## Slovenia

# Pharmaceutical Assistant's and Technician's **Work Placements**

Srednja šola za farmacijo, kozmetiko in zdravstvo

Education and Culture DG
Lifelong Learning Programme

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# Pharmaceutical Assistant's and Technician's Work Placements in Slovenia

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# 1. Introduction

## Dear Student

◆ *This information package is designed to give you an overall view of vocational education and work in the pharmaceutical sector in Slovenia, together with some useful background information related to legislation on and dispensing of pharmaceuticals. We hope that the package will help you in preparing for your period of practical training in our country. On reading this material package you may find both differences and similarities in pharmaceutical work in comparison to your country. However, due to your position as a foreign student at your placement address your duties may be limited to those you would be allowed to carry out in your own country.*

*From a learning viewpoint it might be beneficial for you to go through both your own country's material package and that of your destination country and to compare the two.*

*In Chapter 2 you will find a general description of our country's education system and more information on how pharmaceutical training is provided in our country.*

*Chapter 3 gives an overview of the structure of the pharmaceutical sector and how it is organised.*

*Chapter 4 defines how pharmaceutical professions are defined and their core expectations. This chapter focuses on the services that are available for foreign students as placement opportunities in our country. The sub-chapters also include descriptions of daily work which are intended to assist you in defining the work you will encounter during your practical training period. These "snap shot" descriptions have been written by students during their practical training periods.*

*Chapter 5 describes the most relevant legislation governing the pharmaceutical sector in Slovenia.*

*Chapter 6 has some links to help you with search for more detailed information.*

*Chapter 7 describes some specific terms and acronyms.*

*We hope you will find this information package useful and we wish you every success with your practical training period in our country!*

# Welcome to Slovenia!

Piran

Ljubljana

Lake Bled


◆ *We are pleased that you have chosen our small country as the site for practical training in the course of your studies. Slovenia (officially the Republic of Slovenia) is a Central European country. It covers a territory of 20,273 km2 with 2,051,000 inhabitants. The capital of Slovenia is Ljubljana. It is situated in the central part of Slovenia and has 265,000 inhabitants.*

*The official language is Slovene; Hungarian and Italian are also official languages in the respective ethnically mixed areas. With the majority of the population you can easily communicate in English. Many people also understand German and, in the areas bordering on Italy, mainly Italian.*

*The Republic of Slovenia is a young country. It declared its independence from the former Socialist Federal Republic of Yugoslavia by plebiscite on 25 June 1991. By 1 May 2004, the Republic of Slovenia became a full member of the European Union. The monetary unit Euro was introduced in Slovenia on 1 January 2007.*

*Although Slovenia is a small country, its landscape is outstandingly diverse and interesting. It is in this tiny piece of Europe that four geographical units, the Alps, the Panonian Plain, the Karst and the Mediterranean are joined. Therefore, Slovenia is the only European country where you can enjoy swimming in the Mediterranean Sea, climb 2000 m high peaks in the Alps, explore the rich underground world in some of its 9,000 caves, or take a leisure bicycle ride through the meadows and fields of the Panonian Plain.*

# 2. Educational System

## 2.1. Slovenian Educational System

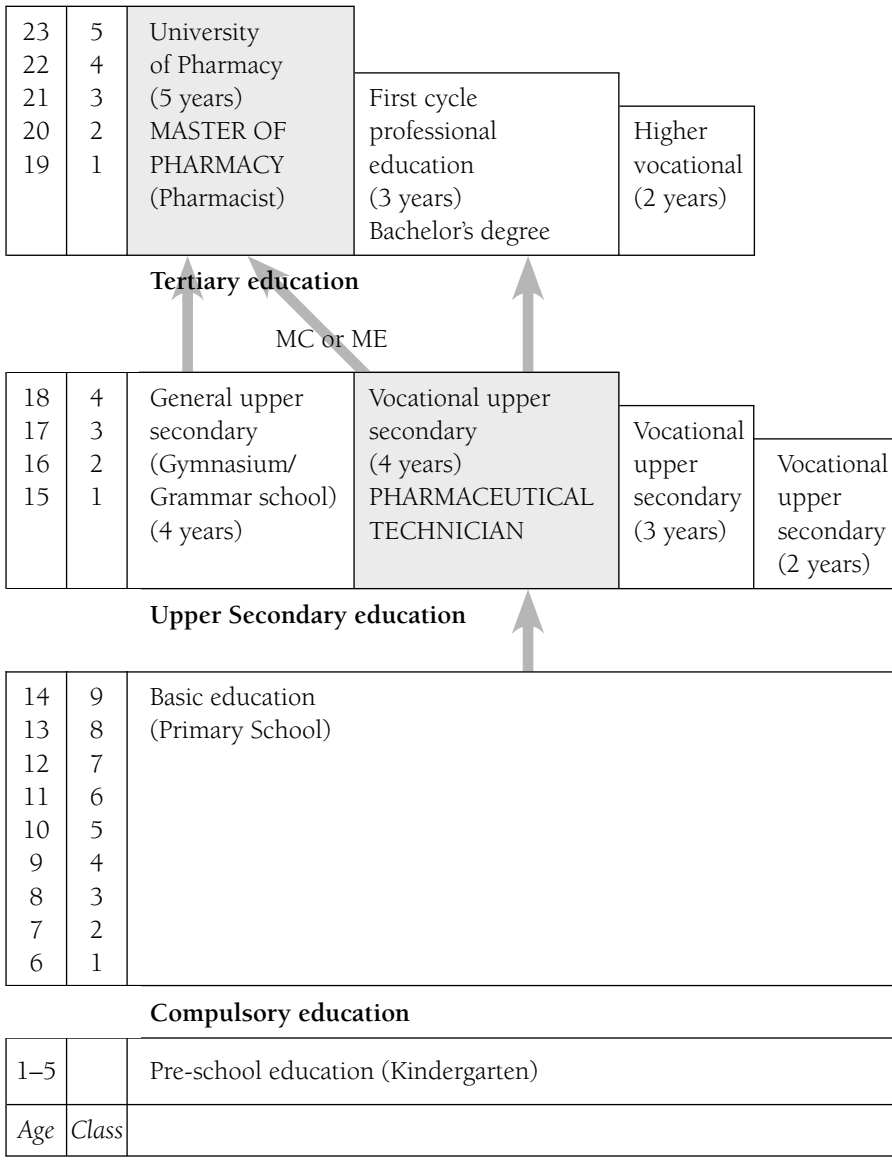
◆ In the Republic of Slovenia children start attending the primary school at 6 years of age. Primary school is compulsory and lasts 9 years. After completed primary school, youngsters may choose between several types of optional education in secondary schools. They have a choice of general education or different forms of vocational and secondary professional, vocational and technical education. General education is completed with the baccalaureate (maturity examination), which facilitates the candidate's transition to the tertiary level of education: study at universities, academies or at different professional colleges.

Young people wishing to obtain their profession faster, may join various forms of vocational, secondary technical or vocational-technical education. Schooling, with respect to the program chosen, takes 2 to 4 years. The school system in the Republic of Slovenia is shown in the diagram 1.

## 2.2. Pharmaceutical Education

◆ Young people pursuing their professional education in the area of pharmacy, may enrol in the programme of secondary vocational-technical education to qualify for the post of pharmacy technician. Schooling takes 4 years. It is completed with a vocational matura examination. Students that are successful enough and wish to continue their studies at the Faculty of Pharmacy must pass an additional general matura exam either in physics or chemistry. The study of pharmacy takes 5 years and enables the candidate to obtain the title of Master of Pharmacy.

In Slovenia, the secondary professional education programme for the post of pharmacy technician is provided by three secondary schools: by the Secondary School for Pharmacy, Cosmetics and Healthcare in Ljubljana (Srednja šola za farmacijo, kozmetiko in zdravstvo Ljubljana), by Gymnasium and Secondary Chemistry School Ruše (Gimnazija in srednja kemijska šola Ruše) and by School Center Novo mesto (Šolski center Novo mesto). The university study of pharmacy is provided by the Faculty of Pharmacy in Ljubljana.




MC Baccalaureate (matura course (1 year))
ME Additional exam in one matura course

**Diagram 1.**
**Educational system in Slovenia with placement of pharmaceutical education.**

## 2.3. Curriculum Content

◆ During the four years of study, students attend lessons in general subjects and vocational modules. General subjects are mainly mandatory. Most of them are covered in the first two years of the study. Vocational modules prevail in the last two years (Curriculum content, vocational modules and core competences are described in the Appendix).

During their studies each student performs 443 hours of practice at school and 190 hours of practical training at work.

A part of programme of secondary vocational-technical education is the open curriculum. This curriculum covers 562 hours, and the school forms it quite independently. The contents of the open curriculum are designed by the school in cooperation with the Social Partners and within the framework of their organisational capacities. Therefore, the contents may vary and may differ among various secondary schools offering education programmes for pharmacy technicians. Some optional modules within the open curriculum have catalogues of knowledge laid down at the national level. A few hours of the open curriculum are generally dedicated to the upgrading of basic skills, such as mathematics and chemistry. Most hours of the open curriculum are intended for deepening and upgrading expert knowledge. The school decides which contents of the open curriculum will be offered as optional, while others may be prescribed as compulsory for all students.

