SHIN & KIM

Healthcare & Life Sciences

In the pharmaceutical, medical, bio and healthcare industry, it is vital to respond quickly against the unfavorable government regulations and the ever-changing government policies. This industry is also fast changing along with paradigm shifts from innovative ventures companies with specialized technologies including IoT, big data and artificial intelligence.

The Healthcare & Life Sciences Team at Shin & Kim is a combination of experts in corporate and IP law, antitrust and regulatory matters and former government officials who have worked in regulatory agencies including the Ministry of Food and Drug Safety, Health Insurance Review & Assessment Service, and provides unique and unparalleled legal services.

Our team is known for its specialty in being a one-stop shop for comprehensive legal issues including regulatory matters in dealing with various agencies such as the IRB, Ministry of Food and Drug Safety, Ministry of Health and Welfare, Health Insurance Review & Assessment Service and the National Health Insurance Corporation during the whole life cycle of a medicine, from its development to clinical trial, item approval, insurance registration, pricing and adjustment, distribution and post management. We also provide total comprehensive service for other closely related areas such as medical devices, food, cosmetics, life-science related products and actual expense medical insurance.

Our team not only provides legal service on how to deal with various government investigations and regulations but also goes further as a business partner by providing to the client strategic solutions and guidance on how to actively use government policies at the client's advantage, how to preemptively minimize its risk and how to find solutions for complicated policy issues.

Key Services

Shin & Kim's Pharmaceutical, Medical, Bio and Healthcare Team provides the following services:

Development and marketing of pharmaceuticals

- Regulation of the Ministry of Food and Drug Safety during the development stage including clinical tests of drugs, medical devices and examination by the IRB and clinical trial agreement.
- Regulation of the Ministry of Food and Drug Safety in the course of the marketing process of drugs and medical

devices including item approval and report, import approval and report.

Intellectual property and new technology of pharmaceuticals

- Patent application, trademark, infringement prevention and patent prosecution of pharmaceuticals and medical devices.
- Drugs-approval-patent-registration connection system.
- Legal and business strategies to protect intellectual property on new health care products including medical devices using AI technology.

Pharmaceutical registration in connection with health insurance, drug pricing and health care benefit standards

- Determination of whether a drug or treatment material falls in the realm of medical care benefit, and if so, the maximum price determination and adjustment process.
- Medical care benefit standard of health insurance and establishment and amendment of medical charges.
- New medical technology assessment on new medical practices and determination of whether such medical practice may become the subject of medical care benefit.

Investigation and sanctions on medical institutions

- On-site investigation or business suspension by the Ministry of Health and Welfare against health and medical service providers such as medical institutions or pharmaceutical companies.
- Administrative sanctions on health and medical human resource licenses including suspension or cancellation of license of a health care provider or pharmacist.
- Response to the cutbacks after examination on medical care expenses or propriety assessment conducted by the Health Insurance Review & Assessment Service.
- Recovery actions against unjust enrichment and damage claims filed by the National Health Insurance Corporation.

Antitrust and rebate

- Response to investigations and sanctions by the Korean Fair Trade Commission or Ministry of Health and Welfare with respect to rebate on drugs and medical device.
- Reduction in drug price and suspension of health care benefit on drugs in connection with rebate.
- Compliance with fair trade regulations including prevention of rebate, labeling and advertising.

Establishment and operation of healthcare institutions and entrance into domestic and international market

- Establishment, assignment, M&A and investment of health care institutions, medical companies and pharmaceutical companies.
- Regulatory matters on advertisement of healthcare institution, drugs, medical device and cosmetics.

- Overseas expansion of domestic healthcare institutions and pharmaceutical companies.
- Domestic expansion of foreign healthcare institutions and pharmaceutical companies.
- Legal risks of a new business model.

Experience

Advisory

- Advice to a private equity fund specializing in bio industry on its investment to Sillajen, a bio company.
- Advice to a domestic invitro diagnosis company on its acquisition of a U.S. medical diagnosis company.
- Advice to a domestic pharmaceutical company on its acquisition of a Danish bio venture company.
- Advice to a U.S. antibody-medicine bio firm on its establishment of a joint venture for development of immune anticancer drugs with a domestic pharmaceutical company.
- Advice to a domestic pharmaceutical company on its establishment of a joint company with an Indonesian pharmaceutical company.
- Advice to a domestic investment company and a finance company on their investment in a bio subsidiary of a large domestic hospital.
- Advice to a company on its establishment of a joint company with a U.S. supplement food company.
- Advice to a domestic university hospital on its establishment and merger of a medical foundation with a focus on labor union issues and review of contract.
- Advice to a domestic pharmaceutical companies on its management right protection.
- Advice to the Korean Medical Association on comprehensive legal issues.
- Advice to a company on its establishment of a foreign general hospital at Songdo International Business District.
- Advice to Seoul National University and Johns Hopkins Hospital on their joint operation project to build an international hospital in Song-do.
- Advice to domestic pharmaceutical companies on their issuance and listing of shares.

Litigation

- Representation of a large domestic pharmaceutical company in its patent litigation with respect to the nullification of the registered patents and patent usage rights of pharmaceuticals including Sildenafil, Tadalafil, Rivaroxaban, Rosuvastatin, Candesartan Cilexetil, Docetaxel and Losatan.
- Representation of a company in pharmaceutical price reduction due to patent infringement.

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