable tab within our pharmacy preparations (局での調剤) addendum [template](#).

Partner Requirements

- ☐ Third party providers, such as an affiliate program (アフィリエイトプログラム) or affiliate marketer (ウ アフィリエイト) who connects consumers to online pharmacies and/or telemedicine providers must ensure all partners are approved by LegitScript. Approval can be obtained through one of the following pathways:
 - ☐ Pharmacies and medical providers partnered with applying merchants may demonstrate their current compliance with Japanese regulations by providing current and valid documentation of their pharmacy and pharmacists' license or documentation of their MHLW telemedicine training certification respectively.
 - ☐ Pharmacies and medical providers partnered with applying merchants may submit their own application for LegitScript certification. Please note that the outcome of their compliance review may affect your own certification, if there is an active partnership.

Legal Compliance

- ☐ Make sure your website's language and product offerings follow prefecture and national laws and regulations.

- ☐ For example, it is not permissible to advertise any prescription-only drug to consumers/patients on the internet in Japan.
- ☐ Has your business or one of its principals been subject to discipline within the last five years? Has your business had any licenses or certifications that were lost, revoked, or not renewed? Has your business had to recall products?
 - ☐ Please provide evidence/documentation detailing this discipline, and to support any disciplinary action resolutions. Please reference our [Terms & Conditions](#) for examples of Disciplinary Action.
- ☐ Ensure your website features a privacy policy that is compliant with the Act on the Protection of Personal Information (APPI).

Patient Services

- ☐ Make sure all advertising is in line with the Medical Care Act and the Medical Care Act Enforcement Regulations, as well as Notice No.148 of 29 September 1998, issued by the Pharmaceutical Safety Bureau.
 - ☐ Additionally, adhere to any business-model specific advertising requirements, including the MHLW's "Basic Policy for Promoting Online Medical Examinations and Other Remote Medical Care."
- ☐ Are you an online pharmacy providing over-the-counter drugs? OTC pharmacies must display the following information on their website:
 - ☐ Name of the store.
 - ☐ Photo of the store (appearance, display status of pharmaceuticals).
 - ☐ Names of the professionals (pharmacists/registered sellers) on staff, responsibilities, etc.
 - ☐ License details (license number, name of store owner, location, etc.)
 - ☐ Contact information, including outside business hours.
 - ☐ Expiration dates of pharmaceuticals sold.
 - ☐ Risk classification of pharmaceuticals sold.

Transparency

- ☐ Is your website still under development/expecting updates? Please prepare wireframes/screenshots and the expected timeframe of completion.
- ☐ If applicable, please create a test patient account and provide us with a username and password to access your patient/client portal.

- ☐ Please be prepared to provide us with a list of all prefecture(s) your business serves along with any other international jurisdictions your business serves, if applicable.

Affiliates

- ☐ Ensure affiliates or affiliations with your business are compliant and operating legally. This includes, but is not limited to: co-owned businesses of the business' owners or principals, supplying wholesalers or distributors, partner pharmacies/provider networks, and marketing or promotional partners.
 - ☐ Common barriers can include affiliations with the sale or marketing of prescription-only or designated substances online, unapproved medicines, impermissible claims or ingredients.
- ☐ Please be reminded that all [applicable](#) business models utilized/promoted on the submitted domain must be approved by LegitScript, per our [Terms & Conditions](#).
 - ☐ Does your platform promote/link to a third party telemedicine provider or pharmacy? If so, the promoted URL is subject to the partner requirements listed within the "[Partner Requirements](#)" section of this document.

Questions? Email our team at Certification@LegitScript.com