Baker McKenzie.

The Health Pod

Japan Pharmaceuticals Market – Drug Development Episode Guide

Overview of drug development in Japan

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The drug development process consists of (i) carrying out a baseline study to find a candidate substance which could be a new drug, (ii) undertaking a non-clinical study using animals to investigate toxicity, pharmacokinetics and develop a drug efficacy/safety profile etc., (iii) conducting Phase 1 to 3 clinical trials and (iv) based on the data obtained from these studies, submitting an application for regulatory approval to Japan's Ministry of Health, Labor and Welfare (MHLW).

1. Development strategy
   - A foreign pharmaceutical company may have two strategies: (i) establishing a subsidiary in Japan, which will obtain and hold the Marketing Authorization and (ii) having a partnership with a distributor, which will obtain and hold the Marketing Authorization.
   - The decision should be made based on the anticipated scale of the product market and resources required for these options.
2. Clinical trials
   - Under the PMD Act, Marketing Authorization is granted where the drug is found to be effective and does not have harmful effects which outweigh its efficacy based on data which is obtained in compliance with J-GCP and satisfies standards of data reliability etc.
   - The MHLW will only accept data from clinical trials conducted outside Japan if the trials have been conducted in a way that meets all Japanese requirements for clinical trials, including compliance with J-GCP. Also, the data needs to include an evaluation of whether the drug is likely to be influenced by ethnic factors (both intrinsic and extrinsic factors) and, if necessary, include the results of a bridging study.
   - Prior consultation with the PMDA is recommended in connection with the design of international clinical trials.
   - A foreign entity, which does not have any subsidiary in Japan, may conduct clinical trials in Japan, but must appoint an In-Country Clinical Caretaker for this purpose.
3. Collaboration in drug development
   - The key thing in making collaboration work in the context of an R&D project is the respective contribution and performance of the participants. For the collaboration to work effectively and produce good results, the participants must share a common goal and play their part in achieving that goal using their respective know-how, technologies and other resources.
   - The collaboration agreement needs to be clear as to the rights of each party to the results of the project and newly generated IP, and how they may use the results and IP.
   - With respect to collaborative R&D with academia in Japan, special consideration is required. For example, universities in Japan almost always insist on being compensated when pharma companies make a profit from the jointly owned IP notwithstanding that under Japanese patent law, jointly owned IP can be used by either owner without any compensation to the other.
4. Digital transformation
   - Digital transformation is beginning to change the drug development process in Japan. The MHLW plans to issue guidelines regarding the use of Real World Data in applications for Marketing Authorization.

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