Medicines represent the main area of occupational activity of pharmacy technicians. In the course of their study, prospective pharmacy technicians obtain different expert knowledge and practical skills necessary for quality performance of work within the framework of their occupational competencies. They develop personality traits, such as diligence, perseverance, accuracy, independence, responsibility and communication skills. They become qualified for participation in smaller groups and teams. They learn to make use of up-to-date information technology and expert literature and how to use the obtained information correctly. They become capable of responsible and conscientious management of documentation. They develop a positive attitude to healthy lifestyle and health protection along with moral and ethical conscientiousness and empathy towards people. They learn how to behave rationally with respect to the use of energy, resources and time, and responsibly towards the environment. They develop the ability for precise observation and critical mind.

They learn to prepare different pharmaceutical forms, and conduct chemical, physical and microbiological analyses, which ensure the quality of medicines. They learn about the effects of active ingredients and herbal drugs and obtain skills for dispensing and providing instructions for the use of medicines, medical devices, food supplements and health care products, which are obtainable without medical prescription in pharmacies and specialised shops.

During studies, basic theoretical knowledge is complemented by practical training at school and practical training through work placement. The practical training at school is carried out within the framework of individual vocational modules in specialised laboratories and classes.

In the 3rd and 4th year, students upgrade their knowledge with practical training through work. Most of the students carry out their practical training by working in pharmacies, hospital pharmacies or specialised shops, and some also in the pharmaceutical industry. During their practical training through work, the students link general expert knowledge with practical skills to use it in new situations at solving actual problems encountered in the workplace. They attain skill in appropriate business communication in the workplace: with superiors, other employees and clients. They become aware of the importance of cooperation at work and teamwork. They upgrade their ability to plan, follow up and analyse one's own work and the work of the group. They get trained in business etiquette, attain the ability to quickly adapt to the workplace and greater labour mobility, and develop motivation for lifelong learning.

# 3. Structure of Pharmaceutical Sector in Slovenia

◆ The supply chain of medicines consists of several elements, which are interconnected and function in a legally regulated and controlled system. Medications are products of special importance and their market is subject to detailed legal regulation. The Public Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) is responsible for the implementation of regulatory, developmental and professional tasks in the area of medicines. Supervision of the work of the Public Agency is carried out by the ministry responsible for health. In accordance with the Medicinal Products Act and the Pharmacies Act, pharmacies, wholesalers and marketing authorisation holders or manufacturers of medicines are required to ensure regular and uninterrupted supply of medicines to the population and health institutions.

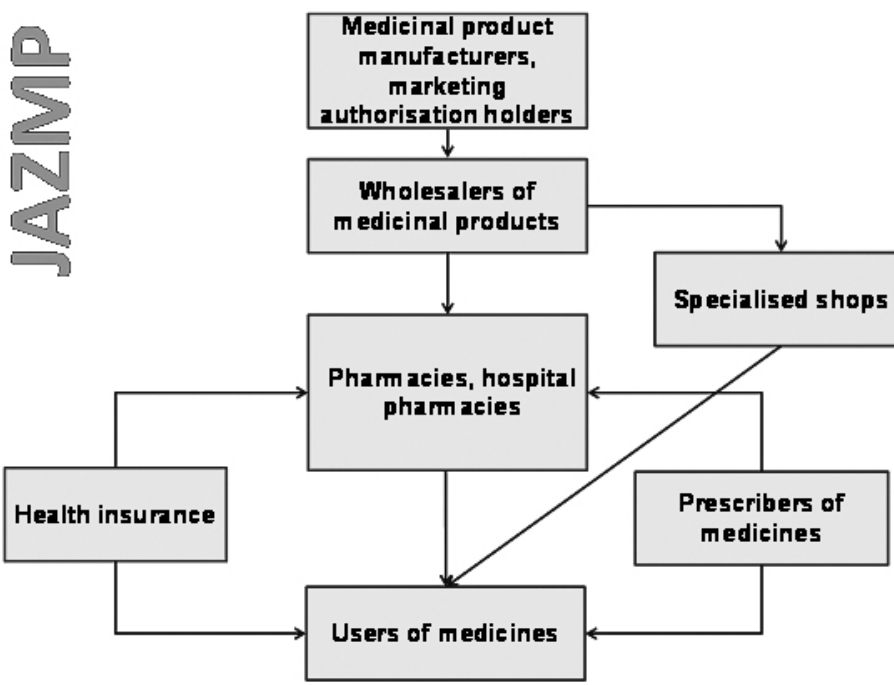



Diagram 2. Structure of pharmaceutical sector in Slovenia

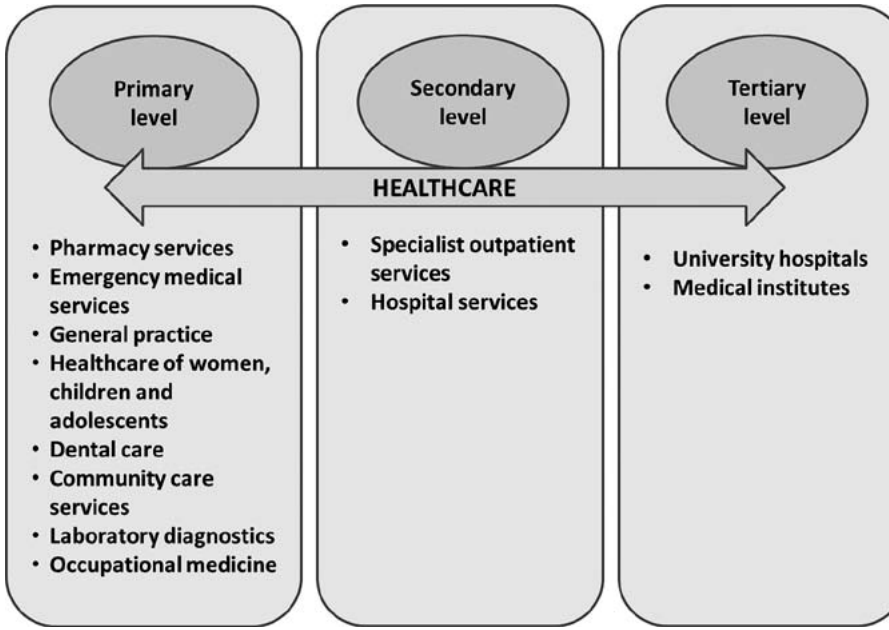



**Diagram 3. The healthcare system in Slovenia**

## 3.1. Medicinal Product Manufacturers and Marketing Authorisation Holders

◆ Medicinal product manufacturers or marketing authorisation holders represent the first link in the supply chain. Any manufacturer wishing to market medicines in the Republic of Slovenia must register or obtain marketing authorisation for each medicinal product. Marketing authorisation is a guarantee of the quality, safety and effectiveness of the medicinal product, as well as the confirmation of the relevant data verification.

Foreign medicinal product manufacturers have their representatives in Slovenia, which take care of marketing, promotion and informing the expert public on medicines. All relevant manufactures of generic and proprietary medicines have their representative offices in the Republic of Slovenia.

In Slovenia, the pharmaceutical industry has tradition and represents a significant share in the economic sector.

We have two large pharmaceutical factories, which produce generic medicines, i.e. Krka and Lek – a member of the Sandoz group.

Krka company was established in 1954. Today it is a public limited company and majority-owned by the Slovenian shareholders and ranks among the major manufacturers of generic pharmaceutical preparations. The manufacture of its products, which are sold in more than seventy countries, is organised in Slovenia, Poland, Russian Federation, Croatia and Germany.

Lek pharmaceutical company was established in 1946. Today it is a member of Sandoz group, the generic division of Novartis, the pioneer in the area of similar biological medicines and big manufacturer of generic medicines.

## 3.2. Wholesalers of Medicines

◆ Wholesalers of medicines are an important distribution bridge between the manufacturers and pharmacies, hospital pharmacies, healthcare institutes, veterinary clinics, and specialised shops selling medicines and medical devices. They conduct the business of wholesale distribution of drugs and medical devices exclusively to legal entities and persons authorized for wholesale or retail trade in medicines, and to pharmacies. In accordance with the legislation, medicinal products shall be delivered only to registered buyers. The basic task of the wholesalers in medicinal products is to provide regular and appropriate choice of medicines that satisfy the requirements of a certain geographical region, and in an appropriately short time, deliver the required supplies to the entire region in question. They must have a sufficient stock of medicines to be able to fulfil orders in due course. They must establish, implement and maintain an effective quality assurance system in all areas of their activity. They must have suitable premises and equipment in accordance with the principles of good distribution and good storage practices. They should appoint a person responsible for reception, storage, dispensing and transport of medicines and overview of documentation that enables traceability of medicines. The person responsible shall hold a university degree in pharmacy. In the Republic of Slovenia there are five bigger and a number of smaller wholesalers of medicines.

