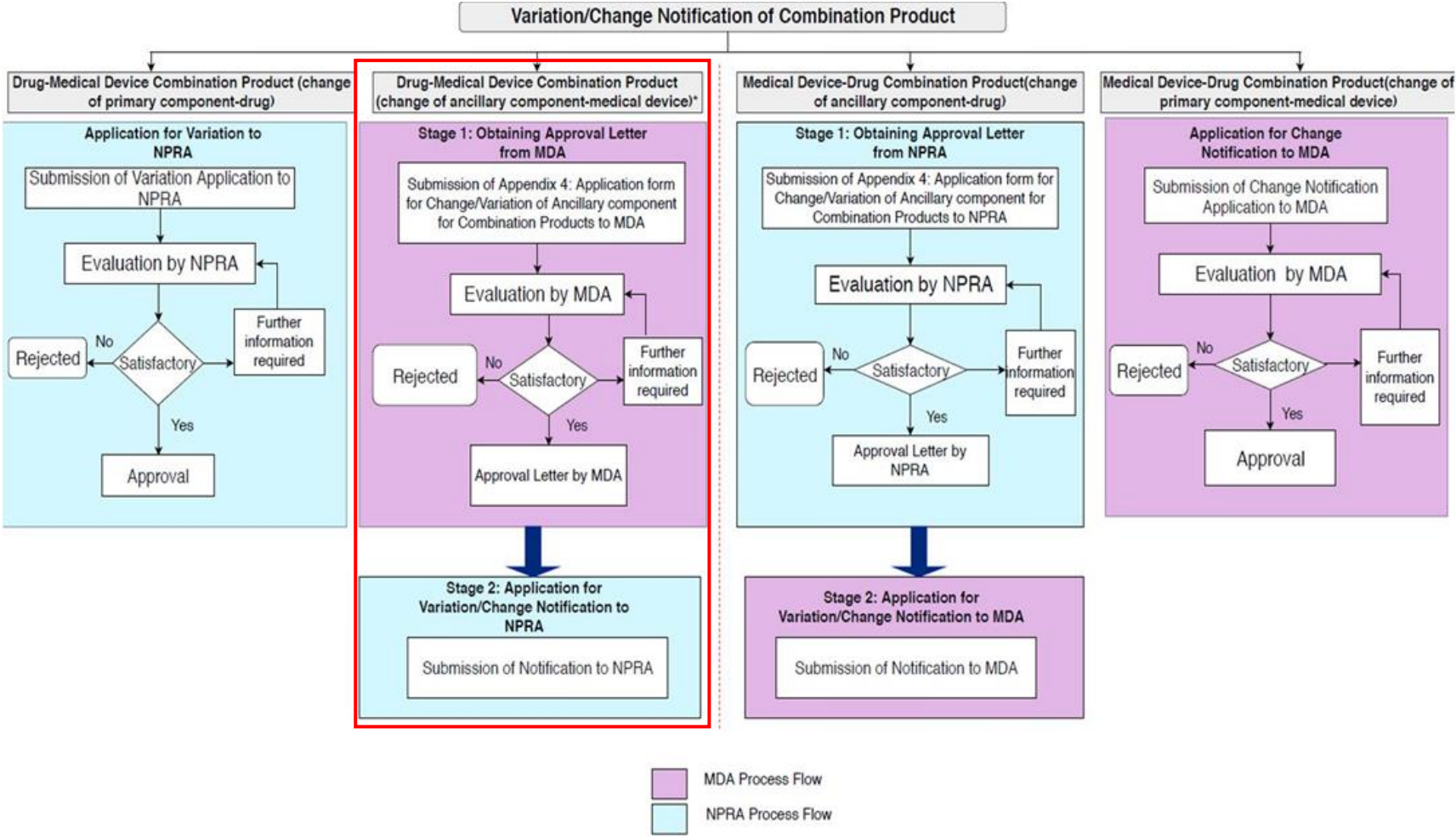


**Overview of Post Approval Changes of a Registered Combination Product (Changes to Ancillary Medical Device Component) Framework**



Explanatory Note\*: Ancillary medical devices that have already obtain prior registration approval with MDA and subsequently approved of their change notification application with MDA SHALL not be required to proceed with this requirement