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Recent Enforcement Trends and Risk Management Tips

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Recent State of Play

- Past 2 – 3 years, enforcement has slowed (with COVID-19, enforcement has gone quiet)
- Ministry of Health & Welfare (MOHW) and Ministry of Food & Drug Safety (MFDS) have no resources to devote to investigations / administrative actions
- Korea Fair Trade Commission (KFTC) has been “less aggressive”
- On the anti-corruption side, the Prosecutor’s Office has no organizational drive to investigate
- For the past few years, enforcement, especially anti-corruption and compliance investigations, has slowed down dramatically

No Follow Up on Expense Report Requirement

- The Korean government had been bolstering its efforts against corruption, implementing expansive anti-corruption laws and even enacting its own version of the Sunshine Act
- Under Korea's Sunshine Act, pharmaceutical and medical device companies are required to collect and keep records of economic benefits provided to HCPs, and prepare and keep aggregated expense reports for the fiscal year
- Reports need not be publicly disclosed, but must be provided to MOHW, if requested
- Failure to prepare or keep reports only carries a fixed fine, but regulators sought to use reports / supporting materials (or lack thereof) as pretext to investigate illegal kickbacks
- Reporting requirement took effect in January 2018, and MOHW and criminal authorities planned to follow up with an industry-wide inspection by 2020
- Regulators were not able to follow through with their plan, and may not be able to do so until the COVID situation stabilizes

MFDS Orders Suspension of Manufacturing and Sales for GMP Violations

- **MFDS orders manufacturing and sales suspension against two CMOs**
  - CMOs (i) used additives without obtaining approval for the change; (ii) falsified manufacturing records; (iii) failed to make the requisite changes to the manufacturing process; and (iv) arbitrarily adjusted the quantities of raw materials
  - In addition to the manufacturing and sales suspension, MFDS ordered a recall of the affected products
  - MFDS' criminal investigation unit initiated criminal investigations including a search and seizure of the manufacturing facilities
- **MFDS will make institutional changes to strengthen enforcement of GMP violations**
  - A GMP special inspection unit established to carry out random inspections without notice
  - Set up the "Clean Call Center" so that anyone can anonymously report manufacturing and quality related violations
  - Strengthen penalties: (i) cancel the GMP certificate for changing the manufacturing process/method without permission and falsifying records; and (ii) assess administrative fines based on revenue generated from violation

KFTC Sanctions Major Pharma Company for Abuse of IP Rights

- **KFTC fines KRW 2.3 billion (approx. US$2M) and criminally refers major pharmaceutical company for abuse of IP rights**
  - In 2017, KFTC conducted a market survey of 70 Korean and foreign pharmaceutical companies for practices relating to exercise of IP rights
  - KFTC found that one of the largest Korean pharmaceutical companies registered (i) a new patent after the original patent expired, and (ii) a new patent for a second product to defend against generic entry (obtained in part by submitting false data)
  - Company filed patent infringement suits against generic manufacturers aware that once a patent infringement suit is filed hospitals/wholesalers would not be able to switch to cheaper generics
  - Company also filed for preliminary injunctions to prevent generics from bidding in public tenders
  - Company was clearly aware that there was no patent infringement and that it had no chance of prevailing in the lawsuits

- **KFTC's first case of abuse of IP rights through sham patent litigation; KFTC to continue investigations of IP rights abuse (sham litigation, pay for delay, product switching)**

KFTC Investigates Medical Device Co for Business Interference

- **KFTC investigates company following complaint from terminated distributor**
  - Company found reason to audit a distributor based on an internal metric that measured compliance risks of its business partners
  - Company sought to audit the distributor, but the distributor refused. Company notified that this was grounds for termination. The parties tried to amicably end the relationship, but the distributor asked for a large amount of compensation. Company terminated the agreement
  - Investigation into the company's relationship with the distributor expanded to an investigation of the company's entire audit practices – including review of audit notices/processes; audit reports; types of information/document requested; and audit clauses in all agreements
- **Auditing distributors is a double-edged sword; manufacturers must strike the right balance**
  - Companies have a legitimate reason to audit distributors they perceive as a compliance risk, but cannot overstep bounds; audits must be carefully scoped to find targeted evidence to support justifiable termination
- **Even if no violation is found, company still had to endure more than 2 years of investigation (onsite investigations, numerous RFIs and employee interviews)**

Mediation Agency Utilized by SMEs to Induce Settlements

- **Instead of filing a complaint to KFTC, smaller distributors/agents/contractors are increasingly opting to file for mediation to the Korea Fair Trade Medication Agency (KOFAIR)**
  - Purpose of the KOFAIR process is not to assess violations, but encourage parties to settle
  - This means that the first-mover – the petitioner, which is usually the terminated counterparty, has a significant advantage
- **Mainly utilized by Korean SMEs against large Korean companies, but now distributors are petitioning KOFAIR to help them settle with multinational companies**
- **Many SMEs prefer KOFAIR because of significant chance that at the end of a process that is shorter than KFTC investigations, companies receive some compensation**
  - About 35 – 55% of the compensation amount initially sought
  - Process is less costly and time-consuming than filing a damage claim with the court

Takeaways

- COVID-19 has created a lull in enforcement
- In terms of anti-corruption and compliance enforcement, the Prosecutor's Office has been going through an internal and political strife that may fundamentally change PO's investigative authority
- During the lull, companies/individuals may have also become more lax in terms of compliance
- When the COVID situation is considered "under control", regulators may be compelled to aggressively investigate to return to pre-COVID status
- Regulators are trying to take a more intelligent and tailored approach to finding traditional violations within the specific context and realities of the relevant industries

What Should U.S. Companies Look Out For?

Considerations for U.S. Healthcare Companies

- Check the company's status of relationships with third party business partners (distributors, agents, vendors)
- Check the status of the business partner's relationships (e.g., distributor-customer interactions)
- Check the company's status of relationships with competitors
- Review existing SOPs, compliance codes, and other internal policies on interacting with customers, competitors and vendors
- Take inventory of and review key agreements with customers, distributors, etc.
- Check recent separation of director-level employees (sales, marketing)
- Check expense reports on economic benefits

Thank you.