# 3.3. Pharmacies, Branch Pharmacies and Hospital Pharmacies

◆ General supply with medicines in the narrow sense covers the dispensing of prescription and non-prescription medicines as well as the preparation of extemporaneous medicinal products. Pharmacies and their branches, which may be publicly or privately owned, supply the population, health facilities and other organisations with medicines.

Pharmacies in the public sector are organised as public pharmacy institutions established by the local community (municipality or town). Generally, public pharmacy institutions consist of several organisational units, pharmacies and branch pharmacies, spread through a wider municipality or town area.

A municipality or town may grant to an individual – the pharmacist who meets the conditions, a concession for the performance of pharmacy service in a private pharmacy in the area.
A branch pharmacy may be opened only in a place where there is no pharmacy, despite the need for medicine dispensing. It may function only under the technical supervision of the pharmacy that established it, and it must ensure at least the provision of ready-made medicines.

An individual pharmacy may, in the place where the doctor works, organize a convenient supply of medicines for the doctor. This type of supply with medicines is practised particularly in remote, scarcely inhabited places, where there is no pharmacy or its branch. A pharmacy may keep a handy supply of medicines also in social care facilities or other institutions that offer healthcare services to their residents, irrespective of the distance to the nearest pharmacy.

In hospitals, the supply of medicines and medical devices used for the treatment and care of hospitalised persons is provided by hospital pharmacies. Hospital pharmacies too may have several organizational units. Thus, for the needs of a comprehensive supply of medicines, they can organize ward pharmacies, galenic laboratories, control-analytical laboratories, a laboratory for the manufacture of parenteral solutions, for the supply of radiopharmaceuticals as well as a radiopharmaceutical pharmacy.

## 3.4. Specialised Shops for Medicinal Products

◆ Certain non-prescription medicines, which have been authorised by the competent authority, may also be dispensed by specialised shops. A department of a shop may be considered a specialised shop, provided that it is structurally separated from other departments so that the sale of other products cannot affect the medicines. They must employ at least one qualified person with minimum secondary education in pharmacy and passed proficiency examination. This person is responsible for the purchasing, storing and sale of medicines as well as for keeping documentation, and should be present throughout the working hours of the shop. In addition to retail sale of medicines, among their commercial activities specialized shops may also sell medical devices, cosmetics, dietary supplements and foods for particular nutritional purposes.

## 3.5. Prescribing of Medicines

◆ Medicinal products for human use may be prescribed by physicians who have the right to independently pursue their professional activity; they may prescribe only those medicines that are marketed under the Medicinal Products Act. In exceptional cases, medicines for human use may be prescribed by doctors of veterinary medicine, however, only for animals and provided that such use was approved by the minister responsible for veterinary medicine.

For prescribing, the required green and white prescription forms and order forms for medicines are used. Medicines that are covered by the health insurance are prescribed on the green prescription form. The white prescription form is generally used for prescribing medicines in private dispensaries, which are not covered by compulsory and voluntary insurance. One prescription form may be used for prescribing one medicinal product in a quantity sufficient for up to three months of treatment. A renewable prescription allows a medicinal product to be supplied repeatedly within a year. Physicians choose to prescribe medicines on the renewable prescription form for patients with well-managed chronic therapy, who must take medicine regularly. The order for medicines is a type of medical prescription by which a public health institution or a legal entity or natural person providing health services prescribes medicines for the needs of their services.

# 3.6. Medicinal Product Prices and Reimbursement for Prescription Medicines

◆ Prices of medicines for human use, which are covered by public funds, are regulated in accordance with the Medicinal Products Act. Criteria, method and procedure for the formulation and determination of maximum prices are specified in the related rules.

The Health Care and Health Insurance Act lays down the compulsory and voluntary health insurance. This law also specifies the rights of insured persons to medicines. Only the listed medicines and foodstuffs for special medical purposes may be prescribed on the account of compulsory health insurance.

Medicines are classified into two positive and one intermediate list. Within the framework of the compulsory insurance, the health insurance company will cover the total costs of medications that are prescribed on a special form (the so-called green prescription) and provided that the prescribed medication is on the 100% positive list. If the prescribed medication is on the 75% positive or on the intermediate list, full cost coverage requires an additional voluntary health insurance. When the prescribed medications are not on either of the above positive lists, the costs are covered by the user or by a superior health insurance.

For certain groups of medications with the same active ingredient, strength and pharmaceutical form the highest approved price that is covered by health insurance (compulsory and voluntary) has been determined.

# 4. Definition of Profession

◆ Pharmacy technicians may be employed in pharmacies, hospital pharmacies, specialised shops for medicinal products, galenic laboratories, in the pharmaceutical industry, in control and analytical laboratories and as wholesalers. Certificate holder is qualified to:

- manufacture a pharmaceutical product in line with the regulation and in compliance with good manufacturing practice;
- dispense and provide instructions for use of non-prescription medicines in a pharmacy under the supervision of a pharmacist;
- dispense and provide instructions for use of non-prescription medicines in a specialised shop;
- dispense and provide instructions for use of herbal drugs and natural compounds;
- perform qualitative, semi-quantitative and quantitative analyses of medicines and stability tests for medicines;
- evaluate the activity, application and most frequent adverse effects of non-prescription medicines;
- communicate effectively with people.

A pharmacy technician who obtained additional knowledge and skills for working in a pharmacy or a specialised shop is further qualified for:

- selling and providing instructions for use of food supplements and other products for maintenance and protection of health;
- communication with clients in a pharmacy or a specialised shop.

A pharmacy technician who obtained additional knowledge and skills for working in the pharmaceutical industry is further qualified for:

- performing analyses and tests to assess the identity, purity and content of active ingredients, excipients, pharmaceutical forms, packaging and dressings by means of instrumental, biological and microbiological methods;
- manufacturing liquid, semi-solid, solid and sterile pharmaceutical forms on an industrial scale.

A key part of the supply of drugs takes place in pharmacies and hospital pharmacies.

# 4.1. Retail Pharmacy – Core Expectation, Health and Work Safety

◆ An important part of healthcare services takes place in pharmacies and their branches, namely the supply of population and healthcare institutions with prescription and non-prescription medications, and the preparation of extemporaneous medicinal products. This is a public service and an exclusive function that every verified pharmacy is bound to provide, irrespective of its size (a small affiliate branch or a big pharmacy) and ownership status (private or public).

Medications are products that prove effective only when used correctly, and therefore appropriate counselling as regards prescribing and use of medications is of key importance for quality supply.

Depending on the needs, besides medications for human use, most pharmacies also dispense prescription and non-prescription veterinary medicines. Some pharmacies also dispense homeopathic preparations.

In pharmacies, people are supplied not only with medicines but also with products for health protection, ancillary medicinal agents, various orthopaedic and medical-technical devices, cosmetics products, diet food, food supplements and many other items of general use.

Self-treatment with non-prescription medications has nowadays become a widespread form of alleviation of health problems without consulting a physician. In last decades it has been gaining in importance particularly because of the rising costs of treatment that health insurances find increasingly difficult to manage, as well as because of the raising awareness of people about the need to care for their own health. Pharmacies have an important role in self-medication, because people who opt for this type of treatment, most often turn for advice to the dispensing pharmacist or pharmaceutical technician.

Recently, pharmaceutical care has become an increasingly important activity by which pharmacists in the pharmacy through various measures try to prevent, detect and solve problems associated with medications that may adversely affect treatment outcome. The concept of pharmaceutical care is primarily intended for the groups of patients who are more prone to medications-related problems. These are chronic patients using several medications, as well as the elderly, adolescents and children.

Pharmacies also provide settings for mentoring activity, where secondary school students and college students

of pharmacy gain practical experience needed for competent and quality performance of their future profession. Tutors-pharmacists also look after the trainees who undergo compulsory practical training prior to taking the proficiency exam.

Major pharmacies, especially public institutions that combine many organizational units, have highly developed pharmacy-information activity which is intended to inform employees about new developments in legislation and regulations as well as in the profession, while it also performs an important function of public relations.

Pharmacies have an important role in public health care in the local community and carry out various activities to promote healthy lifestyles and prevention of modern diseases.

Public pharmacies may run their own manufacturing units, galenic and analytical control laboratories, where medications, ancillary medicinal agents and galenic products are manufactured and tested. Galenic product is a medicine that is prepared in a galenic laboratory of the pharmacy in accordance with the valid pharmacopoeia and is intended for retail sale in the pharmacy concerned. In some galenic laboratories, besides small-scale production of galenic products, they also manufacture food supplements, cosmetics and medicines that are authorized and marketed in the entire territory of Slovenia as well abroad. Galenic laboratories must have adequate facilities and equipment, well-defined production processes in terms of GMP and the staff of adequately trained professionals. Analytical control laboratory performs supervision over the quality of products manufactured by the galenic laboratory, and takes part in the quality assurance as regards products and services within the domain of public pharmacies. Analytical control laboratory must have a pharmacist on staff who has appropriate knowledge of drug testing and who is responsible for the release of products.

