

Comparative analysis of the medicinal compounds of the ship’s “medicine chests” in European Union maritime countries. Need for improvement and harmonization

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ABSTRACT

Background: The contents of the ship pharmacy, namely “medicine chest” and its compliance with the respective regulations concerning the type of drugs to be provided for merchant vessels involved in long distance voyages and without a doctor on board were analysed. The current existing disparity between regulations can make medical assistance more complicated, and more often of low quality, due to frequent off-label use of supplied drugs. This study may represent a starting point leading to a model high-quality medicine chest on board ships.

Materials and methods: A comparative analysis between the medicine chest requirements of 12 European countries and the CEE Directive 31 March 1992 n.92/29 was made. Prescriptions of the aforementioned Directive were compared with the WHO Model List of Essential Medicines (third Edition).

Results: The investigation showed a lack of homogeneity of contents. It emerged that some medicine chests lack of several pharmaceutical categories required by the reference standards. The subsequent comparison of the European Directive with the WHO Model List of Essential Medicines has highlighted the absence of some therapeutic categories that in the ship environment can be of important to ensure adequate therapy in many situations.

Conclusion: There are disparities regarding regulations concerning the ship medicine chests. It is crucial to harmonize these and create a single medicine chest for all the ships without a doctor on board, undergoing periodic updates and revisions, based on epidemiological analysis that will ensure high-quality healthcare to seafarers around the world.

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Key words: healthcare quality, seafarer, medicine chest, standardization, healthcare quality in ship

INTRODUCTION

The set of medicines and other medical supplies on board ships is commonly referred to as the “medicine chest”. At the beginning of the eighteenth century and later in the nineteenth century, physicians who embarked carried with them a case containing some therapeutic aids

of that time, to be used on board if necessary [1]. In the nineteenth century, with the increase of maritime traffic, various European States began to regulate health, safety and hygiene protocols on board ships. Some countries have compulsorily prescribed the presence of a “box (chest) of medications” on the ships [2]. An effort to harmonize Euro-

pean regulations on health care on board ships was made at an international health conference held in Paris in 1851. The deliberations and declarations of this conference led to an agreement after which the signatory States undertook to evaluate the hygienic conditions of the vessels, food supplies, the health condition of crews and the presence of a “chest of medicinal products”, and in attachment the instructions for their use [3].

A solution to keep the medicine chest updated and equipped according to the progress of pharmacotherapy is a frequent review of international agreements to provide a well-stocked pharmacy on board ships. The lack of standardization of the ship’s medicine chest at the global level and the diversity in terms of medicines and medical equipment on board of different flagships make not easy the delivery of enough quality medical assistance on board of seagoing vessels. This is true primarily in case of medical advice provided by international Telemedical Maritime Assistance Services (TMAS).

The first global attempt to address this problem was initiated by World Health Organization (WHO) which published the first edition of the International Medical Guide for Ships in 1967. In this document, the WHO, along with a detailed appendix, recommended a minimum provision of medicinal products as standards that had to be maintained by all the ships in international waters [4]. The lack of consensus on standardized medicine chest on board ships still requires an international collaboration. WHO would represent the best-suited supranational organization to promote efforts of unifying the contents of on-board medicine chests. This problem is further complicated due to the diversity of laws and regulations that govern the distribution and use of medicinal products in different countries. At first, the minimum provision of medicines that each ship must have available on board was shown in two publications. They were namely: a) the International Medical Guide for Ships and b) the Medical First Aid Guide for Use in Accidents Involving Dangerous Goods [5]. On the other hand, many countries have regulated, for their fleet, the types and amounts of drugs which must be available on board.

