Questionnaire

Combination Products (CP)

(Draft)

Please tick appropriate boxes☑ and indicate your comment/statement and return to Dr. Ming-Che Wang at mcwang@cde.org.tw at your earliest convenience.

First Name		
Last Name		
Title	Mr. Mrs. Ms. Dr. Other_____ **(Please circle one)**	
Member Economy		
Position		
Company/Organization		
Questions	**Comment/Statement**	
Regulation of Combination Products (CP) has been implemented?	Yes □ _____	No □ _____
Guidance or Guidelines implemented for CP?	Yes □ _____	No □ _____
Definition of CP		
Components of CP		
Combination methods of CP		
Agency review determinations - who is the lead?		

Pre-market review route of CP submissions?		
Agency “non-primary” component consultations		
Are separate applications required for different components of investigational applications (clinical study) for CP?	Yes □ _____	No □ _____
Are separate applications required for different components of CP applications?	Yes □ _____	No □ _____
GMP/QS requirements for CP?		
Adverse events/Vigilance Reporting Requirements for CP?		
Registration and Listing requirements for CP?		
Other CP Initiatives?		