REGULATORY STRATEGY AND PLAN IN PLACE

GLOBAL DRUG DEVELOPMENT

Goals/ Definition

Regulatory path and plan in place.

Plan for proposed regulatory path through life-cycle of the product.
(*An iterative document that is initiated at FIH, updated continually along the development process, and reviewed through to DTF)

CRITERIA	SAMPLE CONTENT REQUIREMENT	GUIDELINES FOR LEVEL OF DETAIL NEEDED AT EACH GATE

▪ Proposed regulatory path through life-cycle of product defined, including:
  ▪ Clinical development
  ▪ Licensure
  ▪ WHO PQ (if needed)
  ▪ Post-authorization safety surveillance and further product development
▪ Include any specific plans to use alternative development pathways (conditional, accelerated, breakthrough) or registration processes (article 58, tropical voucher, orphan)
	a) Prioritized list of countries where the drug is intended to be introduced[1]
	b) Understanding of country-specific regulatory requirements
	  • Type of submissions (original, supplement/variation, line extension, etc)
	  • **Significant / unique requirements[2]**
	  • Required HA communications and timing
	c) Plans for NRA engagement during development to gain feedback and agreement with development and filing strategy
	d) Key regulatory risks and risk mitigation plans
	e) Plan to ensure proposed indication and labeling aligns with TPP and donor/utilization requirements
	f) Plan for approval and protocol review for clinical trial starts in target countries
	g) Plan to handle monitoring and reporting of adverse events and safety issues during clinical trials and post-authorizations
	h) WHO PQ applicability/programmatic suitability, plan to pursue WHO PQ (if applicable)
	i) Plans for WHO PQ engagement by end of phase 2 (if applicable)
		▪ Updated throughout life-cycle of product reflecting new data and priorities as they develop
		▪ Required at each gate: Detailed plan with timeline and resources for the next phase of development (e.g. detailed plan for Phase 1 required at the FIH gate review), and high-level / draft plan focusing on risk identification and mitigation for all subsequent phases of development

Items in **bold** font reflect suggested reporting guidelines for this stage gate

[1]If India and China are among the likely target countries, content is required at FIH. Otherwise it applies at EP2.

[2]Specific requirements associated with Chinese Pharmacopeia should be updated early