## Opening Hours and Designation Signs

Pharmacy must be designated with the inscription “LEKARNA”, with illuminated pharmacy symbol in green colour and the shape of a cross with the snake and the chalice, and the information on ownership, business hours and the nearest pharmacy on duty. Opening hours of pharmacies shall be based on the local needs for medicines supply, and should not be less than 40 hours a week.

**Illuminated pharmacy symbol**

## On-duty service

During the time when pharmacies are closed, they must ensure that a 24-hour emergency service is available in a larger area through which people can be supplied with medicines at any time. In an area where there are several pharmacies, these should agree on the schedule of on-duty service and determine the sequence order of the night, Sunday and holiday availability. If the pharmacies cannot reach an agreement, the sequence order shall be determined by the Chamber of Pharmacy with respect to the number of pharmacists employed in individual pharmacies.

## Professional staff

Pharmaceutical professional work in a pharmacy is performed by pharmacist and pharmacy technicians. Head of the pharmacy is a pharmacist, who is responsible for the organisation of work and pharmacy management.

Pharmaceutical professional staff may perform their work independently after they have completed their trainee period and proficiency exam. They must take care of their health and hygiene, consider health protection measures and use protective equipment during work. They must undergo continuous professional training and respect the code of ethics for pharmacists.

In pharmacies, pharmacists who passed the proficiency exam may dispense medications independently. Non-prescription medicines that may be issued only in pharmacies may be dispensed by pharmacists as well as by pharmacy technician, however, only under the supervision of a pharmacists. The rest of the pharmaceutical professional staff perform other professional tasks, for which they are personally responsible within the limits of their competences.

## Organisation and equipment

The premises must be arranged and equipped so as to provide quality work in accordance with good pharmacy practice. They must be functional, well maintained and reasonably equipped to allow the implementation of administrative tasks, manufacturing extemporaneous medicinal products, storage and transfer of materials, segregation of clean and less clean professional activities and in particular the dispensing of medications and other goods. Personnel must be allowed unhindered movement and have the possibility of adequate contact with the users.

Each pharmacy must have the following facilities:

- place for the acquisition of goods delivered;
- place for dispensing medicines;
- place for storage of medicines and other goods;
- place for the manufacturing of extemporaneous medicinal products;
- place for cleaning tools and packaging;

- place for counselling;
- place for performing professional-administrative tasks;
- toilets and cloakroom;
- place for on-duty services if these are performed by the pharmacy.

Pharmacy must have the equipment, which enables the manufacturing of solid, semi-solid, liquid and sterile pharmaceutical preparations.

## Professional literature and regulations

Professional staff must always have access to contemporary professional literature for information and advice on medicinal products, manufacturing and quality assurance of medicines and all the health regulations governing pharmacy, medicines, medical devices and illicit drugs (either in paper or electronic form).

## Quality and documentation

Pharmacies must have a quality system established and, with respect to the scope of work, maintain the following documentation:

- record of the traceability of pharmaceutical substances;
- record of the acquisition and dispensing of illicit drugs;
- record of complaints and recalls of medicines, medical devices and other products;
- record of storage conditions of medicines;
- record of medicines dispensed on renewable medical prescriptions;
- record of cleaning and maintaining premises;
- records of equipment maintenance;
- documentation of calibration and validation of equipment and work processes;
- instructions or procedures for performing professional tasks.

## Work activities

All activities in the pharmacy must be carried out in accordance with the principles of good pharmacy practice determining the correct workflow in the pharmacy. A pharmacy must have standard operating procedures prepared for all the activities that were subject to its verification.

Professional staff must ensure that the pharmacy has adequate stock of medicines, the ingredients for the preparation of extemporaneous medicinal products, medical devices and other goods. They are bound to this by law and economic interests. If the product is not in stock, they must ensure that the patient receives it in due time.

The staff carefully reviews each consignment of goods, checks their quantity and quality, arranges them on the shelves and stores them in accordance with the principles of good storage practice. Good storage practice is a quality system relating to the organization, implementation and monitoring of the storage of products in a specified order

before further use. Medicines and other goods should be stored in a pharmacy under conditions that meet the manufacturer's instructions, and in accordance with the regulations of the applicable pharmacopoeia and the law. The packaging must ensure maintenance of cold chain and proper and safe storage of flammable and corrosive pharmaceutical substances. Medicines containing illicit narcotics must be kept in a metal cabinet with lock. Useless and recalled medicines, or those rejected due to complaints, must be kept separate from other goods and locked.

Staff should regularly test the storage conditions (temperature and humidity), calibrate the equipment, check expiry dates and keep corresponding records of these data.

Manufacturing of extemporaneous medicinal products is still part of the daily routine. Extemporaneous medicinal products are medicines that are created in the pharmacy for a particular patient based on the recipe chosen and prescribed by his/her doctor. In manufacturing extemporaneous medicinal product, they must follow the principles of good manufacturing practices and label them correctly. For the majority of extemporaneous medicinal product, the pharmacies have standard operating procedures (SOP) and instructions prepared, which regulate the manufacturing process in detail. The majority of formulae for extemporaneous medicinal products are published in the Code of Extemporaneous medicinal products, verified by the expert committee at the Slovenian Chamber of Pharmacy. This ensures their quality and consistent composition irrespective of the place of manufacture. The most common extemporaneous medicinal products are divided powders, eye drops and a variety of dermal formulations. In some pharmacies, where they have suitable conditions, they also manufacture extemporaneous medicinal products that contain cytotoxic agents.

The main activity in the pharmacy is the dispensing of prescription and non-prescription (OTC) medications, medical devices, dietary supplements and cosmetic products, and counselling on their proper use. In addition to expertise, good communication between pharmacists or pharmaceutical technicians and users is crucial for successful work. The aim of communication is to help, to obtain the right information for counselling, to understand correctly, to suggest correct medications and to improve quality of life. At the same time, the aim of communication is to gain the users' confidence, so that they will keep coming back to the pharmacy because of the quality of service and excellent advice.

## Pharmacy technician student's working day in the retail pharmacy

A pharmacy with a status of a teaching institution can accept students on work placements. They work in the pharmacy under the supervision of a tutor. In the performance of work placements of students from abroad the work has to be customized to certain extent because of language barriers. Students perform the same tasks as described. They help in preparing prescription medicines for dispensing and for residents of the Residential Home for the Elderly as well as extemporaneous medicinal products, and participate in the receipt of medicines and other goods and store them on the shelves. The pharmacy is also visited by English-speaking tourists. In such cases, students from abroad are included in the process of self-medication counselling.

The pharmacist-tutor talks with students from abroad a lot and they both learn about the differences between the two countries. They compare the course of education and training for particular professions, differences in the operation of pharmacies, differences in healthcare legislation, and people's attitude to medicines and health. A few minutes are devoted to other issues – mutual acquaintance and comparison of our traditions. Each day in pharmacy is different. The pharmacy staff likes to work with young colleagues and they are pleased when they learn together and enrich each other.

Pharmacists-tutors take care that students learn and acquire the following skills:

- the processes of dispensing medicines and medical devices on prescription;
- the processes of dispensing non-prescription medicines and counselling on self-treatment;
- safe, correct and effective use of medicines, medical devices and health protection products;
- preparation of extemporanoues medical products for patients;
- supply with medicines and medical devices (stock management);
- keeping records and documentation;
- knowledge and implementation of the law in practice;
- health and safety requirements,
- pharmacy information system (computer skills), and
- an appropriate attitude towards colleagues and visitors to the pharmacy.

**Working time of the student is from 7:30 to 14:00** (possibly twice a week from 13:00 to 19:30).

Upon their arrival to work, the students make note of the temperature and humidity in the dispensing unit and the laboratory. They check the temperature in the refrigerators and operation of the scales with control weights and fill in the relevant records.

They check the supply of medicines on the shelves and in drawers and fill them. They help to maintain the stock


of medicines, medical devices and other products.

They prepare prescription medicines prescribed for the Home for the elderly, and (together with mentor) review the administrative and technical part of the prescription.

Under the supervision of a mentor, they dispense prescription medicines and medicines that may be issued without a prescription, medical devices, and participate in self-medication and counselling. In their work, they use professional literature from the pharmacy's "library", databases, pharmacy information systems, and protocols for self-medication. With their mentor they talk a lot about counselling, attitude to clients, appropriate communication and professional ethics. The mentor encourages them to be professional and at the same time relaxed at work, and together they resolve all queries. In preparing extemporaneous medicinal products under the supervision of a mentor they read administrative and technical part of the prescription. They check the dosage and incompatibilities and select appropriate accessories for the manufacture and packaging. They elaborate preparation and sign it; on the prescription they indicate which components have been used to ensure traceability. At the end they put in order and clean the working areas and equipment.

At around noon, the wholesaler delivers medicines and other goods. Students help in controlling the quantity of goods according to the delivery form, and packaging appearance. They store away medicines that require "cold chain" and check shelf life. Afterwards they put the remaining medicines and goods on the shelves and enter the incoming substances and chemicals in the records of traceability of the starting materials. Mentor alerts students to following the principles of good practices and standard operating procedures.

