Regulatory Affairs by ELC

Drug registration in China

Registration types in China

NDA

- Innovative drug
- Improved new drug
- Class 5.1
- Biological product
- Biosimilar

ANDA

- Generic drug

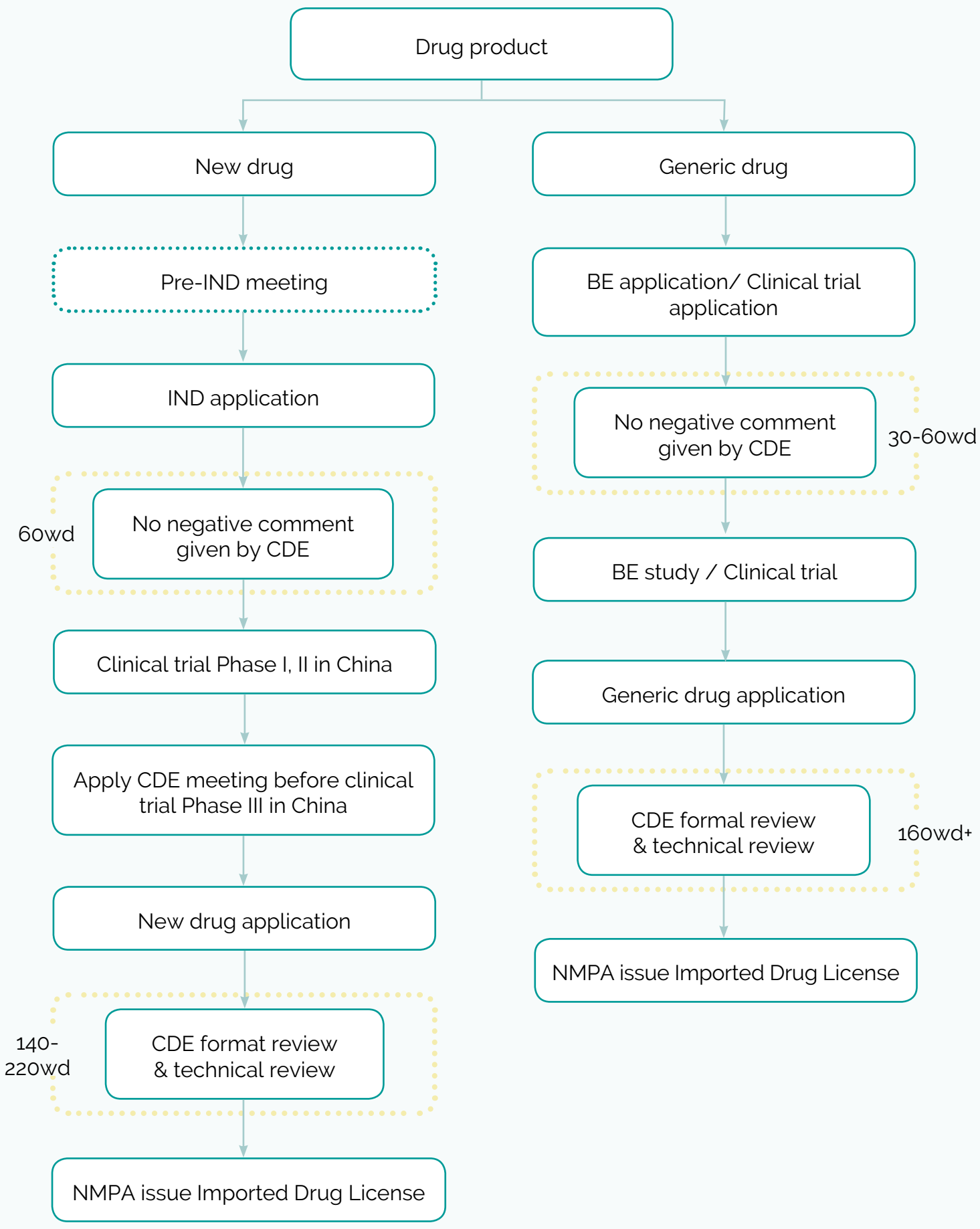
Supplementary applications

- application for variation, addition, or cancellation of the items or contents approved in the original application

Re-registration

- application for continued production or importation of a drug after the expiration of the valid term of the drug approval document (5years)

NDA / ANDA procedure in China



*Note: The registration timeline above is a conservative estimation that we advise our clients to reserve in order to avoid any delay for the market plan.

How can ELC support your project?

ELC can guide you through the process and support you fulfilling all the regulatory and pharmacovigilance requirements before, during and after approval, offering:

regulatory strategy - dossier preparation, due diligence and gap analysis - BR/BT site in the EEA - translation and readability testing - MA holding – submission management - end-to-end pharmacovigilance

To find out more: info@elc-group.com

Concept to Compliance

www.elc-group.com