

Korea Compliance Update

*Asia Pacific Pharmaceutical Compliance Congress
Mini-Summit XIII*

KIM & CHANG | SEPTEMBER 17, 2014

Korea Update 2014

1. Legislation – new sanction for violations
2. Enforcement – still high priority area for government; more institutionalized
3. Industry Codes – trend toward greater coverage, more detailed guidelines
4. Internal Audits – greater need, greater reliance

Compliance: In a Nutshell

Korea has strict anti-corruption laws that are vigorously enforced in life sciences sector

- Dual Punishment System (Pharmaceutical Affairs Law/Medical Devices Law)
- Competition Law
- Anti-bribery provisions under Criminal Code

What is driving enforcement?

- Fighting corruption is on-going government priority generally
- Government believes corruption is keeping drug prices high
- Drug expenditures seen as primary target for containing healthcare spending

Strong reliance by industry on voluntary codes

Laws & Industry Codes

	Competition Law	Dual Punishment System (Pharma/Med Device Medical Services Laws)	Criminal Law
Who Enforces?	<ul style="list-style-type: none"> KFTC Prosecutors 	<ul style="list-style-type: none"> MOHW MFDS Prosecutors 	<ul style="list-style-type: none"> Prosecutors
What's Prohibited?	<ul style="list-style-type: none"> Unfair Solicitation of Customers 	<ul style="list-style-type: none"> Giving Economic Benefits to Promote Sales 	<ul style="list-style-type: none"> Official / Commercial Bribery
Safe Harbors?	<ul style="list-style-type: none"> Industry Codes 	<ul style="list-style-type: none"> Attendant Regulations 	<ul style="list-style-type: none"> None
Liability on company?	<ul style="list-style-type: none"> Admin yes Criminal yes 	<ul style="list-style-type: none"> Admin yes Criminal yes 	<ul style="list-style-type: none"> None

Sanctions

Companies

Competition Authority

- Corrective orders
- Administrative fines

Prosecutors Office

- Criminal fines, imprisonment

Health Authorities

- “Two-strikes out”: Suspension/exclusion from reimbursement (from July 2, 2014)
- Suspension of sales of product

Tax Authority

- Non-tax deductible treatment for promotional expenses

HCPs

Prosecutors Office

- Criminal fines, imprisonment

Health Authorities

- Suspension of medical license

Korea Update : *Legislation*

New “2 Strikes-Out” Rule

Improper benefits to HCPs can impact reimbursement status:

