B. Pharmaceutical Sciences in Society

GIO: To understand systems, economic issues, and legal norms governing healthcare and welfare, together with the roles of the community pharmacies and pharmacists and to act in full compliance with laws and guidelines in order to contribute to the public good as a pharmacist.

(1) Pharmacists Serving the Public

GIO: To understand human psychology and behavior, social structure, and how pharmacists interact with individuals and society.

1. To describe factors influencing human behavior.
2. To discuss various attitudes toward and beliefs about pharmaceuticals held by individual and society.
3. To discuss the purposes of the various systems and regulations and guiding pharmacists’ activities from the perspectives of individuals and society.
4. To discuss the importance of the pharmacist’s adhering to ethical and legal norms.
5. To comply with ethical and legal norms governing professional activity and behavior.

(2) Laws and Regulations Governing Pharmacists and Pharmaceuticals

GIO: To understand the laws and regulations and their significance for the work of pharmacists, pharmaceutical affairs, and public health, particularly those governing the preparation and dispensing of pharmaceuticals and related products (quasi-drugs, cosmetics, medical devices, and regenerative medicine products).

① Laws and Regulations Governing Pharmacists’ Social Position and Responsibility

1. To describe the regulations and their structure governing the work of pharmacists.
2. To describe the provisions of the Pharmacists’ Act with regard to the profession of pharmacists.
3. To describe the provisions of the Pharmacists’ Act with regard to the profession of pharmacists.
4. To summarize the provisions of the regulations governing other medical professions.
5. To describe the provisions and significance of the Medical Care Act with regard to medical ideals and the responsibilities of medical care professionals.
6. To describe the provisions and significance of the Medical Service Act with regard to the medical care delivery system.
7. To summarize the management of personal information.
8. To describe pharmacists’ responsibilities and potential legal liabilities under the Penal Code and/or Civil Code (including product liability).

② Laws and Regulations Ensuring the Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices.

1. To describe the purpose of Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices and the definition of related products (such as pharmaceuticals, quasi-drugs, cosmetics, medical devices, and biologics/tissue-engineered products).
2. To describe the processes from the development to approval of pharmaceuticals and regulations governing those processes.
3. To describe the purpose, systems for conducting, and significance of the results of clinical trials.
4. To describe the laws and regulations governing the marketing and the manufacturing of pharmaceuticals and related products.
5. To describe post-marketing surveillance and post-marketing safety measures.
6. To describe the laws and regulations governing pharmacies and the sale of drugs and medical devices.
7. To describe the provisions of the Law for Ensuring the Quality, Efficacy, and Safety of Drugs and Medical Devices governing the handling of pharmaceuticals.
8. To describe the significance and structure of the Japanese Pharmacopoeia.
9. To describe the laws and regulations governing the management of biological products and the supply of blood products.
10. To describe the relief system for adverse health effects.
11. To describe the need for and significance of the regulatory sciences.

(3) Laws and Regulations Governing Supervised Pharmaceuticals and Substances

1. To describe the regulations governing narcotics, psychotropics, and stimulants' raw materials.
2. To adhere to the preventive regulations governing stimulants, cannabis, opium, designated substances, etc.
3. To adhere to the regulations governing poisonous and harmful substances.

(3) Japanese Social Security System and Health Economics

GIO: To understand the current situation and issues related to the provision of medical care and welfare under the social security system and the roles of the pharmacists.

① Systems of Medical, Welfare, and Long-Term Care Services

1. To describe the mechanisms and features of the Social Security System of Japan.
2. To describe the Japanese health insurance system.
3. To describe the Rules for Health Insurance-Covered Medical Institution or Health Insurance-Covered Pharmacy and Health Insurance-Covered Physician or Health Insurance-Covered Pharmacist.
4. To describe the publicly funded medical care system.
5. To describe Long-Term Care Insurance System.
6. To stay abreast of changes in the drug pricing system.
7. To describe the mechanisms of dispensing, medical service, and long-term care fees.

② Pharmacoeconomics and Health Economics

1. To describe the features of the pharmaceutical market and mechanisms of the distribution system.
2. To stay abreast of trends in national medical care expenditure.
3. To describe generic drugs and their roles in medical care.
4. To describe methods for the economic evaluation of pharmacotherapy.
(4) Roles of Community Pharmacies and Pharmacists
GIO: To understand the current situation and issues concerning local health, medical care and welfare and how pharmacies and pharmacists can contribute to improving them.

① Roles of Pharmacies in the Community
1. To describe the functions and duties of pharmacies in the community.
2. To describe the significance of pharmaceutical management by pharmacies and pharmacists.
3. To describe the role of pharmacies in self-medication.
4. To describe the role of pharmacies in times of disaster.
5. To describe the role of the pharmacies in ensuring appropriate medical expenditure.

② Collaboration among Healthcare, Medical Care, and Welfare Providers at the Community Level and the Role of Pharmacists
1. To describe the concept of community-based integrated care.
2. To describe the roles of pharmacies and pharmacists in supporting home medical and in-home care services.
3. To describe the role of school pharmacists.
4. To describe the social resources available for community health, medical care, and welfare.
5. To discuss community expectations of collaboration among medical institutions, social welfare facilities, and regional administrative bodies.