



SURVEY ON THE PRODUCTION AND PREPARATION OF CYTOSTATIC DRUGS

Please name the period you involve for this survey: Date: ___ (month) ___ (year) to ___ (month) ___ (year)

Name your country: _____

1. Identification of your institution

Institution:	No. of beds in your hospital (if any):
No. of departments:	No. of beds in your oncological department (if any):
No. of oncological departments:	No. of colleagues in your central cytostatic department:
No. of oncological outpatient departments in your hospital:	No. of oncological physicians your pharmacy cooperates with:

2. Evaluation of your daily cytostatic production

Top 5 of cytostatic agents you prepare: If possible, product name or chemical name • _____ • _____ • _____ • _____ • _____	Is it (please tick): <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;">Multi-dose-ampules:</td> <td style="width: 50%; border: none;">Single-dose-ampules:</td> </tr> <tr> <td style="border: none; text-align: center;"><input type="checkbox"/></td> <td style="border: none; text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="border: none; text-align: center;"><input type="checkbox"/></td> <td style="border: none; text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="border: none; text-align: center;"><input type="checkbox"/></td> <td style="border: none; text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="border: none; text-align: center;"><input type="checkbox"/></td> <td style="border: none; text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="border: none; text-align: center;"><input type="checkbox"/></td> <td style="border: none; text-align: center;"><input type="checkbox"/></td> </tr> </table>	Multi-dose-ampules:	Single-dose-ampules:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Multi-dose-ampules:	Single-dose-ampules:												
<input type="checkbox"/>	<input type="checkbox"/>												
<input type="checkbox"/>	<input type="checkbox"/>												
<input type="checkbox"/>	<input type="checkbox"/>												
<input type="checkbox"/>	<input type="checkbox"/>												
<input type="checkbox"/>	<input type="checkbox"/>												

3. Who prepares the cytostatics?

	Yes	No
Pharmacist <input type="checkbox"/> Physician <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacy Technician <input type="checkbox"/>		
The preparing personnel absolves a training	<input type="checkbox"/>	<input type="checkbox"/>
What is the accepted tolerance limit between the calculated dose according to body surface area and the actual dose prepared? 0%, not accepted at all <input type="checkbox"/> Up to 3% <input type="checkbox"/> 3-5% <input type="checkbox"/> Up to ___% <input type="checkbox"/>		
On what basis have you made the decision on chosen tolerance limit? Internal coordination (Pharmacists and Oncologists) <input type="checkbox"/> According to Pharm. Eur. <input type="checkbox"/> Others → please specify: _____ <input type="checkbox"/>		
The preparing personnel is supervised medically by the company's occupational medicine department	<input type="checkbox"/>	<input type="checkbox"/>

	Yes	No
Do you prepare chemotherapy in advance? Yes → If YES, how long in advance? ___days <input type="checkbox"/> No <input type="checkbox"/> By way of exception (e.g. before weekend) <input type="checkbox"/>		
Do you work with standardized guidelines? If so, on what publications are the guidelines based on? General pharmaceutical literature <input type="checkbox"/> QuapoS <input type="checkbox"/> Other <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
How many persons prepare? Pharmacists: _____ Technicians: _____ Amount of preparations per year? up to 2000 <input type="checkbox"/> 2000 – 5000 <input type="checkbox"/> 5000 – 10000 <input type="checkbox"/> more than 10000 <input type="checkbox"/>		
What is the percentage of discarded preparations per year, caused by delay of therapy or patient does not show up? ____ % Do you have a written documentation of the preparations? Do you have a written documentation supported by a computer software? If so, please specify (name of the software): _____	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
Do you have a ED - connection between the pharmacy and the oncological office?	<input type="checkbox"/>	<input type="checkbox"/>