The European Union in the Directive (92/29/EEC) of the Council of 31 March 1992 on the minimum safety and health requirements for improved medical treatment on board ships, has issued a series of recommendations contained in the various annexes. The Annex II, which deals with the allocation of drugs on board ship is divided into nine large categories of medicines for the treatment of various diseases. For each therapeutic category, various drugs have been recommended [6]. The directive ensures that each ship carries drugs belonging to each therapeutic group, depending on the characteristics of the vessel. It also represents a general guideline for member states of

the European Union. European countries having access to international waters must adapt their legislation in compliance with this directive.

The work of harmonization would be useful to reduce the differences in the possibility of delivering high-quality medical care to seafarers. Standardized protocols would get numerous benefits in the unified management of resources, in the preparation of uniform guidelines and treatment protocols and optimization of service on all ships. These efforts would bring economic benefits such as monitoring of costs and consumption of drugs, and especially a minor bureaucratic commitment for port authority which must check and inspect the drugs on board. The final result would be the implementation of a standardized management of onboard pharmacy allowing administering a drug to the patient from the symptoms until pre-hospitalization.

Guidelines on the contents of the medicine chest could represent a relevant point to improve health conditions on board ships. In this analysis, we have compared the contents of medicine chests, in terms of drugs, recommended by the legislation of the European States, for each therapeutic class, referring to Annex II of the Directive (92/29/EEC), which is divided into nine major categories of medicinal products for the treatment of various pathologies [7]. The presence or absence of essential medicines indicated by WHO [8] in the different medicine chests was also analysed.

MATERIALS AND METHODS

In the “Annex II of the Directive (92/29/EEC)” published by the European Commission in March 1992 are reported the 9 major categories of medicinal products required to be on board for the treatment of various pathologies. This work has compared the contents of the “medicine chests” of some European reference maritime countries: France, Germany, Italy, Malta, Spain, United Kingdom, Denmark, Finland, Greece, Netherlands, Cyprus, and Portugal.

The active principles included in the various medicine chests were classified into the nine major categories according to the classification of the Annex II of the Directive (92/29/EEC) [7].

CYPRUS (CY), Section A. This section, published in 2010, lists medicines and medical aids required by Cyprus legislation for sea-going or sea-fishing vessels, with no limitation on the length of voyage [9].

DENMARK (DK), Section A. This section, published in 2007, lists medicines and medical aids required by Danish legislation refers to the minimum provision of the medicine chest for ships with permission for worldwide voyages [10].

FINLAND (FI), Section A. This section, published in 2015, lists medicines and medical aids required by Finnish regulations for sea-going or sea-fishing vessels, with no limitation on the length of voyage [11].

FRANCE (FR), Section A. This section, published in 1996, lists medicines and medical aids required by French regulations for vessels that do not carry passengers and are more than 24 hours away from the port of departure or 8 hours or 100 miles from a nearby port which is equipped with a proper first aid [12].

GERMANY (DE), Section A2. This section, published in 2006, lists medicines and medical aids required by German regulations for ships for merchant traffic and to international navigation short and long with 20 persons or more [13].

GREECE (GR), Section All. This section, published in 1995, lists the medicines and medical aids required by Greek regulations for vessels that do not carry passengers and with no limitation on the length of voyage [14].

ITALY (IT), Section C. This section, published in 2015, lists medicines and medical aids prescribed for domestic vessels and merchant ships for short and long international navigation [15].

MALTA (ML), Section A. This section, published in 2013, lists medicines and medical aids required by Maltese regulations of the minimum provision for ships (including fishing vessels) with no limitation on length or voyages [16].

NETHERLANDS (NL), Section A. This section, published in 2006, lists medicines and medical aids required by Dutch regulations refers to the limitation on the length of voyage [17].

PORTUGAL (PT), Section A. This section, published in 1997, lists medicines and medical aids required by Portuguese regulations for sea-going or sea-fishing vessels, with no limitation on the length of voyage [18].

SPAIN (SP), Section A. This section, published in 1995, lists medicines and medical aids required by the Spanish regulations for vessels engaged in ocean voyages and without a doctor on board [19].