In the afternoon, students again check the temperature and humidity in the dispensing unit and in the laboratory. They fill in records and check the temperature in the refrigerators.

Once the planned work is done, students, together with their mentor, make a plan for the next day and go home.

**A working day from the diary of a student on work placement in the pharmacy**

My name is Maja and I am a fourth-year student of the pharmaceutical program at the Secondary School of Pharmacy, Cosmetics and Healthcare. At the beginning of this school year, I performed a work placement in a public pharmacy.

My working day in the pharmacy started at 7:00 a.m., as always. In the cloakroom I had my locker where I could store clothing and personal belongings after I changed my clothes and shoes. My work uniform consisted of a white overall coat and slippers. I am already used to this outfit since it is also compulsory at school.

After we had our usual quick cup of tea with the staff, we briefly discussed with the mentor my schedule for the day.

My first task in the morning was always the same. I read the temperature and humidity in the dispensary, storage, laboratory and the refrigerator and entered the obtained data into the daily control table. I also checked the accuracy of scales in the laboratory. I placed a calibrated weight on the scales and entered the reading in the diary. I performed this task independently.

Then, together with a pharmaceutical technician, I helped in taking over the goods delivered from the wholesaler. We checked the compliance of the consignment with the delivery note, reviewed shelf life and placed medicines and medical devices on the corresponding shelves in the storage closet. Medicines that must be kept in a cool place, I carefully placed in the refrigerator.

Then, together with a pharmaceutical technician, I wiped the dust off the shelves. Then we reviewed the shelves and drawers in the dispensary and wrote down medications that needed to be brought from the storage. In the storage closet, I placed the recorded medicines on the cart and, assisted by a pharmaceutical technician, I put them away in appropriate places. I also checked the shelf life on each stacked carton. By 8:00 a.m., when the pharmacy opened for customers, all the shelves and drawers had been filled.

My mentor gave me a new task. Following the recipe, under the tutor's supervision, I prepared 2000 g of cooling ointment for stock.

Manufacturing formula:

| | |
|---|---|
| • Cera lanae | 600,0 |
| • Vaselinum album | 600,0 |
| • Aqua purificata | 600,0 |
| • Olivae oleum | 200,0 |

First I washed my hands and disinfected the work surface. I prepared the accessories and components.

During the procedure, I carefully weighed out ingredients and confirmed each recorded mass with my signature.

I weighed white soft paraffin and lanolin into a mixing bowl and heated it in a water bath until the ingredients melted and reached the temperature of 70 °C. I added olive oil into the melted lipophilic phase. Then, while stirring continuously, I added to the molten lipophilic phase boiled purified water heated to the same temperature and mixed until cool. I filled the mixture into 100 g containers and labelled them as appropriate. Cooling ointment protects the skin against irritants that cause inflammation. Water evaporation slightly cools the skin.

When the ointment was ready, I filled ten bottles with paraffin oil and labelled them as appropriate. Paraffin oil is used for softening earwax and is always prepared in the pharmacy in advance.

At 10:00 a.m., I had lunch.

My mentor brought a prescription for powders:
Rp./
Tocopherol plv. a 0,005
Lactosum q.s.
M. f. plv.
D. t. dos. No. XXX (triginta)
D.S. : Two powders 3-times daily

Together with my mentor, we checked correctness of the dosage. I calculated the necessary quantities of active ingredient and filled them. Lactose is most frequently used as a filler in the manufacture of divided powders. My mentor checked the correctness of calculation and weighed the ingredients on the chart. I mixed the ingredients in a mortar following the principle of increasing weights and kept mixing for 10 minutes. While stirring the powders, I repeatedly scraped them off the mortar wall. I weighed thirthy powders and filled them into paper capsules. Under the mentor's supervision, I closed the capsules and labelled them as appropriate.

My mentor showed me how to enter the extemporaneous medicinal products into the computer and print an invoice.

My next task was to weigh teas. Although shops offer a large variety of teas, people still like to buy teas in a pharmacy because they have more confidence in pharmacists. In addition to tea, they always get a kind word and good advice. I weighed a 50 mg of yarrow herb (Millefolii herba) per paper bag. I labelled the bags as appropriate and added instructions for use.

Instructions for use:
Pour 1–2 tea spoons with 2 dl of hot (not boiling) water. Cover and let stand for 10–15 minutes. Strain and drink 2–3 times a day.

Then, under the supervision of my mentor, I prepared a prescription ointment according to the already known procedure. Together with my mentor, we first checked correctness of the dosage and prepared everything necessary for work.

Rp./
Diprosone cr. 15,0
Belobazae 30,0
Olivae oleum 0,5
M. f. ung.
D.S. : Apply to the affected area once daily.

My working day practice ended at 2:00 p.m.

## 4.2. Hospital Pharmacy

◆ Hospital pharmacies are organised by hospitals. They purchuase, and dispense ready-made prescription and non-prescription medicines, manufacture and dispense extemporaneous medicinal products and galenic preparations. They also dispense sanitary supplies and medical devices used for the treatment and care of hospitalised persons. In the Republic of Slovenia, there are 26 hospital pharmacies.

The main task of the hospital pharmacy is to supply patients who are treated on wards and in outpatient departments of the hospital with medicines and other medical supplies. Besides the attention of physicians and medical staff on the ward, a lot of carefully planned professional activities carried out by the pharmacists and pharmacy technicians in the hospital pharmacy are needed to ensure that hospitalised patients will receive appropriate medications. These professional works include:

- purchasing and dispensing of medicines and other materials;
- manufacturing extemporaneous medicinal products (including cytotoxic drugs and radio-pharmaceuticals and those for complete parenteral nutrition – CPN);
- manufacturing of parenteral preparations, sterile products, galenic products, manufacturing and preparation of cosmetic and health protection products;
- manufacturing of purified water;
- quality control of galenic products and pharmaceutical substances;
- verifying analysis reports;
- management of the required documentation;
- carrying out consulting and professional information activities regarding the use of medicines, medical devices and health-protection products;
- carrying out scientific research and participation in clinical studies;
- control of medicines on hospital wards;
- monitoring of adverse reactions to drugs and medical devices.

Nevertheless, professional tasks performed by each hospital pharmacy depend on the type and size of the hospital and personnel in the hospital pharmacy.

### Professional staff

Professional work in a hospital pharmacy may be performed independently by pharmacy professionals who have

adequate degree in pharmacy and have passed proficiency exam. Professional staff in a hospital pharmacy includes pharmacists, pharmacy engineers and pharmacy technicians. Hospital pharmacy can be headed by a pharmacist who has passed the proficiency exam. He/she is responsible for the organisation of work and professional performance of pharmacy services.

## Organisation

In order to supply patients with medicines and medical devices, the hospital pharmacy can organize ward pharmacies on individual wards. A ward pharmacy must have at least two rooms: a place for the receipt of medicines and medical devices and a room for dispensing medicines. When a ward pharmacy organizes the manufacture of extemporaneous medicinal products, it must have a suitable room available for that and a room for cleaning utensils and packaging.

In some, mainly larger hospital pharmacies, they manufacture a variety of parenteral solutions, antitumour medicines and radio-pharmaceutical products. A hospital pharmacy where extemporaneous medicinal products comprising cytotoxic agents and radio-pharmaceuticals, extemporaneous medicinal products for complementary parenteral nutrition, parenteral preparations, homeopathic and galenic products are manufactured and the quality control of galenic products and pharmaceutical substances is performed, must have suitable premises and equipment available to perform these activities.

## Professional literature and regulations

A hospital pharmacy must always have access to contemporary professional literature for information and advice on medicines, manufacturing and quality assurance of medicines and all the health regulations governing pharmacy, medicines, medical devices and illicit drugs (either in paper or electronic form. The list of professional literature and regulations shall be specified by the Slovenian Chamber of Pharmacy.

## Documentation management

A hospital pharmacy must maintain documentation, which comprises:

- record of the traceability of pharmaceutical substances;
- record of the acquisition and dispensing of illicit drugs;
- record of complaints and recalls of medicines, medical devices and other products;
- record of storage conditions of medicines;
- record of medicines dispensed on renewable medical prescriptions;
- record of cleaning and maintaining premises;
- records of equipment maintenance;
- documentation of calibration and validation of equipment and work processes;
- instructions or procedures for performing professional tasks.

If the hospital pharmacy has galenic laboratory and laboratory for the manufacture of parenteral solutions organized, it must keep records of its activity in accordance with good manufacturing practice for pharmacies and good storage practice. The documentation must ensure traceability of staff, materials, processes, products, manufacturing conditions and all quality assurance procedures. Analytical control laboratory must keep the documentation provided for by the good laboratory practice of quality control, which is part of good manufacturing practice.

## Work activities

In order to facilitate the performance of professional tasks, a hospital pharmacy may organise individual organisational units or wards to carry out specific work activities. Each such department shall be headed by a pharmacist, who plans and organizes work and cooperates with their colleagues both within the department as well as in other departments.

