# Regulation of 9 March 2001 No. 439 concerning medical supplies on ships

Laid down by the Ministry of Health and Social Affairs on 9 March 2001 pursuant to § 6–8 of the Act of 2 June 2000 No. 39 relating to the Operation of Pharmacies, and § 47 and § 52 of the Act of 9 June 1903 relating to Public Control of the Seaworthiness of Ships, etc., with subsequent amendments, ref. Royal Decree of 13 June 1969 authorizing the Ministry of Social Affairs to issue regulations pursuant to the Seaworthiness Act, ref. Appendix XVIII paragraph 16a of the EEA Agreement (Council Directive 92/29/EEC). Amended 10 June 2002 No. 530, 13 December 2002 No. 1638, 14 June 2004 No. 888, 8 September 2004 No. 1250 and 22 August 2005 No. 908.

# Chapter I Scope of application and definitions

# § 1 Object

The object of the present regulation is to ensure the availability of such medical supplies on ships as are required for safeguarding the health and safety of employees and passengers. The regulation is intended as a contribution towards the proper procurement, storage, dispensing and checking of medical supplies on ships.

# § 2 Scope of application

This regulation applies to all Norwegian ships. It also applies to life-saving appliances on Norwegian ships, ref. § 13. Unless otherwise provided in any Section (§) of this regulation, the following categories are excepted from the regulation:

- (a) pleasure craft used for non-commercial purposes and not manned by a professional crew;
- (b) tugboats operating in harbour areas;
- (c) mobile offshore units used in the petroleum activities on the Norwegian Continental Shelf and documented to be covered by an emergency preparedness established pursuant to § 9–2 of the Petroleum Act<sup>1</sup> which is at least equivalent to the requirements of this regulation; and
- (d) vessels of the Naval Defence not holding civilian certificates.

1 Act of 29 November 1996 No. 72 pertaining to petroleum activities.

# § 3 Definitions

For the purpose of this regulation, the following definitions shall apply:

- (a) Passenger ship: any ship for which a passenger certificate, passenger ship safety certificate, high-speed craft safety certificate or permit for limited passenger carriage is required pursuant to the Seaworthiness Act<sup>1</sup>;
- (b) Life-saving appliance: any lifeboat, rescue boat, liferaft or workboat;
- (c) Company: the registered owner of a vessel, except when the vessel is bareboat chartered or wholly or partly operated by any natural or legal person other than the owner on the basis of an agreement on the operation of the vessel, in which case the bareboat charterer or the natural or legal person, as appropriate, shall be considered to be the company;
- (d) *Master:* the person having command of a ship;
- (e) *Employee:* anyone who takes up service on a Norwegian ship, including trainees and apprentices, except harbour pilots and shore-based personnel carrying out work on board berthed ships;
- (f) Medical supplies on ships: drugs, medicines and medical equipment, etc., see non-exhaustive lists in Appendix 1 and Appendix 2;
- (g) Narcotics, etc.: drugs referred to in the Norwegian list of narcotic drugs<sup>2</sup>, see Appendix 3;
- (h) *Dispensing:* the issue of medical supplies on ships by an authorized person to the requisitioner or patient and the direct use on a patient of medical supplies by an authorized person;
- (i) Dangerous cargo: cargo described as dangerous in the International Maritime Dangerous Goods (IMDG) Code, issued by the International Maritime Organization (IMO).
- 1 Act of 9 June 1903 No. 7 relating to Public Control of the Seaworthiness of Ships, etc.
- 2 Pursuant to the Regulation concerning Narcotic Drugs and the like of 30 June 1978 No. 8.

#### § 4

#### Categories of vessels

For the purpose of this regulation, the following categories of vessels are established:

Category A: Ocean-going vessels, including vessels engaged in fishing on the high seas with no trade area restrictions and ocean-going vessels not falling within the scope of category B.

Category B: Ocean-going vessels, including vessels engaged in fishing on the high seas in waters less than 150 nautical miles from the nearest port offering medical assistance by qualified personnel or 175 nautical miles from the nearest port offering medical assistance by qualified personnel if the vessel continuously stays within the reach of a helicopter service.

Category C: Vessels operating in harbours and vessels which either stay within 20 nautical miles of the Base Line or have no cabin facilities other than the wheelhouse.

# Chapter II Responsibility and control

## § 5

# Responsibility

The general responsibility for compliance with the requirements of this regulation at all times lies with the company. Employees shall not bear any of the cost of procuring and renewing medical supplies on ships.

The master is responsible for ensuring that the duties prescribed by this regulation are performed.

The master may delegate the dispensing and checking of medical supplies to one or more employees specially designated on the basis of their qualifications, ref. §§ 18, 21, and 22.

## § 6 Control

The Norwegian Maritime Directorate, or whoever is authorized by the Directorate, is responsible for the control of the company's and master's compliance with the provisions of this regulation.

