
Liability on 3rd Parties

Korea Compliance Best Practice Roundtable

Jooha Yang / Roche

6th Asia-Pacific Pharmaceutical and Medical Device Compliance Congress

A background image showing a close-up of a water droplet hitting a surface, creating concentric ripples that spread outwards. The water is a deep blue color.

Good compliance is good business

Why 3rd Party Compliance is important...



Dual Punishment System

No mention of **through “Affiliates or Other Businesses”**

BUT it is possible under the existing provisions to sanction Pharmaceutical/Medical Device Suppliers that provide kickbacks through third parties based on a theory of **accomplice liability and that “affiliates” and “other businesses” are very general terms**

Authorized Interpretation

- Manufacturer’s responsibility includes illegal rebates through CSOs to HCPs/HCOs
- Even though a manufacturer insists the illegal activity is done by CSO independently/separately, **partial or whole responsibility of guidance and monitoring** is still on the manufacturer’ side.

Also shown...



Investigation report

Even when **third parties are the official hosts** of certain events, if a pharmaceutical **company is the main source of the event's funding**, investigative authorities may consider the company **the actual host of such events**.



Article 5

A company shall be deemed to have **directly provided** money or other valuables to medical institutions, etc., or HCPs:

1. When **headquarters/branches/affiliates** provide financial benefits to HCPs/HCOs
2. Provide money or other valuables to **wholesaler or marketing agency** asking deliver to HCPs/HCOs
3. A Company could have known such money or other valuables provided to wholesaler or agency were going to be delivered to HCPs/HCOs

Global Policies



Who is Business partners (3rd party)?

- A. *Any partner promoting and/or distributing Company products based on agreement*
- B. *Any third party supplying good to Company and/or performing services for or on behalf of Company*

Promotion/distribution Partners

- Co-promotion/Co-marketing partner
- Licensing out partner
- Distribution partner (e.g. wholesaler)

Service providers

- Event agency (promotional and medical event)
- Travel agency
- ...

Manufacturing partner

- Manufacturer
- Key supplier
- ...

Co-promotion Trend on the Increase



Major Co-promotion drugs

제약사	제품명	7월 원외처방액
Yuhan	비리어드	132억원
	트라젠타	99억원
	트윈스타	86억원
	미카르디스	19억원
CKD	자누메트	88억원
	바이토린	36억원
	자누비아	40억원
	아토젯	20억원
Daewoong	크레스토	62억원
	세비카	38억원
	넥시움	26억원
	세비카HCT	22억원
Green-cross	바라크루드	90억원
	아타칸	38억원
Hanmi	가브스	11억원
	가브스메트	35억원
DongA	세레타이드	19억원
	햅세라	10억원
	제픽스	7억원
	아셀렉스	4억원
Ildong	콤비글라이즈	12억원
	온글라이자	6억원