Dispensary is the department ordering, receiving and dispensing medicines and providing information about medicines. Pharmacists daily procure the necessary medicines, medical devices, disinfectants and dressings material. Upon the arrival of goods in the dispensary, pharmacy technicians under the supervision of a pharmacist are involved in the receipt of goods. Upon the receipt, goods shall be inspected, recorded and stored as appropriate. The medicines shall be all the time handled so as to ensure their safety and effectiveness. Medicines shall be kept in storage, taking into account shelf life, controlled temperature and humidity in the room and, where necessary, providing cold chain. Toxicomanogenic substances shall be kept separately in safes. Pharmaceutical technicians, under the supervision of a pharmacist are also involved in dispensing medicines, medical devices and other material to hospital wards. Medicines prescribed by a physician in the hospital's outpatient department and intended for the treatment of patients after their discharge from hospital may only be dispensed by pharmacist.

In dispensing medicines to hospital wards, pharmacists cooperate with physicians and other medical staff, thus contributing to a quality, safe and rational use of medicines. Every day, they carefully prepare instructions and warnings for proper and safe use of medicines, keep records of the dispensed medications and monitor medicinal products in stock.

An important professional task of the dispensary, which also requires participation of pharmacy technicians, is the collecting of medicines with expired shelf life. Such medicines in intact immediate packaging are collected in special containers,

intended for this purpose. The containers are then forwarded to the suppliers, who make sure that they are destroyed as appropriate.

Current records are kept of all the activities performed.

Major hospital pharmacies manufacture several medicines themselves. The manufacturing of medicines takes place in the galenic laboratory. There they produce pharmaceutical preparations for the needs of hospitalised patients as well as for patients discharged from hospital. The products include a variety of creams, ointments and ointment bases, suppositoria, powders, ethanol solutions, solutions of reagents and disinfectants, aseptically prepared different eye products and solutions for inhalation.

Mass production facilitates manufacturing of larger quantities of products. All the recipes/formulae are managed by computer, the manufacturing process is accompanied by a manufacturing sheet and each product receives a serial number. The whole galenic preparation manufacturing process is supervised by a pharmacist, while pharmacy technicians implement and monitor individual technological operations, such as weighing, mixing, dissolving, measuring temperature, filling in the appropriate packaging and labelling of the product. They keep current records of all the activities performed.

Hospital pharmacies also manufacture extemporaneous medicinal products. These are intended specifically for a particular patient. Extemporaneous medicinal products are produced mainly when certain medicines are not available on the market or the dose and/or pharmaceutical form need to be adapted to the patient. This is particularly common in paediatrics, when e.g. tablets are used for preparing an oral suspension for easier intake. Extemporaneous medicinal products, similarly as galenic preparations, are manufactured by pharmacy technicians under the supervision of pharmacists.

The quality and safety of preparations are ensured by the analytical control laboratory. In the analytical control laboratory, they check the quality of all starting materials for the manufacturing of preparations, packaging and pharmacy-produced batches of medicines before they are released for use. Analytical procedures are performed in accordance with applicable regulations and taking into account the current pharmacopoeia, such as Ph. Eur., BP, USP, best practices, e.g., good manufacturing practice and good laboratory practice and the legislation in force. Only after analytical methods in the analytical control laboratory demonstrate that the products are of appropriate quality, they are equipped with an analytical code and released for use. Precision and conscientiousness in the performance of work in the analytical laboratory

is particularly important. Therefore, accurate and precise records that facilitate traceability should be kept of all the activities performed.

In the analytical control laboratory, a pharmacy technician, supervised by a pharmacist, may perform the following tasks: taking and preparing samples for analysis, measuring pH, performing titrimetric, polarimetric and spectrometric analyses and high-performance liquid chromatography (HPLC), preparing and labelling reagents and other chemicals, cleaning and calibrating the apparatuses used for analytical procedures, and keeping records of the procedures performed.

In large hospitals with many patients, the work of pharmacy is much more extensive and therefore a hospital pharmacy may have other departments, in which the manufacture of various parenteral solutions (infusion and injection solutions) takes place. They can manufacture preparations intended for individual and parenteral therapy (parenteral preparations for the treatment with cytotoxic agents and preparations for full parenteral nutrition). Work in all specialized departments is carried out under controlled conditions to prevent contamination of products with microorganisms, pyrogenic substances and various particles. In the preparation of cytotoxic therapy, an additional attention should be paid to protect the staff and environment. Pharmaceutical technicians who are specially trained for the purpose, participate in the process of manufacturing products for parenteral use under the supervision of a pharmacist.

Hospitals performing treatment with radio-pharmaceuticals must have their own radio-pharmacy. Pharmaceutical professionals working in the radio-pharmacy, must have the necessary additional knowledge and authorisation to work with unsealed radioactive sources. Radio-pharmacy must be protected. Equipment and materials in the radio-pharmacy must comply with the regulations on protection against ionising radiation. Work in these pharmacies must be carried out in accordance with the requirements of good manufacturing practice, good pharmacy practice and recommendations of the European Association of Nuclear Medicine, which ensure consistent manufacture and control of radio-pharmaceuticals under the criteria of quality and fitness for purpose of use as required by the specification of the product or the marketing authorization of radio-pharmaceuticals.

**Student's working day in the hospital pharmacy (Univerzitetni klinični center – UKC Ljubljana)**

My name is Maja Osmanagić. I am a pharmacy technician by profession, and have been working in the pharmacy of the UKC Ljubljana for a couple of years now.

The pharmacy of the UKC Ljubljana provides ongoing supply of medicines to patients treated on the UKC wards as well as the supply of unregistered medications to patients treated on outpatient basis. Apart from its role as hospital pharmacy, the pharmacy in Dr. Peter Držaj Hospital also runs a public pharmacy service. The prevailing volume of work takes place in the Central Pharmacy located in the main building of the UKC.

For this purpose, the pharmacy has several departments:

- dispensary;
- galenic laboratory;
- quality control department;
- department for parenteral solutions;
- department for preparing cytotoxic therapy;
- department for preparing full parenteral nutrition.

Pharmacy technicians participate in all processes of supply and manufacturing of medicines that take place in various pharmacy departments. All the work processes are carried out under the pharmacist's supervision. Because of the diversity of work in individual departments, I have chosen to describe the work of pharmacy technician in the dispensary of a hospital pharmacy.

Dispensary is that part of the pharmacy where the preparation and dispensing of medicines for clinical wards takes place. The pharmacy of the UKC Ljubljana provides medicines to 80 clinical departments of the hospital. The major university hospitals, such as University Departments of Paediatrics, Gynaecology, Surgery – Clinical Department of Traumatology, Dermatology and Venerology, Otorhinolaryngology and Cervicofacial Surgery, Ophthalmology, and the Department of Infectious Diseases and Febrile Conditions are also parts of the UKC Ljubljana, but are – because of their size – situated outside the Centre's main premises. Owing to the distance from the UKC's main premises, they maintain their own pharmacy departments where pharmacy technicians under the supervision of a pharmacist are in charge of ordering and dispensing medicines, parenteral solutions and medical consumables. In this way, they provide a fast, secure and efficient supply of medicines and other materials needed to ensure proper treatment and care of patients on wards, which would otherwise not be feasible.

Dispensing of medicines to the wards starts at 8:00 a.m. and closes down at 7:00 p.m. Early shift is from 7:30 a.m. to 3:00 p.m., and afternoon shift from 11:15 a.m. to 19:00 p.m.

Pharmacy technicians start their work in the dispensary at 7:30 a.m. A team of six pharmacy technicians is responsible for the preparation of medicines and computer registration of the receipt of delivered medicines.

In the morning, pharmacy technicians first fill up the shelves with missing medicines, which were dispensed to the wards on the previous day. After eight o'clock in the morning, orders for the wards are sent to the pharmacy through the computer. Pharmacy technicians print the order forms, prepare the medicines ordered and write out a dispensing form.

Pharmacy technicians prepare the medicines for dispensing in accordance with the order form and place them on special trolleys. Each medicine is entered into the computer programme with its ID code under which the medicine's name, pharmaceutical form and strength are specified. Besides the ID code with the name, form and strength of the medicine, the order form also comprises the data on the stock of medicine in the pharmacy and the quantity required by ward. After preparing medicines, the pharmacy technician enters the orders into the information system to be exempted from the pharmacy stock. After being checked by a pharmacist, the medicines are dispensed as specified. Ward nurses responsible for the task take over the medicines prepared in the pharmacy and transport them to the wards.

