Annex D

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

	Implementation timeframe / Tasks	2010	2011	2012	2013
I	**Regulation of Manufacturers**				
i	Appoint external advisor to GMP audit team				
ii	Develop stratetgy 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				

	Implementation timeframe / Tasks	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				

Annex D

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

	Implementation timeframe (After allocation of required resources) / Tasks	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-disiplinary team for public education					
v	Launch the dedicated drug safety website					
VI	**Establishment of a Centre for Drug Safety**					

Annex D

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

	Implementation timeframe / Tasks (Preparation of Draft Drafting Instructions)	2010	2011
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		