출처: 신한금융투자, 유비스트

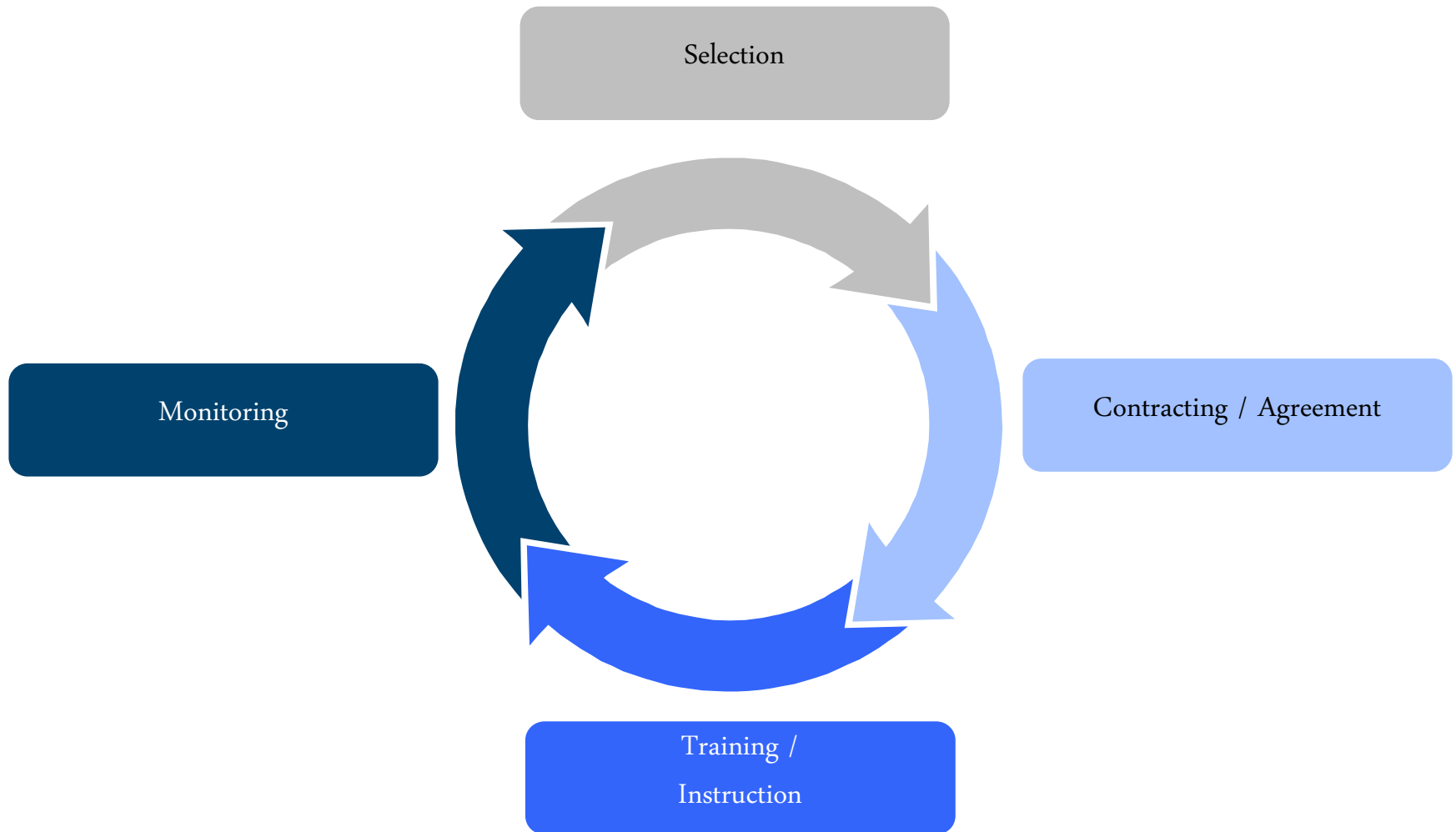
Government Surveillance

- Recognize as new tool of illegal rebates
 - ✓ Clinical trial support, Market research
 - ✓ Through CSO (Contract Sales Organization) and medical journal agency
- Reports by Whistle blowers

Develop "Dos & Don'ts" for partners

Relationship with Business Partners

3rd Party Compliance Lifecycle



What we can do in each step

Trusts, but verifies / Due Diligence

Selection	Contract	Training	Monitoring
<p>Compliance DD</p> <ul style="list-style-type: none"> - Financial report, compliance database, media - Compliance DD Interview - Evidence/Documentation of DD process 	<p>Compliance clause</p> <ul style="list-style-type: none"> - Integrity clause - Obligation to follow all applicable laws/regulation and CoC - Monitoring & Audit clause - Termination on compliance issue 	<p>Regular training</p> <ul style="list-style-type: none"> - Compliance value and principle - Key expectations - Help & Advice; complaints - Consequences of non-compliant behaviour - Take-away message 	<p>Regular Monitoring report</p> <p>Audit before renewal of agreement</p>
<p>Based on Mutual Respect</p>			

Doing now what patients need next