# Chapter III Requirements for ships' medical supplies

## § 7

#### General medical supply requirements

Medical supplies on board shall at the time of procurement be of a quality in respect of their properties, packaging and marking which is equivalent to that of such articles marketed in Norway.

The marking shall be in Norwegian and English. The requirement for marking in Norwegian or English may be waived where it can be documented that those who are to dispense medical supplies on ships fully understand the marking.

#### \$ 8

## Special medical supply requirements

Medical supplies shall be contained in solid and suitable packaging which clearly indicates the generic name of the drug or medicine.

Medical supplies shall be marked with the name of the place where they were purchased and the manufacturer, production number, the date by which they must be used, storage conditions, and user's instructions. The nature and amounts of active ingredients shall appear from the marking.

## § 9

#### Ship's medicine storage unit

Ships shall be provided with a medicine storage unit containing medical supplies which are at least in accordance with Appendix 1 and Appendix 2 for the category to which the ship belongs, ref. § 4.

Fishing vessels operating within the trade area bank fishing II, ref. § 23 of the regulations on trade areas<sup>1</sup>, may be considered to be in category B for the provision of medical supplies, ref. first paragraph.

Vessels less than 15 metres in length belonging to category C and vessels to which a permit for limited passenger carriage is issued may, in lieu of the medicine storage unit prescribed by the first paragraph, be provided with necessary first-aid equipment.

The ship's medicine storage unit shall at all times contain sufficient quantities of medical supplies. In considering this, regard shall be had, *inter alia*, to the number of employees, duration of voyage, final destination and ports of call, types of work to be carried out in the course of the voyage, nature of cargo, and actual trade area.

Regulations of 4 November 1981 No. 3793 concerning trade areas.

#### § 10

## Additional requirements for ships above 500 GT

Ships above 500 GT shall, in addition to the other requirements contained in this regulation, carry necessary first-aid equipment in the engine-room and galley.

### § 11

## Additional requirements for passenger ships

The company shall, in cooperation with a doctor or pharmacist, ensure that the ship is provided with the necessary medical supplies at all times. In considering what supplies are necessary, regard shall be had, *inter alia*, to the number of passengers and their needs, duration of voyage, and actual trade area.

Passenger ships certified to carry 100 passengers or above shall carry on board a kit of medical supplies for acute medical emergencies. The kit of medical supplies for acute medical emergencies shall be a case or similar container with drugs, medicines and medical equipment which can be used by a doctor in treating any common and acute medical condition.

## § 12

### Ships carrying dangerous cargoes

Ships carrying dangerous cargoes shall be provided with such medical supplies as are necessary to treat cases of poisoning in accordance with the Medical First Aid Guide (MFAG), ref. § 25. Where it can be documented that other medical supplies are equivalent or better than those listed in the MFAG, the ship may be equipped for alternative treatment of cases of poisoning. The list of drugs, medicines and medical equipment must be drawn up in consultation with a doctor.

Drugs, medicines and medical equipment which must be carried pursuant to the first paragraph and user's instructions, ref. § 25, shall be kept in a sealed case. The case shall be clearly marked with «first aid – poisoning», the date of the last inspection and a «do not use after» date. A list of the contents of the container shall be kept with the supplies.

For any ferry operated under conditions where it may sometimes be impossible, within a sufficient time-limit or after proper notice has been given, to know the nature of the dangerous substances carried, the sealed case shall contain drugs, medicines and medical equipment and guidance for first-aid treatment in accordance with the first paragraph. Notwithstanding the above, ferries trading on fixed routes where the scheduled duration of the voyage is less than two hours may limit their medical supplies for first-aid treatment to those that in particularly critical situations must be administered within a period of time not exceeding the normal duration of the voyage. The list of drugs, medicines and medical equipment must be drawn up in consultation with a doctor.

### § 13

# Medical supplies on board life-saving appliances

Life-saving appliances shall be provided with medical supplies as indicated by Appendix 1 and Appendix 2 and the additional information provided by chapter VI herein.

# Chapter IV Sick-room, doctor on board

### § 14

#### Sick-room

Ships shall have a sick-room where necessary on grounds of size of crew, number of passengers, duration of voyage, and actual trade area.

## § 15

#### Doctor on board

Ships with a crew of 100 employees or more engaged on an international voyage exceeding three days shall have a doctor on board responsible for the medical treatment of employees.

Other ships shall have a doctor on board where necessary. In considering whether a doctor is necessary, regard shall be had to such factors as risk, trade area, etc.

Additionally, passenger ships shall comply with the requirements of § 25 of Regulations of 2 October 1972 No. 4 concerning the calculation of number of passengers and concerning passenger accommodation, etc.

# Chapter V Requisitioning of medical supplies to ships

### § 16

### Requisitioning

The master, company or the doctor associated with the company is entitled, under the provisions relating to requisitioning of medical supplies from pharmacies<sup>1</sup>, to requisition such medical supplies as are required on board ship. In the case of a medical emergency, it is the duty of the master to make the necessary medical supplies available with the shortest possible delay.