UNITED KINGDOM (UK), Section A. This section published in 2003, lists medicines and medical aids required by UK regulations for merchant ships or fishing boats navigating international waters without travel time restriction and without a doctor on board [20].

As a second step, the list of medicines published in the above Annex II and those of the different countries considered were compared with the WHO Model List of Essential Medicines [8].

RESULTS

The results of the comparative analysis of the contents of medicinal products for systemic use recommended by the European Directive 92/29/EEC and of the 12 European countries examined are summarized in Tables 1 (Cardiovascular system, Gastro-intestinal system, Analgesics and antispasmodics, Nervous system) and 2 (Anti-allergic and anti-anaphylactic, Respiratory system, Anti-infection, Compounds promoting rehydration, caloric intake and plasma expansion).

As shown in Table 1, all 5 classes of cardiovascular drugs indicated by the European Directive are present. For the medicines acting on the gastrointestinal system, Histamine H2 receptor anti-ulcer antagonists are missing from the German, Danish, Finland, French and Dutch medicine chests, whereas the other 6 classes of gastro-intestinal compounds are present. It should be mentioned that in the above five on-board medicine chests, proton pump inhibitor drugs, such as omeprazole, replace the H2-antagonist antiulcer. Even if these are drugs with a different mechanism of action and pharmacokinetics, the therapeutic use is the same, and they can be therefore considered to be interchangeable.

Analgesic and antispasmodics are present in the medicine chests of all countries, except for spasmolytics missing in the Danish, Finnish and Dutch chests. All recommended nervous system compounds are present in the medicine chests of the 12 countries considered.

Analysis of Table 2 shows that all classes of Anti-allergic and anti-anaphylactic, Respiratory system, Anti-infection, Compounds promoting rehydration, caloric intake and plasma expansion, recommended by the European Directive are included in the medicine chests of the 12 countries examined, except for the anti-bacterial sulphonamide, which is missing in the Finnish and French medicine chests.

Table 3 summarizes medicines for external use indicated in the European Directive included in the medicine chests of the 12 countries examined. In general, there is a good correspondence between the European recommendations and the contents of single country medicine chests. The only exceptions are for skin medicines, antibiotic ointments/creams missing in the Danish medicine chest, the antibiotic and anti-inflammatory drops missing in the eye medicines required by Dutch regulations, the antibiotic solutions listed in the ear medicines section absent in the Danish and Germany medicine chest. The antibiotic or antiseptic mouthwashes of the section Medicines for oral or throat infections missing in the Finnish medicine chest.

Data of the analysis of the presence in the "Annex II of the Directive (92/29/EEC)" the so-called Model List Essential Medicine proposed by the WHO, serving as a guide to the development of the national and institutional essential medicine lists [8] are summarized in Table 4. As shown, the main inconsistencies are in the absence of antimalarial, antileprosy, antituberculosis and anthelmintics and antiprotozoals medicines for the Anti-infective medicines class. For the class of Medicines affecting blood, the lack of antianaemia medicines, blood coagulation factors, plasma-derived medicines, and plasma substitutes is noticeable. In the section Hormones, other endocrine medicines and contraceptives, the lack of insulins and other medicines used for diabetes and thyroid hormones and antithyroid

Table 1. Cardiovascular system, Gastro-intestinal system, Analgesics and antispasmodics, Nervous system medicinal products listed in the Annex II of the Directive (92/29/EEC) included (P) or not included (A) in the medicine chests of the 12 European countries examined

