

---

**Quality Standard for the Oncology Pharmacy Service**  
**(QuapoS 4)**

---

## 1. Personnel

### 1.1. Persons dealing with cytostatics

Persons dealing with cytostatics under the direct influence of the pharmacy include:

*Pharmaceutical personnel:*

- Pharmacists and persons being trained as pharmacists
- Pharmacy technicians and persons being trained as pharmacy technicians
- Pharmacy assistants
- Pharmacy engineers

*Non-pharmaceutical personnel:*

- Pharmacy auxiliary staff
- Professionals employed by the pharmacy
- Pharmacy sales staff
- Employees in the store
- Cleaning staff
- Transport staff

### 1.2. Persons in production

Categories of persons working in the cytostatics department include:

*Pharmaceutical personnel:*

- Pharmacists and persons being trained as pharmacists
- Pharmacy technicians and persons being trained as pharmacy technicians
- Pharmacy assistants
- Pharmacy engineers

*Non-pharmaceutical personnel:*

- Pharmacy auxiliary staff
- Professionals employed by the pharmacy
- Pharmacy sales staff
- Cleaning staff
- Maintenance personnel

Only pharmaceutical personnel may be employed in the production of ready-to-administer cytostatic solutions. Before these employees begin their work, they must be adequately educated and trained in aseptic working procedures and in the handling of hazardous substances. Quality standards must be discussed with all employees in order to arouse and promote understanding for and awareness of the diverse problems associated with an oncology pharmacy service.

### 1.3. Hazard evaluation, working rules and instruction

Before starting work in cytostatics production the hazard risks of cytostatics handling need to be evaluated and documented (industrial safety act, hazardous substances regulations). Based on these findings the employees must be instructed. In addition to the persons carrying out the production, all employees dealing with and using cytostatics must be instructed in the sense of s. 3 *GefStoffV* (hazardous substances regulations). This also includes, for example, the cleaning staff and persons employed in the transport service.

The instructions given must be appropriate to the different job categories. Depending on the respective requirements, it includes the following items:

- Effects of drugs
- Proper procedures for dealing with hazardous substances (cytostatics, latex, etc.)
- Hazards and protective measures
- Aseptic technique
- Disposal of contaminated materials and devices and of residues of cytostatics
- Occupational preventive medicine
- Action in the case of accidents

This instruction must be repeated annually (s. 20 (2) *GefStoffV*). In addition, written working instructions must be prepared specific to the particular workplace (s. 20 (1) *GefStoffV*). Cytostatics are classified according to their properties and are included in the pharmacy list of hazardous substances (s. 16 (3a) *GefStoffV*).

This list must be amended to accord with major changes and must be inspected at least once every year. If any changes have been made a new documented risk evaluation has to be performed. Accidents must be documented in an accident protocol. In the case of personal injury, s. 1552 ff. *RVO* (statutory instrument) requires in addition that the accident be either recorded in the first aid logbook (minor injuries, incapacity to work for a period of less than three days) or notified to the responsible statutory insurance body.

#### **1.4. Permanent workplaces**

Well-trained permanent employees must be available in adequate number for the scope of the production. Permanent workplaces should be avoided in the area of centralized cytostatics production. Pursuant to s. 36 (6) *GefStoffV*, however, the number of persons potentially exposed should be reduced to a minimum.

#### **1.5. Occupational preventive medicine**

Employees working in the area of cytostatics production in the pharmacy are dealing with potential carcinogenic, mutagenic and reprotoxic (CMR) drugs. They must be offered regular occupational medical check-ups taking into account all the relevant factors at the specific workplace. These check-ups include:

1. Initial examination before taking up employment.
  2. Follow-up examinations during the employment at intervals of 1 to 2 years.
  3. Examinations at the request of the employee if there is a suspicion of work-related impairment to health.
- It is recommended that the follow-up examinations include biomonitoring to test the effectiveness of the existing protective measures.