The right of companies and masters to requisition narcotics, etc. is limited to those drugs and quantities that are indicated in Appendix 3.

The Directorate for Health and Social Affairs may give shipyards and businesses supplying life-saving appliances to ships permission to requisition medical supplies to newbuildings, ref. the provisions relating to requisitioning of medical supplies from pharmacies<sup>1</sup>. Such permission may be granted on certain conditions.

Medical supplies that are requisitioned shall be lawfully marketed in the country from which they are supplied and be of satisfactory quality, ref. §§ 7 and 8.

All purchases of narcotics, etc. shall be entered in the Control Record Book, ref. § 25.

In purchasing medical supplies for ships, the master shall see to it that the vendor issues a specification in duplicate in Norwegian or English of the articles delivered. The specification shall be kept on board until the next inspection by a competent person pursuant to  $\S 22$ .

### § 17

#### Withdrawal of right to requisition

If the Directorate for Health and Social Affairs finds that the master's or company's requisitioning of prescription drugs is improper, the master's or company's right to requisition prescription drugs under the provisions relating to requisitioning of medical supplies from pharmacies may be withdrawn.

<sup>&</sup>lt;sup>0</sup> Amended by regulation of 10 June 2002 No. 530.

Regulation of 27 April 1998 No. 455 concerning requisitioning and dispensing of medical supplies from pharmacies.

<sup>&</sup>lt;sup>0</sup> Amended by regulation of 10 June 2002 No. 530.

<sup>&</sup>lt;sup>1</sup> Regulation of 27 April 1998 No. 455 concerning requisitioning and dispensing of medical supplies from pharmacies.

# Chapter VI Storage of medical supplies on ships

## § 18

# Storage of medical supplies on ships

Medical supplies on ships shall be stored in such a way that their usability is maintained. Medical supplies shall be kept in convenient order in a locked cupboard, chest, case or similar container, well protected against moisture, frost or intense heat. Medical supplies which should be kept in a cold place shall be stored in a refrigerator. Ships in categories A and B shall be provided with a lockable medicine cupboard. In ships with a sick-room, medicine cupboards shall be located in the sick-room. Only the master and persons authorized by the master shall have a key and access to the medical supplies in the ship's medicine storage unit, ref. § 9. Narcotics, etc. shall always be stored in a locked container.

The medical supplies in the ship's medicine storage units shall be arranged according to the use for which they are intended, ref. Appendix 1.

Disinfectants for technical use shall be stored separately from medical supplies.

### § 19

# Medical supplies on board life-saving appliances

Medical supplies for life-saving appliances shall be kept in watertight, sealed containers clearly marked as containing first-aid equipment, with the date of the last inspection and a «do not use after» date. A list of the contents shall be found in the container.

For vessels lying unguarded in Norwegian ports, including fishing vessels, small freighters and local ferries, narcotics, etc. shall not be stored in life-saving appliances. For these vessels, narcotics, etc. for the life-saving appliances shall be packed in separate, watertight containers and stored in a readily accessible place so that they can easily be picked up in an emergency. It is the master's responsibility to ensure safe storage when the vessel is unattended at the quayside. The life-saving appliances shall be clearly marked to show that their medical supplies do not contain narcotics.

## § 20

#### *First-aid equipment*

First-aid equipment, ref. §§ 9 and 10, shall be kept in a bag, case, cupboard or similar container which shall be clearly marked with «first-aid equipment», the date of the last inspection and a «do not use after» date. A list of the contents shall be kept together with the equipment.

# Chapter VII Dispensing and checking of medical supplies on ships

# § 21

# Dispensing of medical supplies on board

Medical supplies shall be dispensed on board only by the master or persons authorized by the master. Dispensing shall take place only for the treatment of persons staying on board. The dispensing of medical supplies shall, as a main rule, take place in consultation with a doctor or be subject to written instructions given by a doctor in advance. Any act of dispensing shall be recorded by the dispensing person.

If any drug or medicine is dispensed in a larger quantity than is used immediately, it shall be dispensed in a suitable container on which is inscribed the name of the drug or medicine and directions for its use.

Particular care must be exercised when dispensing narcotics, etc. Every act of dispensing of narcotics, etc. shall be entered in the Control Record Book, ref. § 25.

## § 22

#### Inspection and discarding

Medical supplies shall be subject to inspection by a competent person at least once every twelve months. In exceptional cases, the inspection may be delayed for a period of up to five months. Any inspection carried out shall be

documented, ref. fourth paragraph. The phrase «inspection by a competent person» means inspection by a pharmacist or doctor.

For ships provided with a Safety Management Certificate, ref. Chapter V of the Seaworthiness Act<sup>1</sup> with appurtenant regulations, inspection by a competent person may be carried out every three years, provided that the master or any person authorized by the master, ref. § 5, carries out equivalent inspection of the drugs, medicines and medical equipment, ref. first paragraph, at least once every twelve months. The safety management system shall contain a procedure for the checking and inspection of medical supplies on ships.