Drugs	CY	DE	DK	FI	FR	GR	IT	ML	NL	PT	SP	UK	WHO
Cardiovascular													
Cardio-circulatory analeptics – sympathomimetics	P	P	P	P	P	P	P	P	P	P	P	P	P
Anti-angina preparations	P	P	P	P	P	P	P	P	P	P	P	P	P
Diuretics	P	P	P	P	P	P	P	P	P	P	P	P	P
Anti-haemorrhagics including uterotonics if there are women on board	P	P	P	P	P	P	P	P	P	P	P	P	P
Anti-hypertensive	P	P	P	P	P	P	P	P	P	P	P	P	P
Gastro-intestinal system													
Medicines for gastric and duodenal disorders													
– Histamine H2 receptor anti-ulcer antagonists	P	A	A	A	A	P	P	P	A	P	P	P	P
– Anti-acid mucous dressings	P	P	P	P	P	P	P	P	P	P	P	P	P
Anti-emetics	P	P	P	P	P	P	P	P	P	P	P	P	P
Lubricant laxatives	P	P	P	P	P	P	P	P	P	P	P	P	P
Anti-diarrhoeals	P	P	P	P	P	P	P	P	P	P	P	P	P
Intestinal antiseptics	P	P	P	P	P	P	P	P	P	P	P	P	P
Haemorrhoid preparations	P	P	P	P	P	P	P	P	P	P	P	P	P
Analgesics and anti-spasmodics													
Analgesics, anti-pyretics and anti-inflammatory preparations	P	P	P	P	P	P	P	P	P	P	P	P	P
Powerful analgesics	P	P	P	P	P	P	P	P	P	P	P	P	P
Spasmolytics	P	P	A	A	P	P	P	P	A	P	P	P	P
Nervous system													
Anxiolytics	P	P	P	P	P	P	P	P	P	P	P	P	P
Neuroleptics	P	P	P	P	P	P	P	P	P	P	P	P	P
Seasickness remedies	P	P	P	P	P	P	P	P	P	P	P	P	P
Anti-epileptics	P	P	P	P	P	P	P	P	P	P	P	P	P

CY – Cyprus, DE – Germany, DK – Denmark, FI – Finland, FR – France, GR – Greece, IT – Italy, ML – Malta, NL – Netherlands, PT – Portugal, SP – Spain, UK – United Kingdom; WHO – World Health Organization

medicines was observed. Medicines used for depressive disorders are missing in the section Medicines used in mood disorders.

The results of a further analysis of the presence or absence of medicinal products included in the WHO Model List of Essential Medicines in the different medicine chest of the 12 European countries examined are summarized in Table 5. As shown, several inconsistencies are noticeable.

DISCUSSION

In addition to the legal and logistic issues pertaining to the procurement of specific drugs in different countries of the world, this lack of standardization can be an additional

obstacle to effective treatment of diseases and accidents on board ships. A fundamental requirement to guarantee high-quality care is the availability of drugs that increase the possibility of an appropriate therapeutic choice for the treatment of various diseases more often occurring on board ships. Ideally, the medicine chest, taking into account this particularly sensitive category of workers, has to be validated and be uniform for all the ships worldwide, independently from the flags that they are registered under. Life-saving medicines, that are required to treat certain serious medical conditions emergencies, should have priority and serve as the starting point for the desirable standardization of regulation of this matter, both in terms of types and quantities of therapeutic principles to carry on ships.

Table 2. Anti-allergic and anti-anaphylactic, Respiratory system, Anti-infection, Compounds promoting rehydration medicinal products listed in the Annex II of the Directive (92/29/EEC) included (P) or not included (A) in the medicine chests of the 12 European countries examined

Drugs	CY	DE	DK	FI	FR	GR	IT	ML	NL	PT	SP	UK	WHO
Anti-allergics and anti-anaphylactic													
H1 Anti-histaminics	P	P	P	P	P	P	P	P	P	P	P	P	P
Injectable glucocorticoids	P	P	P	P	P	P	P	P	P	P	P	P	P
Respiratory system													
Bronchospasm preparations	P	P	P	P	P	P	P	P	P	P	P	P	P
Anti-tussives	P	P	P	P	P	P	P	P	P	P	P	P	P
Medicines used for colds and sinusitis	P	P	P	P	P	P	P	P	P	P	P	P	P
Anti-infection													
Antibiotics (at least two families)	P	P	P	P	P	P	P	P	P	P	P	P	P
Anti-bacterial sulphonamide	P	P	P	A	A	P	P	P	P	P	P	P	P
Urinary antiseptics	P	P	P	P	P	P	P	P	P	P	P	P	P
Anti-parasitics	P	P	P	P	P	P	P	P	P	P	P	P	P
Intestinal anti-infectives	P	P	P	P	P	P	P	P	P	P	P	P	P
Anti-tetanus vaccines and immunoglobulins	P	P	P	P	P	P	P	P	P	P	P	P	P
Compounds promoting rehydration, caloric intake, and plasma expansion													
	P	P	P	P	P	P	P	P	P	P	P	P	P