Exposure to cytostatics must be documented by the employer in a suitable form. This documentation must include the types and amounts of cytostatics used and the frequency of their preparations for each employee handling these drugs. Furthermore, a continuous use of technical and personal protective measures has to be ensured by implementing standard operating procedures regarding compounding, disposal, and clean-up of cytostatics as well as cytostatics-related accidents and their acute management.

#### **1.6. Training, continuous education and professional specialization of employees**

The goal of training, continuous education and professional specialisation is to provide personnel with theoretical knowledge and practical skills.

Theoretical knowledge:

- Rules and regulations
- Safe handling of hazardous substances
- Hazards and protective measures
- Accident prevention and acute management
- Emergency management
- Disposal of contaminated material
- Drugs and dosage forms
- Stability and incompatibility
- Working in an aseptic area
- Drug effects and pharmacology
- Clinical pharmacy
- Pathology
- Departmental and organisational responsibilities
- Quality assurance
- Personal protective equipment

Practical training:

- Product handling after shipment acceptance
- Aseptic working techniques and their validation in simulations of work flow during compounding
- Handling of disposable articles
- Simulation of accidents and their acute management
- Checking cytostatic prescriptions
- Handling different documentation systems

- Packaging, distribution and disposal
- Handling a decontamination set

### 1.6.1. Training of new personnel

Training of new personnel in cytostatic compounding needs to be performed with specific care since handling cytostatics bear significant risks for humans and product safety. The training requires planning of time and content requirements and should be performed according to a predefined training program.

### 1.6.2. Continuous education and professional specialization of personnel

The goal of continuous education and professional specialization programs is to keep personnel informed about latest developments in science and technology.

Personnel that work in the cytostatic compounding need to undergo yearly training in hazardous substances regulations. They should also have the opportunity to participate in internal and external continuous pharmaceutical education programs.

A certificate should document participation.

Opportunities for professional specialisation in the oncology area should be taken if offered.

## 2. Central Cytostatics Department

The centralized preparation of CMR (carcinogenic, mutagenic and reprotoxic) drugs must take priority over distributed preparation. (TRGS 525, 5.3.1. (1))

### 2.1. Rooms and equipment

Preparation takes place in a separate, clearly designated cleanroom work area, which is separated from the remaining areas by one or more air-locks. The general requirements for workrooms must be met.

The rooms used must not be combined with the remaining pharmacy rooms.

In addition to the technical equipment, the equipment of the department includes the fixtures and furnishings associated with preparation, production and documentation.

The entire equipment of the preparation room must be defined in a fixtures plan and reduced to the necessary minimum.

### 2.2. Room air equipment

1. A cytostatics workbench of type H (or "other design, e.g. with isolated work room") must be used, type tested in accordance with DIN 12980 as laminar airflow (LAF). Cytostatics workbenches with an additional HEPA cassette filter stage beneath the work surface are to be preferred.

2. A workbench exhaust air system should be installed as a further safety measure.

3. Should an exhaust air system not be realizable for technical reasons, it is mandatory to use an LAF with two HEPA filter stages before the air is returned to the production room. If a workbench is operated with recirculated air, the air changes must not exceed 8, and all regulation of the *BuBAV* need to be met.

4. In any case, a ventilation system must be installed that leads adequately conditioned and purified fresh air complying with DIN 1946 into the room for compensating the flow of exhaust air in accordance with TRGS 560 and *ArbStättV*, without impairing the protective function of the cytostatics workbench. The velocity of the input air must not exceed 0.2 m/s.

## 3. Cytostatics Production

### 3.1. Handling of cytostatic shipments

Only trained pharmacy personnel may be allowed to accept shipments of cytostatics.

Packages or shrink-wrapped cytostatics need to be opened in a separated location with personnel wearing a protective gown.

Notification of breaks, contaminations or other damages needs to be documented and reported to the manufacturer and the occupational safety department. The cause of the defect needs to be evaluated and eliminated as soon possible.

