Generic entry – approval process

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1. Submission of Information on Patents by NDA Holder

A NDA holder can submit to the MHLW the information about the patents only on the compound per se after market approval (like the Orange Book in US).

2. Evaluation of Patents by Generic Maker

A generic maker evaluates the validity and strength of each extant patent relating to the brand drug and determines which is the latest patent which could effectively block generic makers from the market before initiating development.

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3. Submission of the “Request for Market Approval” in Advance

The generic maker submits the “Request for Market Approval” with a legal opinion of non-infringement, taking into account the expiry date of the said last patent, and the expiry of a safety monitoring term (Post Marketing Surveillance, or PMS) of the original drug.

4. Market Approval by the MHLW

The MHLW issues the “Market Approval” to the generic drug just after the expiry date of the said last patent, though this can be delayed as the generic maker must file after the completion of the PMS term (and can receive MA one year later)

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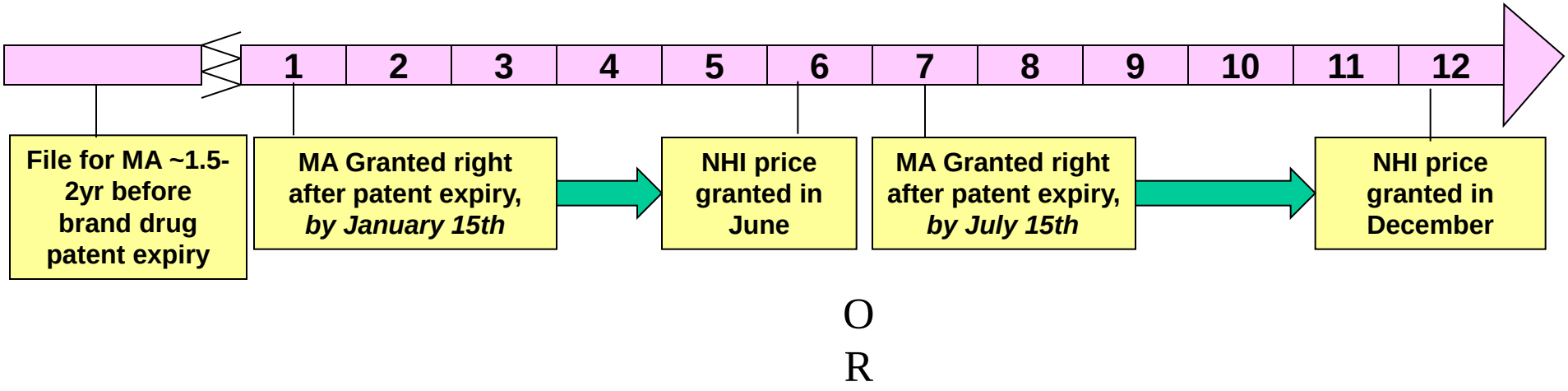
Generic entry – pricing process

Market Approval can be requested by the generic maker well before patent expiry of the brand drug. MA can then be granted right after expiry, and NHI price is granted in June or December of that year.



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Generic entry – pricing process

However, the generic drug maker cannot request MA until after the completion of the *PMS term* of the original drug, and the MA would then be granted after a year of review. Again, NHI pricing is granted in June or December after the MA is granted. If the PMS term expires some time after the patent expiry, the timeline would look like this: