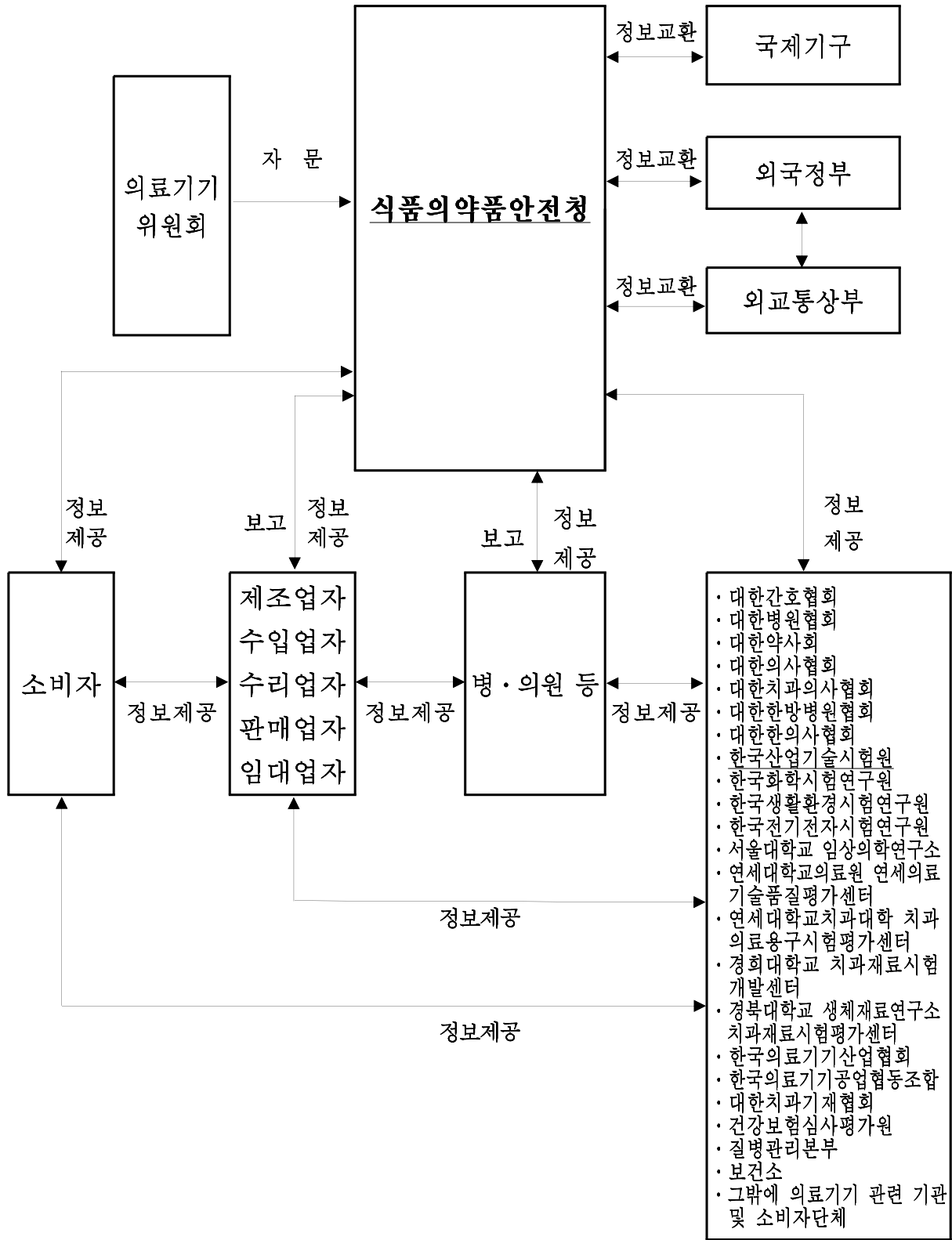


[별표 1]