### 3.2. Personal protective equipment

The directives, regulations and guidelines currently in force (*GefStoffV* (hazardous substances regulations), *TRGS* (technical rules for hazardous substances) 525, Cytostatics Directive of the *Länder*, regulations and leaflets of the *BGW / GUV*) stipulate the use of protective equipment for the employees of a cytostatics department. The personal protective equipment must meet the CE (Communaute' Europe'enne) standards and needs to be specified in the hazard evaluation. Personnel assembling drug products for the cytostatic compounding process and personnel packaging the final product also need to wear personal protective equipment.

The personal protective equipment consists of:

- protective gown (possibly in combination with cuffs)
- protective gloves

and in special cases:

- respiratory protective equipment
- protective eyewear
- overshoes

The special cases are:

- cleaning tasks inside the safety workbench which extend beyond simply wiping the work surface
- clearing up spilled cytostatic materials
- filter replacement in the safety workbench

The kind of personal protective equipment is chosen based on the hazard evaluation of the work environment

#### 3.2.1. Protective gown

Protective gowns must be sufficiently long (covering the thighs) and closed up to the neck. They have long arms with close-fitting cuffs. They should repel liquids at especially exposed positions. For reasons of product protection they should at least be almost sterile and give off as few particles as possible.

#### 3.2.2. Disposable gloves for protection during the production of cytostatic solutions

Suitable gloves or glove combinations must be worn, which are changed regularly and also in the event of contamination.

#### 3.2.3. Breathing protection, protective eyewear, overshoes

In special cases the avoidance of contamination when dealing with cytostatics requires the wearing of breathing protection, protective eyewear and overshoes in addition to a protective gown and protective gloves. These additional measures are mandatory for cleaning the safety workbench, clearing up spillages of cytostatics and during filter replacement at the safety workbench. Breathing protection must consist of a half mask particle filter complying with DIN EN 149. The protective eyewear must provide protection at the side and be capable of being worn over any personal aids to vision. Overshoes must be liquid repelling and cover the entire foot as far as possible.

## 3.3. Equipment for production

### 3.3.1. Technical equipment for the production of cytostatics

In order to ensure minimum safety standards for the production of cytostatics, it is necessary to employ suitable technical equipment (TRGS 525). This must comply with the requirements of the *Medizinproduktegesetz (MPG)* (law on medical devices). In addition, the materials used must fulfil the special criteria associated with cytostatics production. All equipment must be sterile, or must be subjected to disinfection before use. The quality of the devices must be inspected at regular intervals. Technical equipment is also part of the hazard evaluation.

### **3.3.1.1. Infusion pumps for the administration of cytostatics**

Medical devices may be set up, operated and used only for their intended purpose pursuant to the "law on medical devices" and associated statutory orders, and in accordance with generally recognized technical requirements and occupational safety and accident prevention legislation.

## **3.4. Aseptic technique**

Aseptic technique embraces all coordinated, necessary steps that lead to a sterile product by using optimal conditions for germ reduction and avoidance of microbial contamination.

Preparing for and going over the actual compounding process significantly influences the quality of the product.

### **3.4.1. Validation of aseptic technique**

#### **3.4.1.1. Validation**

The production of cytostatics in a safety cytostatic workbench is aseptic drug preparation whose production process must be validated. Compliance with the European Pharmacopoeia in respect of agents for parenteral use is mandatory.

Validation is only possible through inspection of the entire work process and the circumstances under which production takes place, i.e. the following items must be taken into account:

1. the rooms in respect of cleaning and hygiene
2. the safety workbench (LAF - laminar air flow)
3. the work materials
4. the starting materials and
5. the aseptic production method.

Validation of the entire process includes all the well thought-out measures which guarantee that as a result of the production and inspection procedures the final product conforms with all requirements and with the specified quality profile in respect of safety, identity, content, quality and purity.

#### **3.4.1.2. Methods for evaluation of aseptic technique**

Dummy products must be inspected using appropriate microbiological procedures for the absence of microorganisms capable of reproduction. The number and frequency of these procedures are oriented on the situation in the particular pharmacy. A study protocol needs to be established.