For medical supplies in life-saving appliances, the inspection pursuant to the first and second paragraphs shall be supplemented by checks by the master or any person authorized by the master once every month. Medical supplies in inflatable liferafts shall be inspected as part of the annual inspection by an approved service station, ref. the International Convention for the Safety of Life at Sea (SOLAS).

The inspection shall include checking that the medical supplies are in accordance with the requirements of the regulation, that they are stored correctly, that the «do not use after» dates are observed, and that acts of dispensing medical supplies have been recorded, ref. § 21. The supplies of narcotics, etc. must be checked to see if they are in accordance with the Control Record Book and any discrepancies must be recorded and explained.

Medical supplies which are to be discarded shall normally be dispatched to a pharmacy or similar place. Where medical supplies are destroyed on board ship, such destruction shall be done safely and appropriately.

### § 23

#### **Documentation**

Documentation of inspections carried out shall indicate, for each article which the ship including life-saving appliances is required to carry:

- (a) the quantities decided pursuant to this regulation;
- (b) the number of articles counted at inspections; and
- (c) any information on limited life, etc.

The documentation shall be dated and signed and in the case of an inspection by a competent person also provided with the stamp of the business or government agency with which that person is associated.

The documentation of inspections carried out shall be kept on board and on request shown to representatives of the Norwegian Maritime Directorate or the Directorate for Health and Social Affairs or to persons authorized by those agencies.

All documentation of inspections carried out, ref. § 22, and dispensing of medical supplies, ref. § 21, shall be kept on board for at least three years.

# Chapter VIII Medical advice, education, training, handbooks

#### § 24

#### Medical advice and evacuation

Ships shall be given free medical advice by a doctor in the event of messages concerning illness or accidents which are relayed by the coast radio stations or the medical emergency reporting service.

Evacuation of a patient by air ambulance or rescue helicopter from ships in areas for which the Norwegian rescue service has responsibility is organized by the rescue coordination centre concerned in cooperation with the medical emergency reporting service.

# § 25

#### Handbooks, etc.

Ships shall be provided with adequate handbooks, etc. to ensure that first aid and other medical treatment may be given in a medically competent manner.

Ships shall carry the following on board:

- (a) A copy of this regulation.
- (b) A bound and paginated Control Record Book in which to enter purchases, acts of dispensing and sending in for destruction of narcotics, etc., ref. §§ 16 and 21.
- (c) A suitable first-aid booklet in Norwegian and English intended for ships. The first-aid booklet shall be kept together with the supplies of drugs and medicines, etc. The requirement for a first-aid booklet in both Norwegian

<sup>&</sup>lt;sup>1</sup> Act of 9 June 1903 No. 7 relating to Public Control of the Seaworthiness of Ships, etc.

<sup>&</sup>lt;sup>0</sup> Amended by regulation of 10 June 2002 No. 530.

- and English may be waived where documented that the ship's crew understand the language of the first-aid booklet carried on board.
- (d) A brief guide to first aid, which shall be kept together with the medical supplies in each life-saving appliance. The guide shall be in a suitable language and in both Norwegian and English for ships trading in Norwegian waters.

Ships carrying dangerous cargoes, ref. § 12, shall in addition have on board the English-language booklet «Medical first aid guide for use in accidents involving dangerous goods (MFAG)» or the Norwegian-language booklet «Veiledning for medisinsk førstehjelp», issued by the International Maritime Organization.

# § 26 Training

The master or any person authorized by the master to dispense and use drugs, medicines, etc. on patients on board shall have undergone approved training, ref. the provisions relating to qualification requirements, issue of certificates and certificate rights for personnel on Norwegian ships<sup>1</sup>.

# Chapter IX Miscellaneous provisions

### § 27

#### Exemptions

The Directorate for Health and Social Affairs, or whoever is authorized by the Directorate for Health and Social Affairs, may grant exemptions from this regulation on special grounds. The exemption must be necessary and justifiable in terms of safety. An exemption may only be granted where this does not contravene any international agreement to which Norway has acceded.

## § 28 Penalty

Any violation of this regulation is punishable pursuant to § 339 subsection 2 of the General Civil Penal Code<sup>1</sup> unless a stricter penalty is applicable under another statutory provision.

## § 29

Entry into force

This regulation enters into force on 1 June 2001.

#### § 30

# Transitional provision

Each ship shall be provided with medical supplies in accordance with this regulation at the first annual inspection by a competent person, ref. § 22, after 1 June 2001 and not later than 1 June 2002.

Ships which under the first paragraph are temporarily not provided with medical supplies as prescribed by this regulation, shall be provided with medical supplies in accordance with Regulations of 11 December 1981 No. 8748 concerning medical supplies, etc. on board ship until the transitional period is over.

The Regulations of 11 December 1981 No. 8748 concerning medical supplies, etc. on board ship are repealed as from 1 June 2002.