Abbreviations are the same as in the legend to Table 1

Table 3. Medicines for external use listed in the Annex II of the Directive (92/29/EEC) included (P) or not included (A) in the medicine chests of the 12 European countries examined

Drugs	CY	DE	DK	FI	FR	GR	IT	ML	NL	PT	SP	UK	WHO
Medicines for external use													
Skin medicines													
– Antiseptic solutions	P	P	P	P	P	P	P	P	P	P	P	P	P
– Antibiotic ointments	P	P	A	P	P	P	P	P	P	P	P	P	P
– Anti-inflammatory and analgesic ointments	P	P	P	P	P	P	P	P	P	P	P	P	P
– Anti-mycotic skin creams	P	P	P	P	P	P	P	P	P	P	P	P	P
– Burn preparations	P	P	P	P	P	P	P	P	P	P	P	P	P
Eye medicines													
– Antibiotic drops	P	P	P	P	P	P	P	P	P	P	P	P	P
– Antibiotic and anti-inflammatory drops	P	P	P	P	P	P	P	P	A	P	P	P	P
– Anaesthetic drops	P	P	P	P	P	P	P	P	P	P	P	P	P
– Hypotonic myotic drops	P	P	P	P	P	P	P	P	P	P	P	P	P
Ear medicines													
– Antibiotic solutions	P	A	A	P	P	P	P	P	P	P	P	P	P
– Anaesthetic and anti-inflammatory solutions	P	P	P	P	P	P	P	P	P	P	P	P	P
Medicines for oral and throat infections													
– Antibiotic or antiseptic mouthwashes	P	P	P	A	P	P	P	P	P	P	P	P	P
Local anesthetics													
– Local anaesthetics using freezing	P	P	P	P	P	P	P	P	P	P	P	P	P
– Local anaesthetics given by subcutaneous injection	P	P	P	P	P	P	P	P	P	P	P	P	P
– Dental anaesthetic and antiseptic mixtures	P	P	P	P	P	P	P	P	P	P	P	P	P

Abbreviations are the same as in the legend to Table 1

Table 4. Comparison between the WHO Essential Model List and those listed in the “Annex II of the Directive (92/29/EEC)”

WHO Model List of Essential Medicines, 2017	Included in the European Directive 92/29/EEC
MEDICINES FOR PAIN AND PALLIATIVE CARE	Present
ANTIALLERGENICS AND MEDICINES USED IN ANAPHYLAXIS	Present
ANTIDOTES AND OTHER SUBSTANCES USED IN POISONINGS	Present
ANTICONVULSANTS/ANTIEPILEPTICS	Present
ANTI-INFECTIVE MEDICINES	
Antibiotics (at least two families)	Present
Anti-bacterial sulphonamide	Present
Urinary antiseptics	Present
Anti-parasitics	Present
Anti-malarial*	Absent
Intestinal anti-infectives	Present
Anti-tetanus vaccines and immunoglobulins	Present
Antileprosy medicines*	Absent
Antituberculosis medicines*	Absent
Anthelmintics and Antiprotozoals*	Absent
ANTIMIGRAINE MEDICINES	Present
MEDICINES AFFECTING THE BLOOD	
Antianaemia medicines*	Absent
Medicines affecting coagulation	Present
Blood coagulation factors*	Absent
Plasma-derived medicines and Plasma substitutes*	Absent
CARDIOVASCULAR MEDICINES	Present
DERMATOLOGICAL MEDICINES (topical)	Present
DIAGNOSTIC AGENTS	Present
DISINFECTANTS AND ANTISEPTICS	Present
DIURETICS	Present
GASTROINTESTINAL MEDICINES	Present
HORMONES, OTHER ENDOCRINE MEDICINES, AND CONTRACEPTIVES	
Adrenal hormones and synthetic substitutes	Present
Insulins and other medicines used for diabetes*	Absent
Thyroid hormones and antithyroid medicines*	Absent
MUSCLE RELAXANTS (PERIPHERALLY-ACTING) AND CHOLINESTERASE INHIBITORS	Present
OPHTHALMOLOGICAL PREPARATIONS	Present
MEDICINES USED IN MOOD DISORDERS	
Anxiolytics	Present
Neuroleptics	Present
Medicines used in depressive disorders*	Absent