When preparing medicines by orders, if in doubt as regards their strength, quantity or pharmaceutical form, the pharmacy technician shall consult a pharmacist, who may also call the ward nurse responsible for the order, when necessary. In the event that the required medicine is not in the market, they also notify the wards of the possibilities for its replacement, a shorter period of use, etc. If a pharmacy technician, when preparing medicines by orders, finds out that the stocks of certain medicines have been reduced, he/she informs about that the pharmacist, who provides the necessary order. It may happen that the wards will order medicines which are not on stock in the pharmacy. In this case, the medicine, if available on the market, is ordered and the order for the ward left open until the product is delivered to the pharmacy. Upon the receipt of the medicine, the order form is processed and the ward is notified that they can come to collect the medicine. In preparing orders, the technicians often have to handle medicines that require storage in the refrigerator. In this case, the pharmacy technician shall mark the medicine with a label: "CAUTION, STORE IN A REFRIGERATOR!" and take all the necessary steps to ensure the cold chain.

Weekly supplies for ward pharmacies are prepared in the afternoon. An exact day in the week is specified for the preparation of medicines for each individual hospital.

In carrying out their work, pharmacy technicians have certain duties and responsibilities. In order to perform their work, they need knowledge of computer programs for computer-

assisted operations and are responsible for the professional and timely preparation of medicines ordered as well as for precise performance of the tasks that affect the quality of medicines, i.e., the acquisition, keeping and storage of medicines.

Secondary-school students are welcome to assist us in the preparation of medicines in the UKC Pharmacy as well as in the preparation of medicines, parenteral solutions and consumables in all ward pharmacies, thus being offered the opportunity of getting acquainted with hospital material.

Pharmacy technicians at the departments involved in the preparation of parenteral solutions, full parenteral nutrition and cytotoxic therapy, work under special conditions in the aseptic chambers. Due to the high complexity and risks posed by these medicines, students who are with us on work placement, are only enabled to have a look at the premises and learn about the work process through the outer window.

Students are also welcome to work in the galenic laboratory, where they can help in closing and labelling powders, creams, ointments, solutions, disinfectants and ethanol preparations. Under the supervision of a pharmacy technician, they can themselves weigh the necessary ingredients and prepare certain solutions, thus acquiring the appropriate knowledge, which is actually the main objective of their work placement.

The content and adequacy of preparations are established at the quality control department, where students get an insight and explanation of analytical control procedures.

Students on work placement in a hospital pharmacy are expected to have the following skills:

- awareness of health and safety requirements;
- knowledge of the code of ethics for pharmacists;
- know how to work with a computer and use modern software;
- know how to prepare an extemporaneous medicinal product;
- know how to store medicinal products, taking account of theirshelf life, and know how to provide cold chain (storage in a refrigerator) when necessary;
- participate in the procurement of medicinal products;
- know how to correctly handle medicinal products with expired shelf life;
- communicate correctly with other employees in the pharmacy;
- know how to use time rationally and organise their work;
- are accurate and responsible in their work.

**A working day from the diary of a student on work placement in the hospital pharmacy**

I am Veronika, a 3rd-year student of the education programme for pharmacy technicians. I spent my mandatory work placement in the galenic laboratory of a hospital pharmacy.

My working day started at 7:30 a.m. Upon arrival, I registered my presence in a notebook for evidencing the presence of staff in the workplace, then I changed in a cloakroom where I put on a clean overall coat and comfortable working shoes.

In the morning, I helped in the manufacturing of two galenic products. First, we prepared divided powders, which are used for bowel cleansing prior to colonoscopy (colon cleansing powder). Before making the product, a printout of computer-processed manufacturing sheet was made, which comprised the complete recipe for product manufacture, the number of manufacturing process, product serial number, its expiry date, and mass of the preparation after filling, with the permitted limits of tolerance. Assisted and supervised by a pharmaceutical technician, I helped weigh ingredients. Before weighing each individual ingredient in the recipe, I checked the control number of the ingredient and duly entered the individual weighed quantities in the accompanying sheet. I mixed all the weighed ingredients into a homogenous powder. Then I divided the powder by weighing it into a prescribed number of units and filled it in paper bags. I closed the bags and labelled them as appropriate.

Then I helped prepare a gel for the treatment of oral mucosa. We prepared a gel, which contained 1% lidocaine as a local anaesthetic (1% lidocaine hydrochloride in Orabase oral gel). I participated in the filling and labelling of the product. We filled the gel into 10 g tubes, so that we filled each tube with 7,00 g of gel. I labelled the tubes as appropriate.

Later on I participated in the preparation of different disinfectant solutions. We had to prepare 12 l of 0,1% solution of chlorhexidine digluconate. For the preparation we needed (20%) of chlorhexidine digluconate and purified water. The required quantity of disinfectant was prepared in a special container with a built-in stirrer. I measured the required quantity (60 ml) of chlorhexidine digluconate concentrate (20% solution) and put it into the container with built-in stirrer. I added purified water to the level of 12,000 ml. After mixing, I helped to fill the obtained solution into 200 ml bottles. I labelled the bottles as appropriate. I kept current records of all the tasks performed.

In a similar way I helped in the preparation of other disinfectant solutions. Thus, we prepared a working

disinfectant solution, which is used for cleaning and disinfection of surgical instruments and endoscopes.

After a lunch-break I worked in the room where the manufacturing of extemporaneous medicinal products takes place. We had to prepare 60 ml of oral suspension containing 2,5 mg/ml of theophylline for a child. There is no ready-made medication with the prescribed content of theophylline in the form of oral suspension available in the Slovenian market. The extemporaneous medicinal product was manufactured from the active substance in powder form (theophylline plv. Ph. Eur.) and ready-made vehicles for oral suspensions (Ora-Sweet® and Ora-Plus®).

For the manufacturing of oral suspension we needed the following ingredients:

Rp./

| | |
|---|---|
| Theophylline plv. (Ph. Eur.) | 125 mg |
| Ora-Plus® | 25 ml |
| Ora-Sweet® | ad 50 ml |

Under the supervision of a pharmacy technician, I weighed theophylline powder and put it in a mixing bowl. I added part of Ora-Plus® vehicle and mixed until a smooth paste was formed. While stirring, I added the rest of Ora-Plus® vehicle. I added Ora-Sweet® to obtain 50 ml of suspension and mixed it. I transferred the obtained suspension into a beaker. I placed the beaker on a magnetic stirrer and left to mix for 15 minutes. After 15 minutes of mixing, I transferred the homogenous suspension into a 50 ml dark bottle. I closed the bottle, added a dosing spoon and labelled it as appropriate.

In manufacturing this extemporaneous medicinal product, I learned how the pharmaceutical form and dosage are tailored to the needs of a particular patient.

In all the tasks I was assisted by a pharmaceutical technician. My working day ended at 2:00 p.m.

# 5. National Legislation

◆ The manufacturing, marketing and use of medicinal products in the territory of the Republic of Slovenia is regulated by the national legislation and the EU regulations.

The Public Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) is a body competent for medicinal products and medical devices for human and veterinary use, and for blood and blood products, tissues and cells; it also performs the tasks of an official control laboratory. Its mission is to implement the national policy and legislation in the area of medicinal products and medical devices, blood, tissues and cells with the aim of public health protection. It takes part in the delegation of the Republic of Slovenia in professional bodies and working groups of the Council of the European Union and the European Commission in the field of medicines and medical devices, and participates in the European network of official control laboratories as well as in the network of the bodies competent for medicines and medical devices in the European Union.

JAZMP performs supervisory activities and functions as misdemeanors body in the area of medicinal products. Supervision is performed by pharmaceutical supervisors, who monitor compliance with good manufacturing practice (GMP) in the area of medicinal products.

An important part of the JAZMP's activities is the establishment of a pharmacovigilance system. Pharmacovigilance is the system of assessment, collection and evaluation of adverse reactions to medicines and other information about the safety of medicines and actions taken to manage and reduce risks associated with medicines. In the entire territory of the European Union pharmacovigilance is coordinated by the European Medicines Agency (EMA), which manages a database of adverse reactions to medicines observed throughout the EU.

The European Medicines Agency is a decentralised agency of the European Union (EU), responsible for scientific evaluation of medicines developed by pharmaceutical companies and intended for use in the territory of the EU. The role of the Agency is to co-operate with the European Commission, EU Member States, European Economic Area (EEA) Member States and several other groups in the public and private sectors.

### The Medicinal Products Act

The Medicinal Products Act regulates the area of medicines for human and veterinary use and lays down the conditions and measures to ensure their adequate quality, safety and efficacy, requirements and procedures for their testing, manufacturing, prices of medicines, marketing, official

control and supervision in order to protect public health. This Act shall transpose the contents of the EU directives regulating certain issues of the implementation of regulations in the area of medicinal products into the legislation of the Republic of Slovenia.

### Decree on the management of waste medicines

This decree regulates the area of drug residues and useless drugs, which of course do not fall within the normal municipal waste. Pharmaceutical health professionals must raise awareness of people how to deal with waste medicines, and inform them of the possibility of disposal of waste medicines in pharmacies.

### The Pharmacies Act

The Pharmacies Act regulates the area of pharmacy services as part of healthcare supplying the population, health facilities and other organisations with medicines. Together with the Rules on the requirements to be met by the persons engaged in pharmacy activities, the Act stipulates who may have the right to establish a pharmacy or get the concession, and what are the tasks of pharmacies. It lays down the requirements for personnel, facilities and equipment as well as the pharmacy verification procedure.