#### **Appendices**

- 1. Overview of groups of drugs and medicines required to be part of the ship's medicine storage unit
- 2. Overview of medical equipment required to be part of the ship's medicine storage unit

<sup>&</sup>lt;sup>1</sup> Regulations of 9 May 2003 No. 687 concerning qualification requirements and certificate rights for personnel on board Norwegian ships, fishing vessels and mobile offshore units.

<sup>&</sup>lt;sup>0</sup> Amended by regulation of 10 June 2002 No. 530.

<sup>&</sup>lt;sup>1</sup> General Civil Penal Code of 22 May 1902 No. 10.

3. List of narcotic drugs, etc.

# Appendix 1<sup>1,2</sup>

Overview of groups of drugs and medicines required to be part of the ship's medicine storage unit, ref. § 9 and life-saving appliances, ref. § 13.

	Ca	itegor	y (§ 4	4)	
Group	A	В	C	Lifes.appl. A/B	Lifes.appl. C
Cardiovascular medicines					
A Cardio-circulatory analeptics – Sympathomimetics	X	X			
B Anti-angina preparations	X	X	X	X	X
C Diuretics	X	X			
D Anti-haemorrhagics including uterotonics if there are women on board	X	X	X	X	X
E Anti-hypertensives	X				
F Medicines used in treatment of thromboses	x	X	X	X	X
Medicines used for gastric and duodenal disorders					
A Anti-ulcers					
- Histamine H2 receptor anti-ulcer antagonists	X				
- Anti-acid mucous dressings	X	X			
B Anti-emetics	X	X	X	X	X
C Lubricant laxatives	X	X			
D Anti-diarrhoeals	X	X	X	X	X
E Intestinal antiseptics	X	X			
F Haemorrhoid preparations	x	X			
Analgesics and anti-spasmodics					
A Analgesics, anti-pyretics and anti-inflammatory preparations	X	X	X	X	X
B Powerful analgesics	X	X		X	
C Spasmolytics	X	X			
Medicines used for central nervous system disorders					
A Anxiolytics	X	X			
B Neuroleptics	X	X			
C Seasickness remedies	X	X	X	X	X
D Anti-epileptics	X				
Anti-allergics and anti-anaphylactics					
A Anti-histaminics	X	X			
B Injectable glucocorticoids	X	X			
6 Medicines used for respiratory system conditions					

	A Medicines used for bronchial asthma	x	x			
	B Cough suppressants	X	X	X		
	C Medicines used for colds and sinusitis	X	X	X		
		Ca	itegoi	y (§ 4	l)	
	Group	A	В	C	Lifes. A/B	appl. Lifes.appl. C
7	Anti-infection medicines					
	A Antibiotics (at least two families)	X	X			
	B Anti-bacterial sulphamide	X	X			
	C Urinary antiseptics	X				
	D Anti-parasitics					
	– malaria medicine (in malaria endemic areas)	X	X			
	– preparations against lice and scabies	X	X			
	E Intestinal anti-infectives	X	X			
	F Anti-tetanus vaccines and immunoglobulins	X	X			
8	Compounds promoting rehydration, caloric intake and plasma expansion	X	X			
9	Medicines for external use					
	A Skin medicines					
	- Antiseptic solutions	X	X	X	X	X
	- Antibiotic ointments	X	X	X		
	- Analgesic ointments	X	X	X		
	- Anti-inflammatoryointments/corticosteroids	X	X			
	- Anti-mycotic skin creams	X				
	– Burn preparations	X	X	X	X	
	B Eye medicines					
	- Antibiotic drops/eye ointment	X	X			
	- Antibiotic and anti-inflammatory drops	X	X			
	- Anaesthetic drops	X	X			
	– Eye drops for the management of glaucoma	X	X			
	– Eye rinsing solution (eye wash)	X	X	X	X	X
	– Diagnostic means	X				
	C Ear medicines					
	- Antibiotic/anti-inflammatory solutions	X	X			
	- Anaesthetic drops	X	X			
	D Medicines for oral and throat infections					
	- Antiseptic mouthwashes	X	X			
	E Local anaesthetics					
	<ul> <li>Local anaesthetics given by subcutaneous injection (incl. dental treatment)</li> </ul>	X	X			

Amended by regulation of 13 December 2002 No. 1638.
 Supplementary table containing suggestions for use and dosage of drugs and medicines is not included here.