## **3.5. Requisition of ready-to-administer cytostatic solutions**

### **3.5.1. Requisition form**

Requisition of the cytostatics is submitted in writing through the physician on a prescription form.

The prescription is checked in the pharmacy in accordance with §. 7 *Apothekenbetriebsordnung (ApBetrO)* (pharmacy regulations) and cleared for production by the responsible pharmacist.

The prescription must be unambiguous and must include at least the following information:

- Name of the patient
- Date of birth of the patient and/or hospital chart number
- Body weight, height and/or body surface area
- Ward/ units providing oncological treatment
- Cytostatic prescribed (INN name)
- Regular dose and the resulting dosage for the patient
- Adjusted dose based on pharmacokinetic and clinical laboratory data
- Correction factor for any indicated dosage increase or reduction
- Pharmaceutical form

- Type of carrier solution
- Volume of the ready-to-administer solution
- Day of administration and required administration times
- Signature of the physician, date

### **3.5.2. Sending the prescription**

The physician's prescription must be at hand before the compounded preparation is sent off. Data transmission by electronic means over a network is acceptable, as long as applicable legal requirements are fulfilled.

### **3.5.3. Cytostatics dosage in case of impaired renal function**

Cytostatics are drugs with a narrow therapeutic range. An impaired renal function may increase the toxicity of cytostatics and active metabolites through accumulation. A dosage reduction may therefore be necessary for substances, which are eliminated renally to a significant extent. The basis for the decision must be the glomerular filtration rate as the parameter of renal function, and the most recent pharmacokinetic and pharmacological knowledge about the cytostatics used.

### **3.5.4. Cytostatics dosage in case of impaired liver function**

Decreased liver function may significantly influence hepatic clearance of cytostatics. Decrease of metabolic clearance leads to slower cytochrom P450 dependent and independent biotransformation processes, whereas reduction in biliary clearance decreases excretion via the biliary tract. Some cytostatics accumulate with decreased hepatic clearance. Therefore pharmaceutical services are very valuable in providing dosage modifications after evaluating patient specific clinical lab data.

### **3.5.5. Cytostatics dosage modification in case of blood count changes**

One of many parameters that need to be evaluated when dosing cytostatics is differential blood count or bone marrow reserve. However, no fixed parameters currently exist for the evaluation of a patient's individual recovery time after cytostatic application or the bone marrow's capability of regeneration (in contrast to for example liver and kidney function, where parameters exist). The bone marrow may also be the cancer-spreading organ, which makes dosage adjustments even more difficult. In these cases, tight, individualized patient control is indicated (2-3 times per week after completion of chemotherapy cycle) in order to assess and monitor a 'real' myelosuppression.

When treating a patient it is necessary to consider the patient's age and if therapy should be palliative or curative. Based on the severity of myelosuppression, a nadir-adapted cytostatic dose modification will be performed in the subsequent chemotherapy cycle. It needs to be noticed that hematopoietic agents such as G- or GM-CSF may make cytostatic dosage adjustment unnecessary and the dosage intensity may be maintained. This is especially important when curative treatment is the goal. High dose chemotherapy or dose-intensified standard therapy with reduced cycle intervals can only be performed with support of hematopoietic agents.

Thus, dosage recommendations based on myelosuppression can only be considered as guidance instrument. If cure is the treatment goal and myelosuppression is a concern it is especially important to weigh the risks between using supportive measures or lengthen the interval between chemotherapy cycles.

## **3.6. Production**

Production takes place on the basis of the working rules (s. 20 *GefStoffV* (hazardous substances regulations)) and the production specifications which integrates the results of the hazard evaluation. The work techniques defined in the working rules and production specifications are mandatory. Compliance with them must be regularly inspected.