July 2, 2014

BEFORE

- Reduction of up to 20% of maximum reimbursement price of drug

AFTER

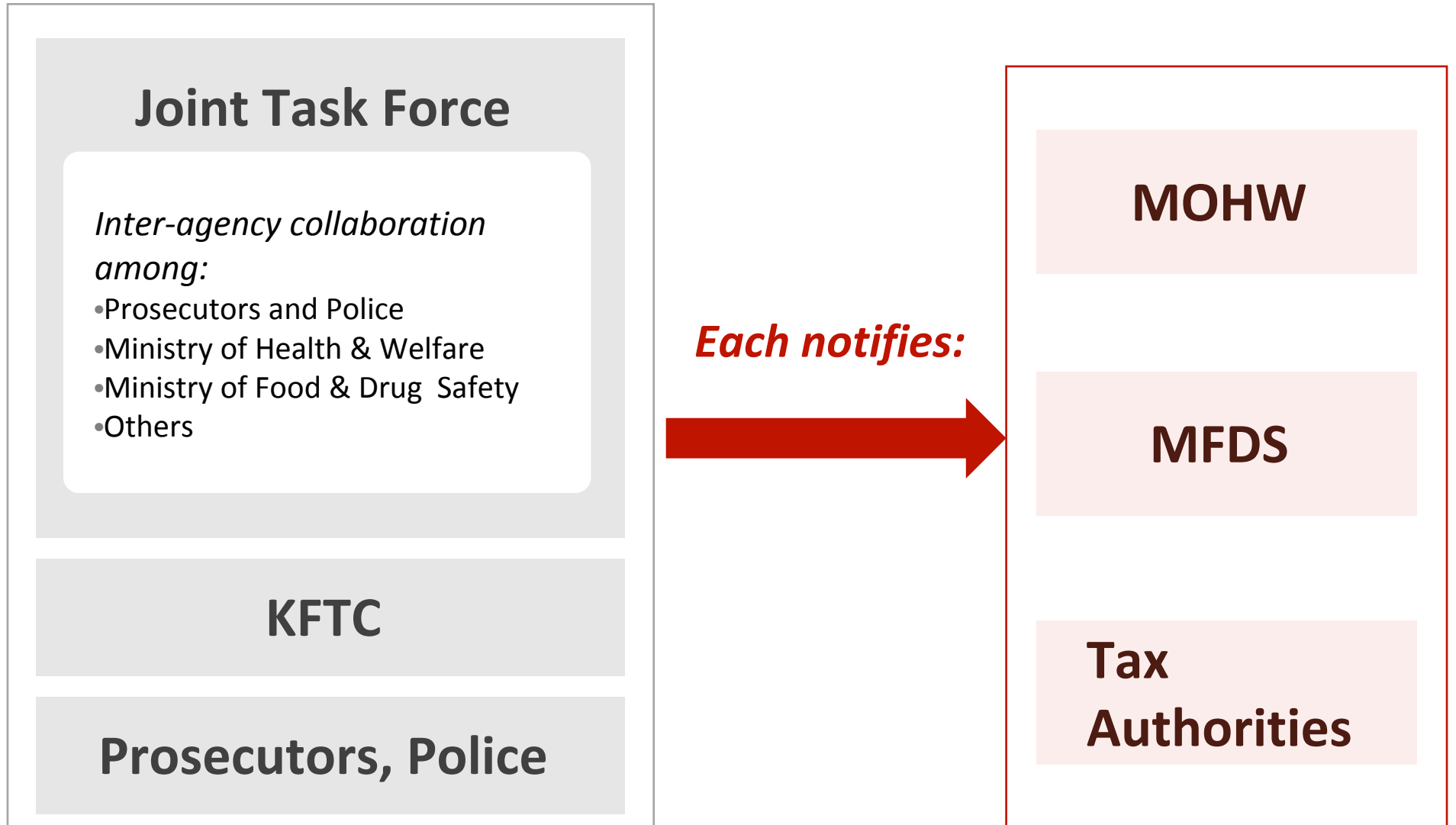
- Suspension of drug from reimbursement for up to 12 months (depending on amount of illegal benefits), or
- Exclusion of drug from reimbursement (if certain conditions are met)

New “2 Strikes-Out” Rule – Open Questions

- Whose actions trigger application of the rule?
- If your co-promoter is found in violation in connection with your drug, can your drug be suspended or excluded?
- What if drug(s) implicated in the violation cannot be identified?
- What happens if there two or more violations involving the same drug?
- Can exclusion be triggered even if there was no previous suspension of the drug?
- Can a company apply for re-listing after a drug is excluded?

Korea Update : ***Enforcement***

Enforcement: Inter-agency Collaboration



Recent Investigations

In 2013-2014, Joint Taskforce (JTF) and KFTC continued as most active enforcers

KFTC carried out investigation of medical device sector

- Found violation of rule that funding of HCPs to attend overseas conferences must be “double-blind”

Most large investigations were of domestic pharma companies (JTF), and found:

- Giving cash or cash equivalents
- Providing meals, entertainment to HCPs under guise of product presentations
- Making payments to HCPs under guise of service arrangements

Recent Investigations – Fees for Services

District Court decision (Sept 2013)

Court Decision

- Dong-A used agency as conduit to funnel benefits to doctors
 - Speaker/consulting fees and fees for taking part in market surveys
 - Sales reps selected doctors
 - Amount of fees based on prescription amounts
 - Fees paid out of sales promotional budget
 - Fees paid for overlapping content or content which was basically the same as materials provided by company/agency
 - No utilization of content by company
- Decision confirmed our standards for determining when payments for services are bona fide
 - Selection of HCPs as service providers should not be influenced by sales
 - Amount of fees should be reasonable and commensurate with actual services provided
 - Services thus obtained should be utilized