Appendix 2

Overview of medical equipment required to be part of the ship's medicine storage unit, ref. § 9 and life-saving appliances, ref. § 13.

		ategory (§ 4)				
		A	В	C	Lifes.appl. A/B	Lifes.appl. C
1	Resuscitation equipment					
	Oxygen apparatus with bag and mask (exceeding litres)	2x	x			
	Spare oxygen apparatus	X	X			
	Mechanical aspirator to clear upper respiratory passages	X	X			
	Set of cannulas for mouth-to-mouth resuscitation (assorted sizes)	X	X	X	X	X
	Pocket masks	X	X	X		
2	Dressing and suturing equipment					
	Suture stapler or suture kit with needles	X	X			
	Adhesive elastic bandage	X	X	X	X	X
	Elastic gauze	X	X	X	X	X
	Tubular gauze for finger bandages, with applicato	rx	X			
	Sterile gauze compresses	X	X	X	X	X
	Sterile absorbent compress	X	X			
	Sterile gauze strips	X	X			
	Cotton wool	X	X			
	Sterile sheet for burns victims	X	X			
	Triangular sling	X	X			
	Disposable polyethylene gloves	X	X	X	X	X
	Adhesive dressings (band-aids, plasters)	X	X	X	X	X
	Sterile compression bandages	X	X	X	X	X
	Adhesive sutures	X	X	X	X	X
	Non-absorbable sutures with needles	X				
	Vaseline gauze	X	X			
	Finger-stalls	X	X	X		
	Head bandage	X	X			
	Eye compress	X	X			
	Eye protector, black	X	X			
	Sports tape	X	X	X		
	Suspensorium, medium	X	X			
	Safety pins	X	X	X	X	X

Category (§ 4)

	A	В	C	Lifes.appl. Lifes.app A/B C
3 Instruments				
Disposable scalpels	X	X		
Stainless-steel instrument box	X	X		
Scissors for bandages and dressings	X	X		
Surgical scissors	X	X		
Tweezers	X	X		
Haemostatic clamps	X	X		
Needle forceps	X	X		
Disposable razors	X	X		
Eye magnet	X			
4 Examination and monitoring equipme	ent			
Disposable tongue depressors	X	X		
Reactive strips for urine analysis (protein, glucose, blood, ketones)	X			
Closable plastic bags with space for w ("tablet bags") or similar	vriting x	X		
Temperature charts	X			
Clinical record chart	X	X		
Stethoscope	X	X		
Aneroid sphygmomanometer	X	X		
Standard medical thermometer	X	X		
Hypothermic thermometer	X	X		
Torch for diagnostic use ("pen torch")	) x	X	X	
5 Equipment for injection, perfusion, pr catheterization	incture and			
Catheterization kit	X			
Rectal drip set (rectal probe)	X			
Disposable filter infusor	X	X		
Venous cannulas	X	X		
Urine drainage bags	X			
Disposable syringes and needles	X	X		
Swabs impregnated with disinfectant disinfection	for skin x	X		
Catheter	X			
	C	atego	ry (§ 4	)
	A	В	C	Lifes.appl. Lifes.app A/B C
6 General medical equipment				
Kidney basin	X			
Bedpan	X			
Hot-water bottle	X			

	Urine bottle	X		
	Ice bag	X	X	
	Cold/hot packs	X	X	
	Cotton swabs	X	X	
	Ear protection/ear plugs	X	X	x
	Sunglasses (men's size)	X		
	Eye bath cup (plastic/glass)	X	X	x
	Eye patch, black	X	X	
	Dental filling material	X		
	Dental hygiene kit	X		
7	Immobilization and setting equipment			
	Malleable finger splint	X	X	
	Malleable hand or forearm splint	X	X	
	Inflatable splint / splinting kit	X	X	
	Thigh splint	X	X	
	Collar for neck immobilization	X	X	
	Stretcher providing rigid support to the back and neck and suitable for helicopter lifts	X	X	
8	Disinfection, disinsectization and prophylaxis			
	Disinfectant for the cleaning of equipment, workbench surfaces, etc.	X	X	
	Water-disinfection compound	X		
	Insecticide	X		

# Appendix 3

Drugs the requisitioning of which requires a Control Record Book entry, ref. § 16, and dispensing, ref. § 21, and with a limited requisitioning right for the company and master.

For vessels in all three categories A, B and C, the indicated number of units is intended for 15 persons (crews). For life-saving appliances, the indicated number of units is intended for life-saving appliances certified for up to 25 persons.

				Category (§ 4)				
	Group	Unit		A	В	C	Lifes.appl. Lifes.appl. A/B C	
3	Analgesics and anti-spasmodics							
	A Analgesics, anti-pyretics and anti-inflammatory preparations							
	Codeine phosphate (max. 30 mg)/paracetamol tablets	NB	20 tablets	3	2			
	Codeine phosphate (max. 30 mg)/paracetamol tablets	NB	50 tablets				1	
	B Powerful analgesics							
	Morphine 10 mg/ml injection	NB	10x1 ml	1	1			
	Morphine 10mg/ml pre-filled syringe for auto-injection	NB	items				6	
	Buprenorphine 0,2mg sublingual tablets	NB	10 tablets	1	1			
	Cetobemidon 10 mg suppositories	NB	10 capsules	1	1			
	C Spasmolytics							
	Diazepam 4 mg/ml enema	NB	5x2,5 ml	2	2			
4	Medicines used for central nervous system disorders							
	A Anxiolytics							
	Diazepam 5 mg tablets	NB	20 tablets	3	2		1	
6	Medicines used for respiratory system conditions	,						
	B Anti-tussives							
	Codeine phosphate 25 mg tablets	NB	20 tablets	2	1			

### Comments to provisions of Sections (§§) herein

#### To § 2 paragraph (c)

This exception applies to offshore units that have valid authorization to engage in petroleum activities, and that are equipped with medicinal products and medical equipment as decided by the responsible operator. The purpose of this exception is that it is unnecessary to have double provision of medical supplies in order to meet the requirements in these regulations and the requirements in the regulations pursuant to the Petroleum Act.