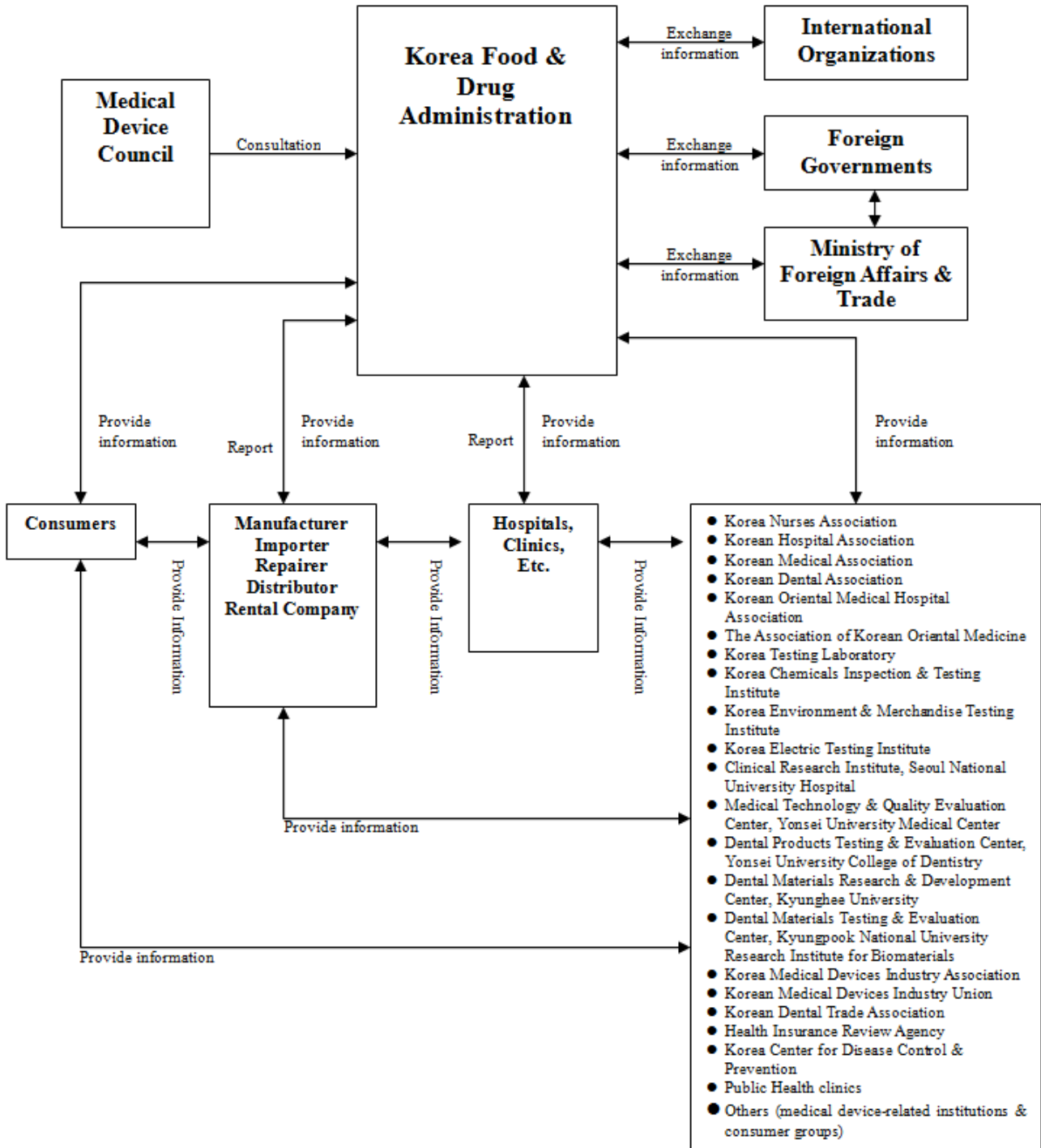
안전성 정보 등의 관리체계(제3조 관련)



[Attached Table 1]

MANAGEMENT SYSTEM for SAFETY INFORMATION Etc.

(Article 3)



Safety Information	Reason for Reporting			
	Summary of Information			
	Number of Products Manufactured (Imported) and Number of Products Distributed (Inventory)			
	Case Brief and Follow-up Actions			
Information on Adverse Side effect	Dates of Adverse Side Effect		Date of adverse side effect being perceived (yy/mm/dd) / / / Date of adverse side effect took place (yy/mm/dd) / / / Date of adverse side effect ended (yy/mm/dd) / / / <input type="checkbox"/> In progress	
	Result of Adverse Event/Side effect		<input type="checkbox"/> Death or life-threatening <input type="checkbox"/> Hospitalization extension of the hospitalization period is needed <input type="checkbox"/> a disorder which is impossible to recover from or results in serious disablement or malfunction <input type="checkbox"/> congenital malformation or abnormality <input type="checkbox"/> Others ()	
	Summary of Adverse Side Effects Etc.	Type of Adverse Side Effect	<input type="checkbox"/> If the Medical Device causes an adverse event of death or a life-threatening result case <input type="checkbox"/> If the Medical Device caused permanent damage; <input type="checkbox"/> If the Medical Device is likely to has risk of seriously threatening public health or aggravate such threat the expansion and <input type="checkbox"/> If the Medical Device necessitates additional medical intervention in order to prevent death or threat to life is additionally needed for prevention of death or threatening of the life <input type="checkbox"/> Others ()	
		Summary of Adverse Side Effects		
		Details of Adverse Side Effects		
	Event brief and follow-up actions			
	Name of facility/institution where adverse side effect took place			
	Address			
	Contact	Telephone	FAX	
Attachment				