4. Rooms and Equipment	Yes	No
Where are the cytostatics prepared? <input type="checkbox"/> At a certain place <input type="checkbox"/> in the nurse's room <input type="checkbox"/> Right next to the patient's bed <input type="checkbox"/> in the room where the medicine is stored <input type="checkbox"/> In a retail pharmacy <input type="checkbox"/> In a hospital pharmacy <input type="checkbox"/> In a room specifically reserved and equipped for this work		
Is this room or place equipped with a Laminar Air Flow? If so, what type of Laminar airflow is it: <input type="checkbox"/> Class II, German Industry Standard No. 12950, Part 10 <input type="checkbox"/> Class GS-GES-04 <input type="checkbox"/> Ventilation with horizontal air flow <input type="checkbox"/> Isolator <input type="checkbox"/> Type H, German Industry Standard No. 12980 <input type="checkbox"/> Type V1, German Industry Standard No. 12980 <input type="checkbox"/> Type V2, German Industry Standard No. 12980 <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Is the Laminar Air Flow being checked yearly?	<input type="checkbox"/>	<input type="checkbox"/>
Is the moving area around the Laminar Air Flow at least 1,5 m ² large and is it not less than 1 m wide at any place	<input type="checkbox"/>	<input type="checkbox"/>
Does the exhausted air from the Laminar Air Flow / from the preparation area leaves the room through a dislinked / closed air conduction? Respectively, led back by an accredited procedure?	<input type="checkbox"/>	<input type="checkbox"/>
Does the air entering the preparing area contain at least 40 m ³ fresh air per person and hour?	<input type="checkbox"/>	<input type="checkbox"/>
Only for equipment working with recirculated air 1. Does the room of preparation extend to at least 10 m ² and a height of at least 2,50 m? 2. Is there a minimum space of 1,20 m in front and 0,30 m to each side of the preparation equipment?	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>

5. Personal protective equipment

Yes

No

Which individual protection does the personnel wear at the place of preparation?

Special clothing for single use

Special clothing for multiple use

Cap

Protective eyewear with side protection

Arm cuffs

Breathing protection (surgical mask)

Area-specific shoes

Gloves

How many pairs?

1

2

6. Supportive tools used for the preparation:

Yes

No

Glas syringe synthetic syringe Luer-Lok syringe
with piston barrier 3-part syringe syringe filled with solvent

Chemospikes with hydrophobe air supply filter and fluid filter

Chemospikes with hydrophobe air supply filter without fluid filter

Needle without filter No air supply system

Sterile compresses /swab?

At any withdrawal of substance

At any transfer to another syringe

Always during resection of air

The cytostatic application is transported to the patient in a

unbreakable, water-resistant and closed box

unbreakable, water-resistant box

other box _____

If an infusion device is delivered together with the cytostatic agent, do you fill the device with:

Saline solution

carrier solution

cytotoxic solution

Who fills?

The person, who prepares the cytostatic agent

A nurse at the bed of the patient

Do you label the product after finishing preparation?

Do you use a symbol which indicates the danger of the cytostatics?

Do you use the „Yellow Hand“?

	Yes	No
Do you use any devices for preparation of cytotoxic drugs? If so, what kind: Mini-Spike Chemo®, B.Braun <input type="checkbox"/> Chemo-Aide Pin®, Baxter <input type="checkbox"/> Cytoluer®, Baxter <input type="checkbox"/> Clave®, Spiros®, ICU Medical Inc. <input type="checkbox"/> Codan® CYTO, CODAN <input type="checkbox"/> NeoSpike Onko®, NEO CARE medical products <input type="checkbox"/> PhaSeal®, Carmel Pharma <input type="checkbox"/> Tevadaptor®, TEVA Medical Ltd. <input type="checkbox"/> Texium™, Cardinal Health <input type="checkbox"/> other: _____ <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If you do NOT use any devices for reconstitution of cytotoxic drugs, what is the reason: lack of the knowledge about these devices <input type="checkbox"/> unconcern with problem of the employer <input type="checkbox"/> lack of the necessity of using these devices <input type="checkbox"/> financial reasons <input type="checkbox"/> other: _____ <input type="checkbox"/>		
Do you use devices for preparation for all drugs or only for special drugs? for all drugs <input type="checkbox"/> for all drugs except <input type="checkbox"/> only for _____ <input type="checkbox"/>		
Do you use closed system drug transfer devices only for reconstitution or also for administration of cytotoxic drugs? We do not use closed system drug transfer devices neither for reconstitution nor for administration of cytotoxic drugs <input type="checkbox"/> only for reconstitution <input type="checkbox"/> only for administration at the ward <input type="checkbox"/> for reconstitution and for administration <input type="checkbox"/> other _____ <input type="checkbox"/>		
Are you satisfied with using of devices for cytotoxic drugs reconstitution?	<input type="checkbox"/>	<input type="checkbox"/>
Your notices and opinions concerning implementation of devices supporting safe handling of cytotoxic drugs: _____ _____ _____ _____		

7. Spill-Kit	Yes	No
Is there a Spill-Kit in the Pharmacy?	<input type="checkbox"/>	<input type="checkbox"/>
Is there a Spill-Kit at the ward?	<input type="checkbox"/>	<input type="checkbox"/>
Is the pharmacy involved in the support and care of the Spill-Kit?	<input type="checkbox"/>	<input type="checkbox"/>
Are there procedures to be followed in case of accidents?	<input type="checkbox"/>	<input type="checkbox"/>
Are accidents being reported in the pharmacy?	<input type="checkbox"/>	<input type="checkbox"/>

