



## MAH or DMAH in Japan?

**In Japan, a MAH, Marketing Authorization Holder, is the Japan-based legal entity that holds the license and product approval needed to place a drug on the Japanese market. Under the PMD Act framework, commercial shipment is not allowed without the required approval and permission, and the MAH carries the core post-approval obligations tied to quality and safety. In Japan, the MAH role is also linked to GQP, Good Quality Practice, GVP, Good Vigilance Practice, and release-to-market responsibility.**

A DMAH, Designated Marketing Authorization Holder, is best understood as a Japan-based MAH that a foreign company designates to act locally on its behalf. The practical point is that a foreign pharma company still needs a Japan-side entity to carry the regulated holder role in Japan.

The closest European equivalent is the EU MAH, meaning the legal entity that holds the marketing authorisation in one, several, or all EU Member States. In the centralised route, EMA performs the scientific evaluation and the European Commission grants an authorisation valid across the EU plus Iceland, Norway, and Liechtenstein. Like Japan, the MAH remains responsible for ongoing compliance after approval.

The key difference is that Japan is more explicitly built around a Japan-based holder with local release, quality, and vigilance accountability, whereas in Europe the MAH concept is broader and spread across the EU regulatory network. In Japan, the holder structure is tightly connected to local GQP/GVP operations and in-country control of market release. That is why foreign companies entering Japan often face a sharper early choice: build your own Japanese MAH capability or appoint a local designated holder. In Europe, companies still need an MAH and compliant local infrastructure, but the “designated local MAH” model is not the same central market-entry decision point as it is in Japan.

### What this means for when entering Japan

#### Option 1: Set up your own Japanese subsidiary and make it the MAH

This is the most control-oriented route. Your Japanese affiliate becomes the regulatory owner, builds the required local quality and vigilance functions, and controls strategy, label lifecycle, variations, safety governance, and commercialization alignment. This is usually the strongest long-term model for companies that expect a meaningful Japan business, multiple products, or strategic pricing and lifecycle management in-country.



## Pros

- Full control over the approval, post-marketing commitments, lifecycle management, and partner choices.
- Better long-term asset control, especially if Japan is strategically important.
- Easier alignment between regulatory, medical, market access, safety, supply, and commercial priorities in one organization.
- Better platform if you plan a pipeline, not just one product.

## Cons

- Highest upfront cost and complexity. You need a real Japan entity and compliant local systems for GQP, GVP, release, quality agreements, pharmacovigilance, recalls, and inspections.
- Slower initial entry if you are starting from zero.
- More management burden, especially for smaller biotech companies with one asset.

## Option 2: Use a third-party DMAH, meaning a local Japan-based MAH service provider

This is the fastest way to establish a compliant local holder without first building a full Japanese subsidiary. It is often attractive for emerging biotech, orphan products, or companies testing the Japan market before committing to a full buildout.

## Pros

- Faster entry and lower fixed overhead than building your own MAH capability.
- Access to local regulatory operations, documentation handling, safety systems, and practical PMDA/MHLW execution from day one.
- Useful when the foreign company wants to stay lean or has limited internal Japan experience.

## Cons

- You give up a meaningful degree of control because the local holder sits outside your company.
- Governance becomes contractual, not hierarchical. That can create friction around change control, deviations, safety decisions, labeling timelines, recalls, artwork, and release priorities.
- Transferring the MAH role later to your own subsidiary can be operationally painful and strategically disruptive.
- Investor and partner diligence often asks, "Who really controls the Japanese asset?" With a third-party holder, the answer can be less clean.



### Option 3: License or partner with a Japanese pharma company that becomes the MAH

This is different from a pure DMAH service model. Here, the local partner is not just an outsourced regulatory holder, it is also the commercial and often medical organization. For many Western pharma and biotech companies, this is the classic Japan entry route.

#### Pros

- Strongest local execution if the partner has market access, KOL reach, medical, safety, supply, and reimbursement capability.
- Lowest infrastructure burden for the foreign company.
- Often the best route when Japan is important, but the company does not want to build a direct business yet.

#### Cons

- You surrender the most control over strategy, positioning, and often economics.
- The product may become one of many priorities in the partner's portfolio.
- Recovering control later is difficult.
- This is less a regulatory outsourcing choice and more a business model decision.

## How you can frame your choice

For a company aiming at Japan, the decision is usually less about a textbook definition and more about three strategic questions:

#### 1. Is Japan a core market or an opportunistic one?

If it is core, building your own MAH usually wins in the long run. If it is opportunistic or uncertain, DMAH or licensing is often more rational.

#### 2. How much control do you need over the asset?

If Japan label strategy, lifecycle management, pricing logic, and future combinations matter, avoid structures that leave the holder role outside your direct control.

#### 3. How many products are coming?

One product can justify DMAH. A pipeline usually justifies your own MAH platform.

## Practical recommendation by company type

**Small biotech, one product, limited Japan experience:** start with **DMAH** or a **Japanese commercialization partner**, depending on whether you want to retain commercial control or not.



**Mid-size pharma, 2 to 5 planned products, serious Japan ambition:** strongly consider building your **own Japanese MAH subsidiary**, even if you temporarily outsource parts of operations during setup.

**Large pharma with long-term commitment to Japan:** own **MAH** is usually the right answer. Outsource execution where efficient, but keep holder control.

## Bottom line

- **MAH in Japan:** the Japan-based legal entity that holds the approval and carries local quality and safety responsibility.
- **DMAH in Japan:** the practical model where a foreign company designates a Japan-based MAH to act locally on its behalf. PMDA often calls this a **designated Marketing Authorization Holder**.
- **EU equivalent:** closest to the **EU MAH**, but Japan puts more operational weight on the Japan-based holder's local GQP, GVP, and release responsibilities.

## In short

**Own MAH:** highest control, highest investment, best long-term platform.

**DMAH:** fastest lean entry, but with meaningful loss of control.

**Japanese partner as MAH:** lowest burden, but also lowest control and usually lower long-term upside.



Decision factor	Own MAH	Third-party DMAH	Japanese partner as MAH
Keep strategic control of product	Best	Acceptable only if governance is strong	Weak
Enter quickly with limited resources	Weak	Best	Strong
Build long-term Japan platform	Best	Temporary solution	Usually weaker
One product only	Often overbuilt	Good	Good
Multi-product pipeline	Best	Can become inefficient	Depends on partner strategy
Strong internal regulatory capability	Best	Good	Not necessary
Minimal Japan headcount	Weak	Best	Best
Maximize long-term value capture	Best	Medium	Weak to medium
Limit operational burden	Weak	Good	Best