### **3.6.1. Production specifications**

A production specification for cytostatic preparations includes:

- the designation of the cytostatic
- the pharmaceutical form
- the kind and designation of the finished drug to be used
- the kind and designation of the medical product to be used

- the designation of the method for proper production
- the designation of the equipment to be used
- the maximum permissible deviation from the value specified in the requisition
- the kind of packaging and labelling
- the information to appear on the label
- the information on the shelf life of preparations and unopened stock solution
- the information about special points to be observed during administration.

### 3.6.2. Documentation

During the preparation at least the following data are recorded and documented using a suitable method:

- Date and time of the preparation
- Batch designation of the ready-to-use medicinal product used and, if necessary, any residues (cytotoxic, solvents, carrier solutions)
- Quantities of solvents and carrier solutions used
- Name and quantity of the cytotoxic used
- Unusual events during the preparation
- Name of the person performing the preparation

### 3.6.3. Label

The label prepared on the basis of the production documentation includes at least the following information:

- name of the producing pharmacy
- name of the patient
- date of birth or admission number of the patient
- ward designation, units providing oncological therapy
- amount and name of cytostatic contained
- kind and amount of carrier solution
- pharmaceutical form
- required time of administration
- storage conditions
- production date and shelf life or, better, expiry date

## 3.7. Delivery of the finished products to the entity providing oncological therapy

For "In-house" transport the finished products are delivered in unbreakable, liquid tight, closable containers labelled with the inscription "Caution Cytostatics". (TRGS 525 5.6) "

If the finished product will be transported out of the institution it needs to comply with hazardous freight regulations (*Gefahrgutverordnung GGVS*).

Cytostatic compounds partially belong to the group of hazardous freights. They have the UN number 1851 and need to be arranged under 'drug, liquid, toxic'.

## 3.8. Valuation

The costs of a preparation are divided between the following areas:

1. Material costs
  - medicinal product
  - carrier solutions
  - consumables

2. Personnel costs
3. Extra charges

- The applicable contracts must be taken into account when billing the health insurance provider.

### **3.9. Information resources**

The basis of an oncology pharmacy service is its resources to research and answer almost all questions regarding antitumor therapy. Essential information resources consist of a personal library with relevant print media as well as computer resources including access to relevant software. This particularly includes Internet access allowing for retrieval of scientific database information, use of search engines, available links, electronic mail, and other services.

Audio and video material for educational purposes should also be available.

### **4.0. The pharmacy as coordination center of cytostatic therapy**

The pharmacy as central facility in the cytostatic therapy implements the quality management of the oncology pharmacy service and assumes responsibility for patients and staff in all areas of cytotoxic therapy.

The pharmacy records and processes all the medical and toxicological data relevant to the cytotoxic agent and, as far as possible, the accompanying and supportive measures as well.

The available information can be epidemiologically evaluated, documented with regard to clinical, pharmaco-economic and ecological aspects, integrated in advisory procedures and used for training the personnel.

#### **4.1. Waste disposal**

The principles of waste disposal are

- waste avoidance
- waste recycling
- waste disposal.

Its aims are

- personal protection
  - environmental protection.
- Hazardous wastes and objects contaminated with these are collected
- separately from other wastes
  - at the place they originate
  - in appropriate, labelled collecting vessels.

In general, cytostatic waste is considered hazardous waste. It should be collected in specific containers, which can be hermetically sealed after filling. Cytostatic waste needs to comply with hazardous freight regulations (GGVS) and applicable national and regional statutory requirements .

#### **4.2. Decontamination after inadvertent release**

A decontamination kit must be permanently located in every area where cytostatics are dealt with. The responsibility for ensuring this is ideally carried by the pharmacy as a central unit.

The decontamination kit contains among other items:

- Instructions for the decontamination procedures
- Marking material
- Disposable gown
- Overshoes
- Breathing protection mask (P3)
- Protective gloves
- Additional pair of gloves providing adequate mechanical protection against glass splinters
- Protective eyewear with side protection, which can be worn over personal eyewear
- Disposable cloths or wadding
- Water and ethanol for dampening
- Aids for collecting up broken glass

- Adequate number of robust waste containers
- Form for documentation of an accident

The removal and disposal of spilled cytostatics may be performed only by properly instructed personnel. The procedure to be followed after inadvertent release is part of the working rules and the annual instruction.

