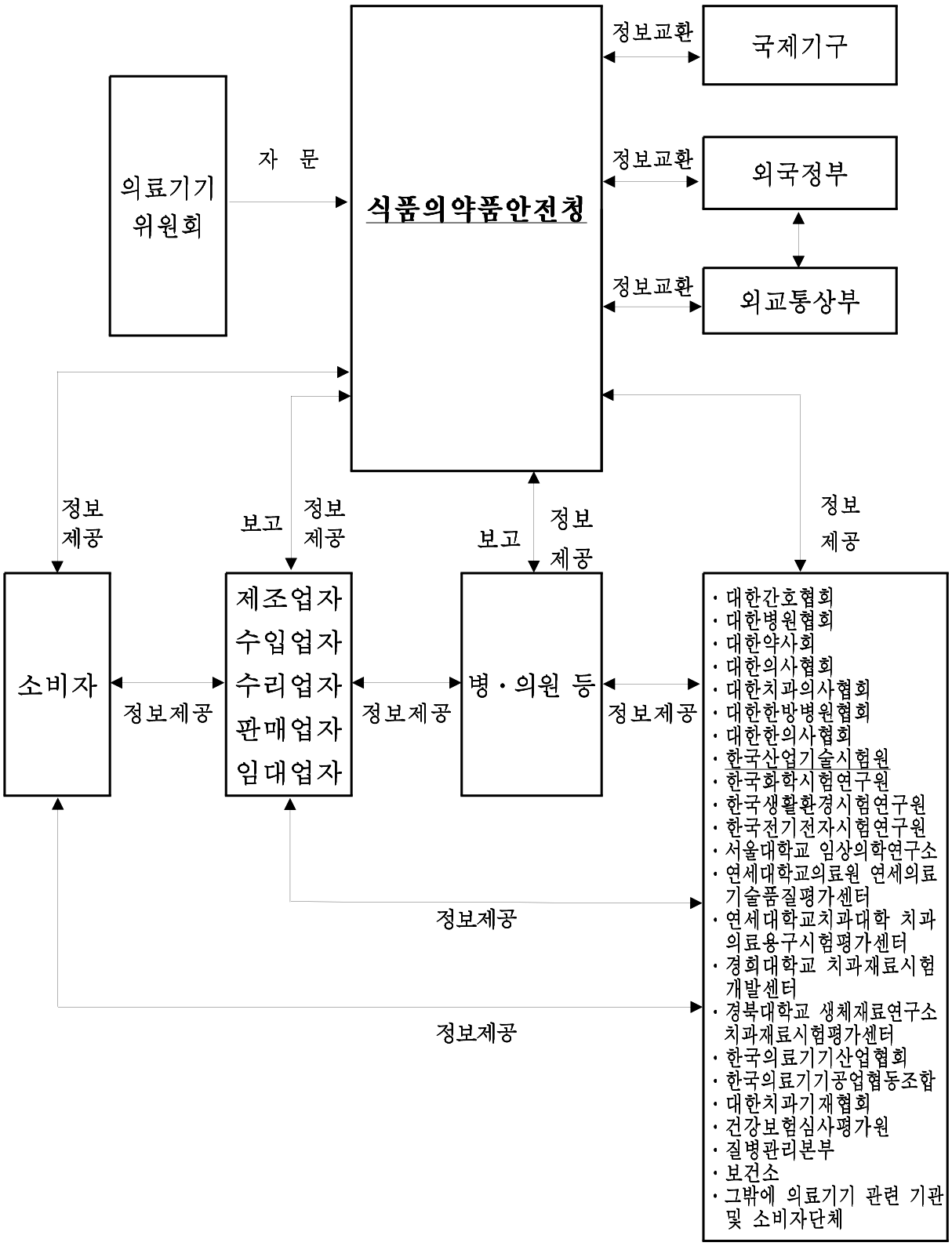
[별표 1]

