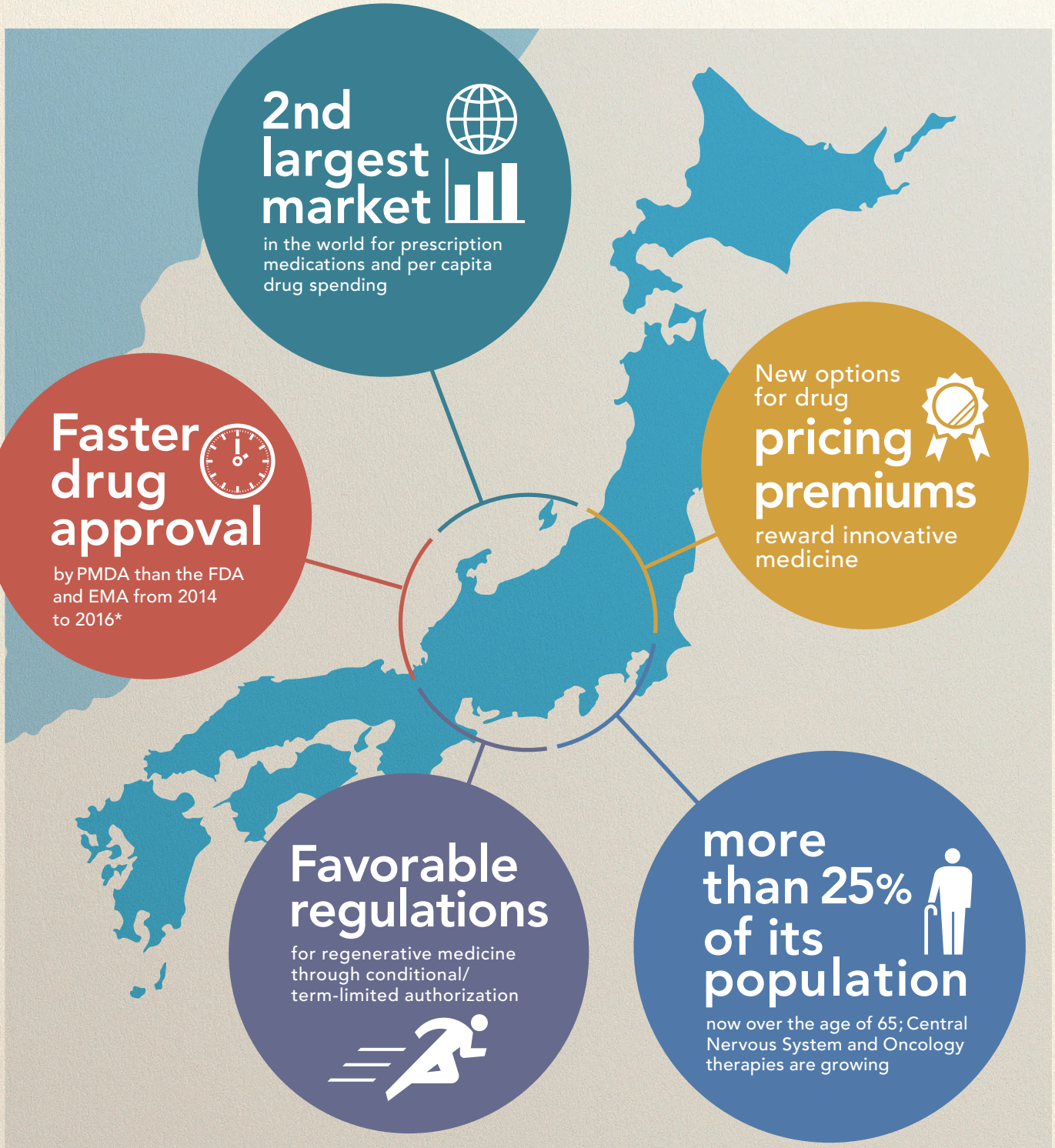
CMIC
Pharmaceutical Value Creator

Your Strategic Partner for Japanese Market Entry

The Japanese market is growing and changing



Although quality and innovation standards in Japan are comparable to that of the U.S. and European markets, the Japanese market can hold many regulatory and lingual obstacles for the first-timer. As Japan's first CRO, CMIC is your most experienced partner in Japan. Let our experts guide you in navigating the market.

*Bujar M, McAuslane N, Liberti L. 2017. R&D Briefing 62: New drug approvals in ICH countries 2007-2016. Centre for Innovation in Regulatory Science.

Tailor our services to meet your Japanese market entry needs

CMIC provides end-to-end solutions for market entry into Japan. Our 50+ experienced consultants will help you determine the best strategy in accordance with Japan-specific changing regulations and unique environment, working flexibly with your company's plans for market entry. We provide options for entry at any stage in drug development: before clinical trials have started abroad, after approval abroad or after commercializing in a different country. As a Pharmaceutical Value Creator, CMIC strives to provide value by spanning our services across the entire drug development value chain.

Featured services for Japanese market entry

PRE-CLINICAL | CLINICAL PHASE I-III | APPROVAL | POST-APPROVAL

ICCC services

* An In-Country Clinical Caretaker (ICCC) is required for foreign companies to conduct trials in Japan.

MAH related services

* A licensed Marketing Authorization Holder (MAH) is required for obtaining approval and marketing in Japan.

Consultation services for market entry

Establish a company in Japan: Solutions for establishing a presence in Japan.
Out-Licensing to other pharma: Partnering services as an add-on option.

Laboratory

- Pre-clinical data gap analysis

Regulatory Affairs

- PMDA consultations & Clinical Trial Notification (CTN) submissions

Investigational Product Manufacturing

- Investigational Product visual inspections, packaging & labeling per Japanese regulations

Medical Affairs

- Medical affairs organization setup, consultation & resources for Japan

Regulatory Affairs

- CTD preparation, submission & correspondence
- Inspection support & interpreter services
- National Health Insurance (NHI) reimbursement pricing and consultation

Post Marketing Surveillance & Clinical Research

- Post Marketing Surveillance services

Commercial Supply

- Visual inspections, packaging & labeling per Japanese standards

Sales and Marketing

- Commercial planning, setup and resources for Japan

CMIC
Pharmaceutical Value Creator

CMIC Group

EMAIL：information@cmic.co.jp　WEBSITE：www.cmicgroup.com/e