#### To § 3 (f)

Includes antidotes, that is medical products indicated as necessary for the treatment of cases of poisoning as indicated in the MFAG (Medical First Aid Guide for Use in Accidents Involving Dangerous Goods) pursuant to § 25.

#### To § 3 (g)

The relevant drugs will belong to group A or group B in Norway and are listed in Appendix 3. The master of a vessel must be particularly aware of the fact that any purchase of strong analgesics and sedatives other than those listed in Appendix 3 may come under this definition and that special requirements with regard to storage, keeping of records, etc. are thus demanded.

#### To § 4

Classification of vessels into categories must be based on the following:

- the trade area for which the vessel is certified
- other documents that restrict the trade area of the vessel.

Vessels certified for the trade areas of small coasting, fjord fishing or in-shore fishing belong to category C.

#### To § 7

The quality of medical supplies must be in accordance with the standards described in the current edition of the World Health Organization's «Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce».

Medical equipment must bear the CE mark, or must meet equivalent requirements in countries where the European Union has concluded a mutual recognition agreement, pursuant to the Medical Equipment Act (Act of 12 January 1995 No. 6 relating to medical equipment).

It cannot be expected that every master of a vessel is able to evaluate whether goods that have been ordered meet these requirements. It is therefore recommended to use pharmacies or ship chandlers who can provide documentary evidence that their products meet the requirements laid down in the regulations.

Medicinal products and medical equipment traded within the European Economic Area must meet these requirements.

Some items found in ship's medicine storage units cannot be classified either as medicinal products or as medical equipment according to the Medicinal Products Act (Act of 4 December 1992 No. 132 relating to medicinal products) and the Medical Equipment Act (Act of 12 January 1995 No. 6 relating to medical equipment) respectively. Consequently, no specific requirements apply to these products.

As a general rule, medical supplies must be labelled in both Norwegian and English. However, one of these languages can be omitted when the conditions in § 7 last sentence are met.

#### To § 9

The pharmacy that supplies the goods should supply medical products in general use in the groups of medicinal products that are defined in the Appendices. Medicinal products that have a broad application should be chosen. The pharmacy should take into consideration the fact that personnel with no formal medical education will administer the medicinal products. Hence, emphasis should be placed on choosing medicinal products that have the least risk of serious consequences as a result of incorrect use and side-effects.

If the shipping company employs a doctor, the choice of medicinal products should be made in consultation with him or her (also pursuant to § 11 of this regulation).

The provision in paragraph 3 that ship's medicine storage units may in certain cases be omitted and replaced with appropriate first aid equipment applies only to vessels that operate in areas within immediate reach of medical services on land, and to small fishing vessels operating in coastal waters.

#### To § 10

The requirement for first aid equipment must be evaluated in relation to the risk factors that are present. On large vessels it may also be appropriate to have first aid equipment in the control room. Among other things, the first aid

equipment must be able to be used to stop severe haemorrhages, to cool the skin after burns (if cold water is not directly available) and to wash out the eyes if chemicals have been splashed in them.

#### To § 11

The kit of medical supplies for acute medical emergencies should contain equipment for administration of oxygen, for intravenous infusion in the event of haemorrhage and circulatory failure, and for intubation. The equipment may also include an automatic defibrillator for use in the event of cardiac arrest.

#### To § 12

Maritime transport of dangerous cargo is governed by the Regulations of 21 May 1987 No. 406 relating to maritime transport of special and dangerous cargo in bulk or as packaged goods.

#### To § 14

For vessels, with the exception of fishing vessels, § 23 of the Regulations of 15 September 1992 No. 707 concerning the accommodation and catering service on ships applies.

For fishing vessels, § 19 of the Regulations of 15 October 1991 No. 713 concerning the location, etc. of accommodation and concerning the catering service for crew on fishing vessels applies.

For passenger ships, § 25 of the Regulations of 2 October 1972 No. 4 concerning calculation of number of passengers and concerning passenger accommodation, etc. applies *in addition*.

#### To § 15

A shipping company may also employ a nurse on board its vessels. The duties and responsibilities of a nurse on board Norwegian vessels are governed by the regulations laid down in the Health Care Personnel Act (Act of 2 July 1999 No. 64 relating to the rights and duties of health care personnel).

#### To § 16

A ship chandler may expedite an order for medical supplies for a vessel. In such cases, the pharmacy shall receive the original order and deal with the order, except invoicing, as though the medical supplies were to be sent directly to the vessel.