### **4.3. Extravasation (paravasation)**

For cytostatic therapy, the accidental escape of cytostatic agents with necrotizing potential into the surrounding tissue represents a serious complication requiring immediate treatment.

Guidelines for prevention and an action catalogue and documentation sheet for the treatment of extravasation must be at hand in all wards and units providing oncological therapy.

A kit for immediate treatment of extravasation contains all the materials necessary for the specific therapeutic schemes of the substances used, and must be permanently ready for use in an open, accessible place in the ward or unit.

### **4.4. Chrono-oncology**

Chrono-oncology is a method of treatment in which the times of administering cytostatic drugs are chosen with awareness of the existing biological rhythms of the patient, the therapeutic aim being to improve the bioavailability and efficacy of the cytostatics while simultaneously achieving a reduction in the extent of their adverse effects. Insofar as clinical results are available, the knowledge gained in the area of chrono-oncology is intended to be used in the sense of optimising the relationships between dosage, therapeutic effect and adverse effects, to the benefit of the patient.

### **4.5. Handling cytostatics on the wards/units**

Nurses and physicians have the main responsibilities in handling cytostatics on the wards and units.

These include accepting, storing, preparing for administration, and administering cytostatics as well as handling patient's excretions (patient's family members may also be involved) and managing accidental spilling of cytostatics.

The oncology-specialized pharmacist should support and advise the wards and units in the establishment of operating procedures for safe handling cytostatics and the correct use of personal protective equipment, so that safe working technique can be guaranteed.

### **4.6. Handling cytostatics in the doctor's office**

In the doctor's office, cytostatics produced by a pharmacy should only be accepted by personnel trained in handling cytostatics.

The delivery should be checked for completeness, damage, plausibility and expiration.

Parenteralia should only be delivered by the pharmacy in a readily accessible form. The infusion system should already be attached to the carrier solution containing the cytostatic so that no additional handling is necessary.

The pharmacist should advise that administration is only performed via appropriate vascular access. Infusion systems should not be detached from their primary solution and then reattached to a different solution.

Only the care giving physician in cooperation with his nurses should administer the cytostatic.

The patient is kept under observation during the administration.

Protective measures for personnel have to comply with current regulations and should at least consist of a protective gown, gloves and an absorbent padding.

After completion of the administration of the cytostatic, contaminated material should be sealed and disposed according to applicable national and regional statutory requirements.

### **4.7. Handling cytostatics at home**

Certain cytotoxic therapy regimens demand that an active substance be administered over a period of 24 hours to several days. This type of therapy is performed both during hospitalisation and as outpatient treatment.

Patients, family members and personnel working in the home care setting need to be trained in the handling of cytostatics in this environment.

The following points should be specifically stressed during their training:

- Special handling of cytostatics
- Handling of application devices
- Management of spilling or other incidents
- Management of paravasation
- Handling patient's excretions
- Cytostatic waste disposal

An individual care plan should be established in cooperation with the responsible pharmacist (see chapter 5.1).

#### **4.8. Management of clinical studies**

The oncology specialized pharmacist contributes through his participation to the quality assurance of therapy optimising and clinical drug development studies.

His main focus lies particularly on the study medication, its adequate shipment, storage, production and compounding, distribution and disposal under consideration of all applicable rules and regulations (e.g., GCP, GMP).

#### **4.9. Management of excretions**

Excretions of patients, who receive anticancer chemotherapy, may contain significant amounts of cytotoxic substances.

Health protection measures should be provided to all persons handling these excretions. In addition applicable disposal rules and regulations need to be followed.

### **5. Pharmaceutical Care of the Patient**

The initial quality oriented and well-structured pharmaceutical care service for the oncology patient should be performed by the responsible pharmacist immediately before or during the first chemotherapy cycle. Services to the patient should consist of counselling the patient and supervising his care from a pharmaceutical point-of-view.