### Health Services Act

Pharmacy services are part of healthcare. Their activities are regulated in accordance with the Health Services Act. Health activity includes measures and activities performed by healthcare professionals, following the medical doctrine and using medical technology, in health protection, prevention, detection and treatment of patients and injured persons.

### Health Care and Health Insurance Act

The Health Care and Health Insurance Act is a legal basis for the implementation of compulsory and voluntary health insurance. Compulsory health insurance is guided by the principles of social justice and solidarity between the healthy and the sick, the old and the young, the rich and the poor, and is implemented by the Health Insurance Institute of Slovenia (HIIS). Voluntary health insurance is implemented by other health insurance companies.

Compulsory health insurance enables the insured persons to exercise the right to health services, medicines, medical devices and to cash compensation such as salary compensation during sick leave and other costs related to the exercise of rights to health services. Ensured persons claim healthcare services on the basis of the verified and valid Slovenian Health Insurance Card. Some services are fully covered by HIIS, while for others the insured persons must pay the difference to the full value of services from their own funds, unless they have a voluntary (supplementary) health insurance.

Foreigners, who are not covered by health insurance in the Republic of Slovenia, have the right to emergency or necessary healthcare services for which the payment shall be made in accordance with the EU legislation, international agreements or from the state budget.

## Patients Rights Act

The Patients Rights Act regulates the area of safeguarding and exercising the fundamental rights of patients. The rights which are governed by the Patients Rights Act are not the rights arising from the compulsory or voluntary health insurance, but the rights connected with these, the so-called universal rights that every user of health services is entitled to; they refer in particular to the respect for patients' autonomy in making decisions about their own healthcare, privacy, personal data protection, equality and safety, the protection of patients' best interests, and access to information. Patients may contact the Representative of Patients' Rights for free advice, help or even a mandate to represent them in exercising their rights under this Act.

## Slovenian Chamber of Pharmacy

The task of the Chamber of Pharmacy is to ensure efficient and professional pharmacy services. This is an independent professional organization, established to represent the pharmacy services and pharmacy profession. It takes care of the professional development of the activity, protects the honour of the profession, takes care of the fulfilment of professional obligations, and protects the professional and economic interests of its members. The Chamber membership is mandatory for public–retail-pharmacies, pharmacists-concessionaires and hospitals that have hospital pharmacies organised on their premises. Membership in the Chamber is also open to legal entities and private entrepreneurs involved in the manufacturing and marketing of medicines and medical supplies. An important task of the Chamber is to provide expert supervision of the pharmacy services, draft rules of good pharmacy practices and take measures in the case of their violation. The arbitral tribunal functioning within the Chamber deals with complaints that the users of pharmacy services may have with regard to professional conduct in individual pharmacies.

## Code of Ethics for Pharmacists

The Chamber of Pharmacy is responsible for the adoption and respect of the Code of Ethics for pharmacists. Pharmacists adopt the Code by signing a personal declaration whereby they undertake to perform their work diligently, professionally and with dignity, and that in exercising their profession they will not allow differentiation on the basis of gender, religion, race nationality, political affiliation or social status, that they will protect the classified information and will show due respect towards their teachers and colleagues.

### Slovenian Pharmaceutical Society

Slovenian Pharmaceutical Society has been active since 1950, bringing together on a voluntary basis professionals working in different branches of the pharmaceutical industry, in pharmacies, educational and research institutions, industry and state administration. Membership in the Slovenian Pharmaceutical Society is open to all pharmaceutical professionals and other associate professionals operating in pharmacy or allied fields, students of the Faculty of Pharmacy or to 4th year students of the secondary school of pharmacy. Membership is organised into affiliates by regional principle and into sections by professional interest. The activities are carried out in 9 affiliates and 11 sections. The Society organizes a number of professional and social gatherings of its affiliates, and the most deserving members are awarded the Minařik's recognition. It publishes professional books, publications, and Farmacevtski vestnik and Farmakon periodicals. Slovenian Pharmaceutical Society is a member of many international organizations (FIP – International Federation of Pharmacists, EUFEPS – European Federation of Pharmaceutical Sciences, ESCP – European Society of Clinical Pharmacists, EAHP – European Association of Hospital Pharmacies, and EFMC – European Federation for Medicinal Chemistry), and organizes scientific symposia under their auspices

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# 7. Glossary

**Galenski izdelek** – Galenic product – a medicine that is prepared in small series in a galenic laboratory of the pharmacy in accordance with the valid pharmacopoeia and intended for retail sale in the pharmacy concerned

**Galenski laboratorij** – Galenic laboratory – a part of a pharmacy where galenic products are produced

**Lekarna** – Pharmacy

**Bolnišnična lekarna** – Hospital pharmacy

**Bolnišnica** – Hospital

**Medicinski pripomoček** – Medical-technical device

**Zdravilo** – Medicine

**Recept** – Prescription

**Magistralno zdravilo** – Extemporaneous medicinal products are medicines that are created in the pharmacy for a particular patient based on the recipe chosen and prescribed by his/her doctor

# Appendix

## Curriculum content, vocational modules and core competences

| *Mandatory vocational modules* | *Total number of hours* | *Module Aim* |
|---|---|---|
| Health Education | 68 | The aim of the module is to ensure that the student will have the necessary knowledge and understanding to be able to undertake helath promoting activities in all stages of life. |
| Anatomy and Physiology | 102 | The aim of the module is to provide the student with knowledge of the structure and functioning of human body. |
| Microbiology and Epidemiology | 102 | The aim of the module is to ensure that the student will have the necessary knowledge and understanding to be able to work safely in a microbiology laboratory. |
| Laboratory Work in Pharmacy | 102 | The aim of the module is to ensure that the student will have the necessary knowledge and understanding to be able to perform various technological operations (weighing, sifting, mixing …) and to use the equipment in a pharmaceutical laboratory correctly. |
| Medicinal Products | 255 | The aim of the module is to get the student acquainted with the activity, use and adverse side effects of active substances, and in detail with medicines that can be obtained in pharmacies without prescription. The student will also get acquainted with main categories of medicinal products that are subject to medical prescription. |
| Production of Medicines | 221 | The aim of the module is to ensure that the student will obtain the necessary knowledge and understanding to be able to produce different extemporaneous medicinal products for patients that are effective and safe for use. |

| | | |
|---|---|---|
| Medicinal Product Analysis | 170 | The aim of the module is to ensure that the student will obtain the necessary knowledge and understanding to be able to carry out analyses (e.g. volumetric and gravimetric) and tests in accordance with good practices (GP). |
| Herbal Medicines and Natural Compounds | 272 | The aim of the module is to get the student acquainted with the structure of herbs as well as the functioning and use of relevant herbal drugs in pharmacy. The student will also get a broad information of the activity and use of natural compounds in pharmacy. |

**An example of optional vocational modules (implemented at Srednja šola za farmacijo, kozmetiko in zdravstvo, Ljubljana)**

| *Optional vocational modules* | *Total number of hours* | *Module Aim* |
|---|---|---|
| Genetics | 34 | The aim of the module is to provide the student with the basic information about genetics in general, genetic disorders, heredity and gene technology. |
| Information and communication technology | 70 | The aim of the module is to provide the student with knowledge and skills needed to use ICT equipment and software. |
| Business Skills and Communication | 102 | The aim of the module is to get the student acquainted with the role and importance of business skills. The student will get acquainted with the principles of good interpersonal communication, develop social skills, teamwork and the principles of effective conversation. |
| Dispensing of Medicinal Products in Pharmacies and Specialised Shops | 102 | The aim of the module is to get the student acquainted with the laws and regulations in the area of healthcare. The student will be trained in the communication with clients of pharmacies and specialised shops. The student will get the necessary knowledge to be able to give advice on self-healing and recognize risk groups of users and alarming symptoms that require consultation with a pharmacist or a physician. |

| | | |
|---|---|---|
| Preparing for vocational matura in expert knowledge | 16 | The aim of the module is to help students to prepare themselves for the final exam in expert knowledge. |
| Cosmetic Products | 102 | The aim of the module is to provide the student with the knowledge of the structure of the skin, hair and nails, and the major diseases of the skin. The student will be able to understand the importance of ingredients in cosmetic products, advanced technological forms of cosmetic products and the activity and use of cosmetic products. |
| Hospital Pharmacy | 34 | The aim of the module is to get the student acquainted with the specificity of hospital pharmacy work and technological processes as well as with working conditions for the preparation of specific therapies (work in an aseptic unit, full parenteral nutrition, therapy with cytotoxic drugs). |
| Production of Medicines – Selected chapters | 68 | The aim of the module is to upgrade the students' knowledge of manufacturing of medicinal products. They will get acquainted with the specific features of various pharmaceutical forms that are not manufactured in pharmacies, such as different types of tablets, and they, as pharmacy technicians, have to know. |
| Medicinal Products – Selected Chapters | 34 | The aim of the module is to upgrade the student's knowledge of the activity, use and adverse side effects of medicines. |

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