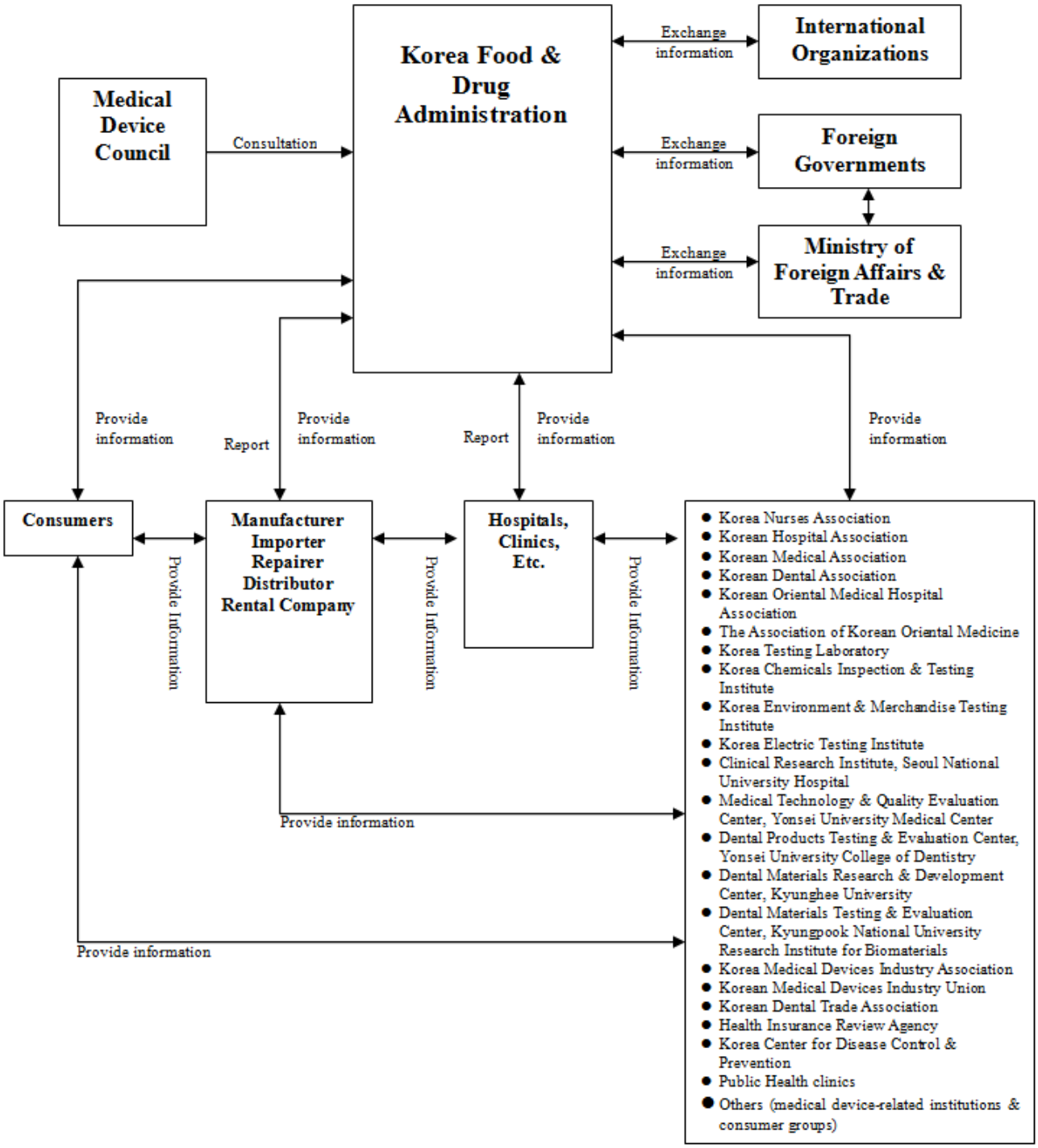
안전성 정보 등의 관리체계(제3조 관련)



[Attached Table 1]

MANAGEMENT SYSTEM for SAFETY INFORMATION Etc.

(Article 3)



[별지 제1호서식]

(앞쪽)

의료기기 부작용등 안전성 정보 보고서

구분	보고종류	☐ 안전성 정보 ☐ 부작용 보고		
		☐ 최초보고 ☐ 추가보고 ☐ 최종보고		
보고자정보	대 표 자			
	상 호 명 (업 체 명)			
	유 형	☐ 의료기기제조업자 ☐ 의료기기수입업자 ☐ 의료기기수리업자 ☐ 의료기기판매업자 ☐ 의료기기임대업자 ☐ 의료기관개설자 ☐ 동물병원개설자 ☐ 소비자 ☐ 기타 ( )		
	주 소			
	연 락 처	담당자명	전 화	
		FAX	E-mail	
의료기기정보	제 품 명	품 목 명	형 명	
	분류번호		등 급	
	허가번호			
	제조번호 (Lot 번호)			
	제조원 (수입의 경우)			
환자정보	성 명			
	성 별	☐ 남 ☐ 여	나 이	
	기타 특이사항			

210mm×297mm(일반용지 60g/㎡(재활용품))

(뒤쪽)