The content of patient counselling should cover effects of the cytostatics and supportive therapeutics used, location of effects, method of administration, relevant adverse effects and drug interactions. It is also important to discuss with the patient how adverse effects should be handled and how they can be avoided.

Pharmacy services should be present and continuous during the whole therapy cycle and complement the medical care. It is beneficial to provide the patient with written information material and instructions. The content of patient counselling should be documented in the pharmacy. An interdisciplinary cooperation with physicians, nurses and other involved healthcare professional is desirable.

#### **5.1. Developing a pharmaceutical care plan**

Developing a pharmaceutical care plan is a key component in the concept of pharmaceutical care. The plan allows to provide continuous high standard care to a patient over any given time period.

Pharmaceutical care plans are structured after the SOAP concept:

S - Subjective Information: Subjective information includes e.g. patient provided presenting symptoms and patient-drug related problems.

O - Objective Information: Objective information is any information measured or observed.

A - Assessment: After the subjective and objective information has been collected, the pharmacist should analyse and assess the drug related problems.

P - Plan: Therapeutic goals should be defined and implemented with the patient and the care giving physician.

The pharmacist establishes interventions for achieving these therapeutic goals. Success of these interventions can be evaluated by using certain control parameters.

## **5.2. Supportive therapy**

### **5.2.1. Management of nausea and vomiting**

Nausea and vomiting are perceived by patients as frightening and particularly unpleasant adverse effects of cytostatic therapy. Their severity may even lead to premature termination of therapy. Thus, it is pertinent to provide efficient antiemetic supportive therapy.

The choice of an appropriate therapeutic intervention should be guided by the following aspects:

- Emetogenic potential of the cytotoxic therapy
- Individual risk factors of the patient
- Different phases of nausea and emesis
- Therapeutic guidelines of professional organizations based on evidence-based medicine (EBM)
- Pharmaco-economic aspects

The implementation of the chosen therapeutic intervention should be supported by

- Cooperation between patient, physician, pharmacist and other involved professionals
- Compliance-supporting measures
- Additional prophylactic measures

### **5.2.2. Pain management**

Most tumor patients experience pain during the course of their illness. Cause, kind and intensity of pain can be different. Pain needs to be diagnosed early and therapy should be consequent and appropriate including all different treatment options. It is important to include pain management in patient's care plan and it should include pharmacotherapeutic approaches as well as other treatment alternatives.

### **5.2.3. Alopecia**

Alopecia is a for the patient burdensome adverse effect of many cytostatic therapies. In patients treated with cytostatic therapy. Alopecia can be very bothersome to patients.

Although alopecia treatment options are still very limited, aspects and concerns about alopecia should be considered in the care plan and addressed during patient care.

### **5.2.4. Mucositis**

Inflammation of the mucosa –mucositis- can be found in several locations. Examples are stomatitis, oesophagitis, or cystitis. Many tumor patients experience mucositis, because it is a very common side effect of cancer chemo- and radiation therapy. Mucosal lesions can be very painful and significantly impair the cancer patients' quality of life.

It is one of the pharmacist's responsibilities to give specific recommendations for individual patients regarding mucositis prophylaxis and treatment. As part of quality assurance the pharmacist also develops general prophylaxis and treatment guidelines in collaboration with other oncology healthcare professionals.

### **5.2.5. Management of diarrhoea**

Diarrhoea is a serious complication of cancer therapy. Specific cytostatics as well as radiation therapy can cause diarrhoea as an adverse effect.

Immunological, infectious or cancerous processes can also cause diarrhoea and need to be included in the diagnostic evaluation.

Untreated diarrhoea may lead to weakness, electrolyte imbalance and exsiccosis, and may rapidly escalate.

It is one of the pharmacist's responsibilities to ensure implementation of early and adequate treatment of diarrhea.

### **5.2.6. Nutritional Advice and Therapy**

Almost all oncology patients suffer from extreme weight loss. This not only leads to worsening of the patient's general condition, but cachexia also causes more therapy intolerance and an increased risk of developing adverse effects.