Recent Investigations - Trends

More investigations triggered by whistleblowers

- Disgruntled employees, vendors, bona fide
- Reflects more protection for whistleblowers, acceptance of whistle-blowing

Dawn raids continue to be main investigative tool

Tax authorities referred suspicions of giving illegal benefits to MOHW, MFDS for investigation – possible more such cases in future

KFTC 's criminal complaints (for fair trade law violations) now being assigned to Joint Taskforce – likely to widen scope of findings and implicate HCPs

Recent Investigations – Implications for Companies

Whistleblowing

- Requires robust internal compliance reporting systems (hotlines, etc.)

Dawn raids

- Highlights importance of dawn raid preparedness , including training

Potential liability for third party conduct

- In practice, companies are giving more consideration to contractual safeguards / training / due diligence (including audits) of third parties

Korea Update : *Industry Codes*

Industry Codes

Industry and increasingly, government, see industry codes as important benchmarks for compliance

- In practice, violation of code can be deemed violation of law BUT compliance with code does not guarantee protection against liability

Currently, codes provide for :

- Value and frequency caps on some benefits
- Procedural requirements : prior approvals, prior or post reporting, depending on the type of benefit

Trend toward more detailed guidelines

Partial Safe Harbor: Pharma & Device Codes

○ *Included in Codes* ○

- Samples
- Donations
- Support for 3rd party organizers of academic conferences
- Sponsorship for HCP participation in academic conferences
- Support for clinical trials
- Company-hosted product presentations
- Fees for post-marketing surveillance studies
- Fees for market research
- Advertisements and exhibitions (including booths)
- Lecture & consulting fees (only in device code)

○ *Not Included in Codes* ○

- Stand alone meals
- Holiday gifts
- Cultural courtesy gifts (weddings/funerals)
- Free use of equipment
- Support for investigator initiated studies
- Patient assistance programs

Industry Codes - KPMA

Korea Pharmaceutical Manufacturers Association (202 members)

- Adopted Ethics Charter and Code of Conduct (July 2014)
- Spurred by recent strengthened legislation (2 strikes-out rule)
- Contain broad-stroke rules to ensure ethical business practices
- Newly addressed areas in Code of Conduct include:
 - Appointment of compliance officer
 - Rules on promotion of products through print media and internet
 - Patient assistance programs

Industry Codes - KRPIA

Korea Research-based Pharmaceutical Association (36 members)

Drilling down on more detailed rules, recently adopted guidelines on:

- Exclusion of VAT in fees for post-marketing studies
- Venues for company-hosted meetings (Venue Guidelines)
 - Not extravagant (so-called 6 star hotels prohibited) or a similarly luxurious facility;
 - Located within area where most participants (75% or more) work or reside; and
 - Cannot be a resort or somewhere commonly recognized as a primarily tourism, amusement or entertainment venue
 - Venue with a hot spring/beach, or with golfing/skiing/ casino/water park facilities is prohibited
 - Exception recognized if no other appropriate venue available in the area where most participants work or reside



Korea Update : ***Trends in Compliance Audits***

Compliance Audits

- ***More companies conduct internal audits*** to check for compliance with anti-bribery/anti-corruption laws and policies
- ***Forensic reviews*** (employee laptops, emails) are now often an integral part of audits
- ***Whistleblowing*** is often the trigger
- ***Tracking usage patterns on corporate credit cards*** is a widely-used investigative tool
- But often difficult to determine whether employees gave benefits to HCPs (and thus created legal exposure for the company) or retained for own use
- ***Termination*** of employees for compliance violations may be difficult

Korea Update : *Key Takeaways*

Korea Update 2014 – Key Takeaways

- ***Rules are strict;*** enforcement remains high government priority
- ***Greater cooperation among gov't agencies*** means higher risk of multiple sanctions ***for same conduct***
- Violation can now lead to loss in drug reimbursement status
- Industry making efforts to provide greater coverage, more detailed guidelines ***in voluntary codes***
- More companies relying on ***internal compliance audits to assess and mitigate risk***

Thank you