Requisitioning of medical supplies must conform to the current regulations relating to requisitioning and dispensing of medicinal products from pharmacies.

By lawfully marketed is meant that both the product and the supplier have national authorization in the country where the purchases were made, that is to say that the product is an approved medicinal product and that the supplier is an authorized supplier of medicinal products.

In Norway, only pharmacies can supply medicinal products to vessels, pursuant to the Medicinal Products Act (Act of 4 December 1992 No. 132 relating to medicinal products), with the exception of business enterprises that have special authorization to supply complete ship's medical storage units, for example medical supplies for life-saving appliances.

In accordance with the Regulations of 27 April 1998 No. 455 relating to requisitioning and dispensing of medicinal products from pharmacies, pharmacies must ascertain the legitimacy of every requisition, and may demand documentation such as master's certificate, trade certificate, or similar documents, before dispensing prescription drugs.

These regulations apply only to the dispensing of medical supplies to *Norwegian* vessels. Foreign vessels are normally equipped with medical supplies in accordance with the regulations of the relevant country. In cases where these regulations are unavailable, the medical supplies of the vessel may be supplemented in accordance with these regulations.

In cases of dispensing of medical supplies to foreign vessels, reference is made to the Regulations of 27 April 1998 No. 455 relating to requisitioning and dispensing of medicinal products from pharmacies and to the regulations and guidelines relating to the import and export of medicinal products.

In order to export medicinal products that are classified as narcotic substances in accordance with the Regulations of 30 June 1978 No. 8 relating to narcotic substances etc. an export certificate (an export permit) is required, with certain exceptions. Such certificates are issued for each individual export. «Export» also includes delivery to vessels registered abroad that are in a Norwegian port. Deliveries from Norwegian pharmacies to Norwegian vessels in foreign ports are not defined as export. However, in order to ensure that the delivery passes through the various customs authorities, an export certificate should be obtained. The export certificate should then be marked, for example: «on transit to a Norwegian vessel».

When vessels engaged in international trade carry narcotic substances on board in accordance with these regulations, this is not regarded as import, export or transit of narcotic substances in Norway, pursuant to § 11 of the Regulations of 30 June 1978 No. 8 relating to narcotic substances etc.

#### To § 17

If a master of a vessel has lost his right to requisition prescription drugs, the shipping company or the shipping company's doctor may make such requisitions. The duties of the master of the vessel such as keeping records of the dispensing of medical supplies and checking medical supplies (pursuant to § 5) are not affected by the withdrawal of the right to requisition.

#### To § 18

Medicines that require cold storage may be kept in locked containers kept in unlocked refrigerators.

#### To § 21

A master of a vessel shall not independently initiate treatment with prescription medicines without first seeking medical advice, unless clear instructions, approved by a doctor, have been given on how to deal with the treatment situation in question.

A record of dispensed medicines a patient has received should include the patient's name, the name of the medicine and the quantity dispensed, the time the medicine was dispensed and details about any consultation with a doctor and, in consultation with the patient, the complaints that the medicine was given for. This requirement applies irrespective of the type of medicine or the medicine's prescription status.

#### To § 22

The monthly inspection of medical supplies for life-saving appliances shall consist of checking that they are present and that the seals are unbroken.

When inspecting medicinal products and medical equipment, attention shall be paid to the following:

- that the store of medicinal products and medical equipment is neat and orderly
- that the supplies are in accordance with the list of contents in the Appendices to this regulation
- that the special storage requirements are met
- that medicines are clearly labelled in accordance with this regulation
- that undated medicines, and other items with a short shelf life, are replaced or will be replaced.

As far as possible, inspection of medical supplies should be undertaken through a Norwegian pharmacy. If a vessel does not call at a Norwegian port within the given time limits, the inspection should be carried out through either a foreign pharmacy, or a company that is licensed to carry out such inspections according to the national legislation, or by an authorized seaman's doctor.

#### To § 24

Coastal radio stations relay requests for medical advice to Radio Medico, Haukeland Hospital. For vessels within the area covered by the Norwegian Rescue Service, requests for assistance in cases of emergency are relayed to a medical emergency coordinating centre, preferably to the centre with medical responsible for the rescue helicopter base in question. If necessary, the medical emergency coordinating centre in question should request helicopter assistance from the rescue service.

Medical evacuation from a vessel shall be carried out in accordance with the guidelines for the Norwegian Air Ambulance Service, insofar as the guidelines can be adapted to maritime conditions.

The bodies that have tasks laid down in this provision should prepare operational procedures describing cooperation between the bodies concerned. These procedures may be prepared as part of the internal control system pursuant to the Supervision Act (Act of 30 March 1984 No. 15 relating to the public supervision of health services).

#### Appendix 1

A list of examples of relevant medicinal products in the different groups has been drawn up. The generic names, indications and suggested directions for use are given for the medicinal products.

#### To Appendix 3

If one or more of the medicinal products in the list are not on the market, they must be replaced by a medical product that is as similar as possible.