8. Disposal of possibly toxic waste and storage of not emptied cytostatics	Yes	No
For collection of cytostatic waste we use		
Transport box in combination with a tool for automatic lamination	<input type="checkbox"/>	<input type="checkbox"/>
Transport box only	<input type="checkbox"/>	<input type="checkbox"/>
Other box _____	<input type="checkbox"/>	<input type="checkbox"/>
For a future use of an opened bottle we		
close the bottle with a plugger, cover and leave the cannula closed	<input type="checkbox"/>	<input type="checkbox"/>
pull out the cannula and replace them in case of reuse	<input type="checkbox"/>	<input type="checkbox"/>
Other (please specify): _____	<input type="checkbox"/>	<input type="checkbox"/>
After application of cytostatics to a patient, do you follow a certain procedure for cytostatic waste disposal?	<input type="checkbox"/>	<input type="checkbox"/>

9. Accidents and incidents during preparation	Yes	No
Which accidents / incidents occur most frequently? (multiple answers possible)		
<input type="checkbox"/> Spill of cytostatics		
<input type="checkbox"/> Stab wounds at the personnel		
<input type="checkbox"/> Leak bags or pluggers		
<input type="checkbox"/> Broken boxes or bottles		
<input type="checkbox"/> Other → please specify: _____		

10. Application of cytostatics to the patient:	Yes	No
Do you recommend the nurse to wash-out the catheter with a physiological saline solution before application of the cytostatics?	<input type="checkbox"/>	<input type="checkbox"/>
If a central venous catheter is applied, do you recommend the nurses to wash-out the catheter with a physiological saline solution after an intravenous injection or infusion with cytostatics?	<input type="checkbox"/>	<input type="checkbox"/>

11. Dose modification	Yes	No
Do you modify the dose with a procedure regarding the individual parameters of the patient?	<input type="checkbox"/>	<input type="checkbox"/>
Do you take samples to evaluate pharmacokinetic parameters of the patient?	<input type="checkbox"/>	<input type="checkbox"/>

12. Extravasation-Kit	Yes	No
Is there an Extravasation-Kit?	<input type="checkbox"/>	<input type="checkbox"/>
Is the pharmacy involved in the support and care of the Extravasation-Kit?	<input type="checkbox"/>	<input type="checkbox"/>
Are there procedures to be followed in case of accidents?	<input type="checkbox"/>	<input type="checkbox"/>
Are accidents being reported in the pharmacy?	<input type="checkbox"/>	<input type="checkbox"/>

13. Ambulatory care	Yes	No
Do you cooperate with an institution of ambulatory care?	<input type="checkbox"/>	<input type="checkbox"/>
If so, is it an institution of:		
Home care	<input type="checkbox"/>	<input type="checkbox"/>
Palliative care	<input type="checkbox"/>	<input type="checkbox"/>
Institution of the hospice movement	<input type="checkbox"/>	<input type="checkbox"/>
Do you have a named contact?	<input type="checkbox"/>	<input type="checkbox"/>

14. Quality management system	Yes	No
Do you have a QMS implemented in your pharmacy?	<input type="checkbox"/>	<input type="checkbox"/>
If so, is it the		
Certification of preparation of cytostatics by the QuapoS (DGOP)	<input type="checkbox"/>	<input type="checkbox"/>
Certification of regional authority, incl. the preparation of cytostatics	<input type="checkbox"/>	<input type="checkbox"/>
Certification by an external company, incl. the preparation of cytostatics	<input type="checkbox"/>	<input type="checkbox"/>
If not, do you plan to start with QMS?	<input type="checkbox"/>	<input type="checkbox"/>

15. Cooperation with institutions actively involved in oncological therapies	Yes	No
Is there a detailed description of medical processes and / or processes of care in the oncological department of the institution you cooperate with?	<input type="checkbox"/>	<input type="checkbox"/>
Are pharmacists or other clerks of the pharmacy involved in the development of such processes?	<input type="checkbox"/>	<input type="checkbox"/>
Are pharmacists involved in the pharmaceutical care of oncological patients, resp. part of the oncological team?	<input type="checkbox"/>	<input type="checkbox"/>
Does your pharmacy organize or escort clinical trials in oncology?	<input type="checkbox"/>	<input type="checkbox"/>

16. Your recommendation for improvements in the safety of personnel preparing cytostatic drugs:

17. Which institutions or persons appear relevant to you regarding the further development of quality standards and directives for workplace-safety in the preparation of cytostatic drugs?

Please deliver the filled survey at the NZW-Registration
or by fax to 0049 40 791 43 601

Thanks a lot for your participation

