

**(A) Implementation Plan for Review Committee Recommendations
with Existing Resources**

Tasks	Implementation timeframe	2010	2011	2012	2013
I Regulation of Manufacturers					
i	Appoint external advisor to GMP audit team	■			
ii	Develop strategy for communication and liaison with industry	■	■		
iii	Introduce microbiological monitoring model	■	■		
iv	Stipulate detailed requirement of AP, Head of Production & Quality Control		■	■	
v	Introduce new licensing condition to have manufacturers to invite AP to attend board of governors' meetings involving safety, efficacy and quality matters		■	■	
II Enhancement of Pre-Market Control					
i	Set up expert advisory group on BABE	■			
ii	Shorten the approval period of clinical trial applications	■	■		
III Regulation of Wholesalers, Importer/Exporters and Retailers					
i	Trade consultation	■			
ii	Prepare Code of Practice for wholesalers, importer/exporters and retailers		■	■	
iii	Tightening up licensing conditions		■	■	
iv	Revise DH inspection report forms & implement	■	■		
v	Introduce new licence for secondary packaging		■	■	
vi	Require to keep written records of orders by retailers and doctors		■	■	
vii	Research on electronic record system for import/export of drugs including conducting feasibility study		■	■	

Tasks	Implementation timeframe				
	2010	2011	2012	2013	
IV Enhancement of Drug Procurement					
i	Set up contractual agreement between purchasers and suppliers to keep samples of each batch of drugs that are still within the expiry period				
ii	Set up working group with the trade on enriching the registered drug database				
iii	HA to improve on drug procurement				
iv	Prepare guiding principles on drug procurement for private medical sector				
v	Encourage private hospitals to develop automated inventory management system				
V Enhancement of Pharmacovigilance and Risk Communication					
i	Establish a pharmacovigilance advisory body				
ii	Produce a pharmacovigilance bulletin				
iii	Establish liaisons with International Society of Pharmacovigilance and other pharmacovigilance counterparts				
iv	Establish a working group on enhancement of drug information				
v	Update recall guidelines				
vi	Improve on public communication adopting a risk-based approach including informing relevant stakeholders, such as Consumer Council, etc.				
vii	Seek assistance from expert for upgrade of the computer system of DH and the provision of information technology support for enhancement of drug information				
VI Raising of Penalty					
i	Provide the Court with more aggravating factors in the brief facts of each case to reflect the seriousness of the case				
ii	Review the sentencing of each court case				

(B) Implementation Plan for Review Committee Recommendations with New Resources

Tasks	Implementation timeframe (After allocation of required resources)	1/2 year	1 year	2 years	4 years	6 years
	I Regulation of Manufacturers (Transition to WHO (2007) GMP standard then to PIC/S GMP standard)					
i Develop training programmes for DH and trade		■				
ii Set up multidisciplinary GMP inspection team			■			
iii Initiate HK membership of PIC/S				■		
iv Impose PIC/S standard API and contract laboratories licensing requirement						■
v Introduce structured training for AP				■		
II Enhancement of Pre-Market Control						
i Require BABE studies as registration requirement for generic drugs by phases		■				
ii Shorten the approval period of applications for registration and change of registered particulars		■				
III Regulation of Wholesalers, Importer/Exporters and Retailers						
i Enhance inspection based on risk assessment		■				
ii Establish an inspection team to advise C&ED on import and export of drugs			■			
iii Devise a system to enhance the import/export control of drugs		■	■			
iv Increase the quota sent to C&ED for consignment check			■			
IV Enhancement of Drug Procurement						
i Enhance vigilance using risk-based approach in post-delivery surveillance including microbiological and chemical testing			■			
ii Enhance training to staff on compliance with Good Dispensing Practice including repacking activities		■				
iii Upgrade the central inventory monitoring computer system				■		
V Enhancement of Pharmacovigilance and Risk Communication						
i Set up a dedicated team to promote pharmacovigilance work			■			
ii Develop electronic ADR reporting interfaces for healthcare providers				■		
iii Establish ADR reporting guidelines and impose new requirements for industry		■	■			
iv Set up a dedicated, multi-disciplinary team for public education			■			
v Launch the dedicated drug safety website				■		
VI Establishment of a Centre for Drug Safety			■			

**(C) Implementation Plan for Review Committee Recommendations
requiring Legislative Amendments**

	Implementation timeframe	2010	2011
Tasks (Preparation of Draft Drafting Instructions)			
I	Enhancement of Pre-Market Control		
i	Replace the word "poison" with other suitable words after consultation with trade by the Pharmacy and Poisons Board		
ii	Delete the words "to be marketed for use within Hong Kong" on the registration certificate		
iii	Lengthen the validity of clinical trial certificate to "not more than 5 years"		
II	Regulation of Wholesalers, Importer/Exporters and Retailers		
i	Introduce new licences for wholesale and retail of non-poisons		
ii	Introduce new requirement to maintain record of transactions of Part II poisons & non-poisons		
iii	Empower PPB to revoke ASP licence after ASP convicted of serious drug offence		
iv	Require to keep Part I poisons in locked receptacles		
v	Require the presence of pharmacists during all business hours of ASPs		
III	Tightening of Penalty		
i	Require the convicted persons to pay the analytical costs		