<table>
<tr><td rowspan="4">안전성정보</td><td colspan="2">보고사유</td><td colspan="2"></td></tr>
<tr><td colspan="2">개요</td><td colspan="2"></td></tr>
<tr><td colspan="2">생산(수입)실적 및
판매(재고)현황</td><td colspan="2"></td></tr>
<tr><td colspan="2">경과 및
후속조치</td><td colspan="2"></td></tr>
<tr><td rowspan="9">부작용정보</td><td colspan="2">부 작 용
발생기간</td><td colspan="2">인지일 (년 월 일.)
발생일 (년 월 일.)
종료일 (년 월 일.)
☐ 현재 진행중</td></tr>
<tr><td colspan="2">부작용결과</td><td colspan="2">☐ 사망이나 생명에 위협
☐ 입원 또는 입원기간의 연장
☐ 회복이 불가능하거나 심각한 불구 또는 기능저하
☐ 선천적 기형 또는 이상을 초래
☐ 기타 ( )</td></tr>
<tr><td rowspan="3">부작용
개요등</td><td>유형</td><td colspan="2">☐ 사망이나 생명에 위협을 주는 결과를 초래한 경우
☐ 영구적 손상을 초래한 경우
☐ 심각한 공중보건 위협이나 확대의 우려가 있는 경우
☐ 사망·생명의 위협 예방을 위해 필수적인 추가적 의료적 개입 필요
☐ 기타 ( )</td></tr>
<tr><td>개요</td><td colspan="2"></td></tr>
<tr><td>세부
내용</td><td colspan="2"></td></tr>
<tr><td colspan="2">경과 및
후속조치</td><td colspan="2"></td></tr>
<tr><td colspan="2">부작용발생
시설/기관명</td><td colspan="2"></td></tr>
<tr><td colspan="2">주소</td><td colspan="2"></td></tr>
<tr><td colspan="2" rowspan="2">연락처</td><td>전 화</td><td>FAX</td></tr>
<tr><td></td><td></td></tr>
<tr><td colspan="2">첨부자료</td><td colspan="2"></td></tr>
</table>

[Attached Form No. 1] (Front)

Report of Safety Information of Medical Devices Including Adverse Event Side effects, Etc.				
Classification	Type of Report	□Safety Information □Adverse Event Side effects Report		
		□Initial Report □Supplementary Report □Final Report		
Reporting Party	Name of Representative			
	Company Name			
	Type of Business	□Medical Device Manufacturer □Medical device Importer □Medical Device Repairer □Medical Device Distributor □Medical Device Rental Company □Medical Institution □Veterinary Hospital □Consumer □Others ( )		
	Address			
	Contact Point	Name of Contact	Phone Number	
Information on Medical Device	Name of Product	Name of Product	Model	
	Device Classification No.		Class	
	Product License No.			
	Batch No. (Lot No.)			
	Name of Manufacturer (in case of an imported device)			
Information on Patient	Name			
	Gender	□Male□Female	Age	
	Other Special Notes			

210mm×297mm(A4 60g/㎡(recycled))

(Back)

<table>
<tr><td rowspan="4">Safety Information</td><td colspan="2">Reason for Reporting</td><td colspan="2"></td></tr>
<tr><td colspan="2">Summary of Information</td><td colspan="2"></td></tr>
<tr><td colspan="2">Number of Products Manufactured (Imported) and Number of Products Distributed (Inventory)</td><td colspan="2"></td></tr>
<tr><td colspan="2">Case Brief and Follow-up Actions</td><td colspan="2"></td></tr>
<tr><td rowspan="11">Information on Adverse Side effect</td><td colspan="2">Dates of Adverse Side Effect</td><td colspan="2">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) ___/___/___
☐ In progress</td></tr>
<tr><td colspan="2">Result of Adverse EventSide effect</td><td colspan="2">☐ Death or life-threatening
☐ Hospitalization extension of the hospitalization period is needed
☐ a disorder which is impossible to recover from or results in serious disablement or malfunction
☐ congenital malformation or abnormality
☐ Others ()</td></tr>
<tr><td rowspan="3">Summary of Adverse Side Effects Etc.</td><td>Type of Adverse Side Effect</td><td colspan="2">☐ If the Medical Device causes an adverse event of death or a life-threatening result case
☐ If the Medical Device caused permanent damage;
☐ If the Medical Device is likely to has risk of seriously threatening public health or aggravate such threat the expansion and
☐ 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
☐ Others ( )</td></tr>
<tr><td>Summary of Adverse Side Effects</td><td colspan="2"></td></tr>
<tr><td>Details of Adverse Side Effects</td><td colspan="2"></td></tr>
<tr><td colspan="2">Event brief and follow-up actions</td><td colspan="2"></td></tr>
<tr><td colspan="2">Name of facility/institution where adverse side effect took place</td><td colspan="2"></td></tr>
<tr><td colspan="2">Address</td><td colspan="2"></td></tr>
<tr><td colspan="2" rowspan="2">Contact</td><td>Telephone</td><td>FAX</td></tr>
<tr><td></td><td></td></tr>
<tr><td colspan="3">Attachment</td><td colspan="2"></td></tr>
</table>