SAFEGUARD CYBER

JAPAN'S NEW PHARMACEUTICAL COMPLIANCE REGULATIONS

Japan is adding the Product Information Offering Activities of Ethical Drugs Act to their pharma code of conduct, similar to other standards set for pharma in North America.

NEW REGULATIONS GO INTO FORCE OCTOBER 1, 2019.

WHAT DOES IT MEAN?

The Act was developed to ensure safe and effective use of products, and improve health and hygiene through the regulation of advertisements and related activities conducted by manufacturers and members.

The regulations address three components:

COMPONENT	DETAILS
PRODUCT INFORMATION	• Applies to information about effect-efficacy, adverse reactions, third-party validation, and quoted information • Prevents defaming competitors, exaggerating symptoms of diseases, recommending drugs at public disease awareness activities, and the use of expressions that can induce improper use of products • Requires companies to provide necessary product details, state complete study findings, and provide information requested by the Ministry of Health, Labor, and Welfare (MHLW)
RESPONSIBILITIES OF EMPLOYEES	• Comply with the outlined principles • Avoid conducting any misleading activities • Pursue self-improvement • Prohibit the use of improper materials

COMPONENT	DETAILS
RESPONSIBILITIES OF MANUFACTURERS	• Submit reports requested by the MHLW and local government, and ensure fidelity with healthcare professionals' records • Establish an internal department and a revision/supervision committee • Secure appropriateness of materials based on advice provided by review/supervisory committee • Evaluate employee activity & provide regular education • Implement supervision to regularly monitor activities • Create and manage procedure manuals & proper business records retention • Deal with improper activities • Manage complaints immediately • Provide education and ensure compliance among outsourced companies and business partners

WHAT'S AT STAKE

Japan is the 3rd largest pharmaceutical market on the planet, behind only the US and China. The market is **expected to reach $126 billion** in the next five years.

SafeGuard Cyber's NextGen compliance platform is currently used by 15 out of the top 20 pharma & life sciences companies to automate real-time compliance. Our solutions operate worldwide, in 18 countries, in over 50 languages. We empower enterprise compliance teams to create their own rule sets and capture data that matters, while remaining compliant and reducing overall workloads through automation across:

- Branded social channels
- Internal collaboration networks
- Field team interactions with HCPs over mobile chat
- Field team open text data entry in Veeva

Already a customer? Reach out to your rep to start protecting your business in Japan today.