Nutritional therapy needs to focus on the patient's well being. Maintaining the patient's weight should not be the primary focus of attention, but some appetite and enjoys eating certain foods.

Part of nutritional counselling should be to discuss changes in taste sensation that may occur during cancer chemotherapy and the increased energy requirements. The pharmacist should also provide together with the physician and other members of the healthcare team guidance on how the patient might benefit from dietary changes.

Provision of related written information material and instructions is beneficial to the patient.

### **5.2.7. Management of Undesirable Drug Effects on the Skin**

The pharmacist must be capable of recognising adverse drug reactions (ADR) on the skin and of offering suggestions for medical treatment.

### **5.2.8. Unconventional methods of cancer therapy**

The oncology specialised pharmacist should be knowledgeable about complementary and alternative medicine (CAM) regarding cancer treatment. If requested he should be able to give advice about unconventional treatment methods which are not approved or accepted by the school of medicine. However, some scientific evidence of those unconventional treatment methods is mandatory.

Products and methods need to be assessed from a professional standpoint. Furthermore, it is necessary to evaluate if the patient's health is at risk by applying these methods. Many unconventional treatment methods are blunt charlatany and the patient needs to be protected from them.

Interactions between alternative medicines and currently applied therapy regimes need to be assessed and ruled out.

During patient counselling the pharmacist should respect the patient's views regarding alternative medicines and take his opinions seriously. However, it is also the pharmacist's responsibility to stress the importance and safety of evidence-based medicine and to inform the patient of the risks involved when using alternative medicines.

## **6. Research and development**

*The present text reflects the state of the discussion within the European Society of Oncology Pharmacy (ESOP).*

In oncology, research and development should preferably be conducted in interdisciplinary fashion. Pharmaceutical-oncological services make important contributions to research activities. Results from research and development improve efficacy, suitability and quality of the offered procedures and services. In any research environment including pharmaceutical science, qualified pharmacists should be involved in designing and conducting the trials. In research, scientific and ethic rules as well as the guidelines for the individual field of research based thereupon must be complied with.

Prior to the study, a suitable and focussed goal must be defined in writing. All research activities including the rationale must be documented completely. The necessary resources as well as their efficient utilization must be determined in advance. Responsibility for scientifically and ethically acceptable performance must rest with one individual. For quality assurance, appropriately standardized methods and procedures must be used.

Confidentiality of clinical research data is essential. The results must be documented in standardized form and filed together with the corresponding original documents in a safe and easy to retrieve way. For electronic data, special approaches are required. The results must be assessed regularly with respect to their correctness and completeness. Records from clinical trials and public health studies must be archived in conformance with the applicable national regulations.

All research results, including negative ones, must be released for verification by scientific peers and made accessible to the general public. The person in charge of research shall authorize publication and release of information. Essential contributions to planning, performance and publication of the trial are prerequisites for authorship. Detected errors should be processed by the first author, and in cases of severe errors the person in charge must retract the work. Prior to inception, written contracts relating to intellectual property rights must be concluded with the sponsors.

## **Attachment**

### **A. Requirements to the drug manufacturer**

Drug manufacturers are a main source of information regarding drug compounds and pharmaceuticals. Their obligation to provide essential information on the safe handling (safety data sheet) and safe use (Summary of Product Characteristics (SPC)) has to be complemented by additional information and appropriate measures. There is in part a substantial lack of information especially with regard to precautions for the safe handling of oncology drugs, and being responsible for drug acquisition, the oncology specialised pharmacist should request this information from the manufacturer.

### **B. Return of shipments to the manufacturer**

Return of shipments of cytostatics to the manufacturer and wholesaler, respectively, have to be coordinated with the recipient.

The packaging container must allow for safe transformation and safe removal of the cytostatics. The shipment has to be labelled according to the applicable rules and regulations.

### **C Living Will**

As part of the pharmaceutical care, the pharmacist can refer to the possibility of a living will.