*Categories of medicinal products not included in the “Annex II of The Directive (92/29/EEC)”

Among the most relevant Essential Medicines not included in the medicine chests, there is a major shortage for the class “Medicines Affecting Coagulation” in terms of content

of drugs interfering with coagulation mechanisms. Seafarers are particularly exposed to the risk of serious accidents [21], which can result in bleeding. Circulatory system diseases

Table 5. Analysis of the availability of pharmacological specialties reported in the WHO Model List of Essential Medicines, not included in the European guidelines (Annex II European Directive 92/29/EEC), as shown in Table 4

Drugs	CY	DE	DK	FI	FR	GR	IT	ML	NL	PT	SP	UK
Anti-malarial	A	P	P	P	P	P	P	P	P	A	A	A
Antileprosy medicines	A	A	A	A	A	P	A	P	A	A	A	A
Antituberculosis medicines	A	A	A	A	A	A	A	A	A	A	A	A
Anthelmintics and Antiprotozoals	P	P	P	A	P	P	P	P	A	P	P	P
Antianaemia medicines	A	P	A	A	A	A	A	A	A	A	A	A
Blood coagulation factors	P	P	A	P	P	P	A	P	P	A	P	A
Plasma-derived medicines and Plasma substitutes	A	A	P	A	A	P	P	P	P	P	P	P
Insulins and other medicines used for diabetes	A	A	A	P	P	A	P	A	A	A	A	P
Thyroid hormones and antithyroid medicines	A	A	A	A	A	A	A	A	A	A	A	A
Medicines used in depressive disorders	A	A	A	A	A	A	A	A	A	A	A	A

Abbreviations are the same as in the legend to Table 1

are the most frequent death causes, followed by external causes such as accidents and violence [22]. In view of this, availability of certain life-saving drugs is desirable for giving as much as possible proper health care and preventing fatalities. Another shortage is represented by antiprotozoal, antimalarial, anthelmintic, scabicides and pediculicides. The "Annex II of the Directive (92/29/EEC)" as well as other European Medicine chests lack of many products of this class (Table 2). This may be problematic as infectious and parasitic diseases occupy the 3rd place among the causes of death on board ships [22]. Moreover, "Medicines used in mood disorders" such as subclass of antidepressants, included in the WHO Model List of Essential Medicines, are missing from the "Annex II of the Directive (92/29/EEC)" (Table 2). This is another important lack, because seafarers may experience psycho-emotional problems and increased fatigue [23]. Another class of drugs absent from European Medicine chests are antidiabetic drugs such as insulin, metformin, glucagon and other specialties, provided by the WHO Model List of Essential Medicines, present only in Finland, France, Italy and United Kingdom medical chests. The lack of certain types of drugs may force doctors to make different prescriptions from those, which they would have made in the case of availability of more specific therapeutic agents [24]. One consequence of this shortage may be a great off-label use of medications. Off-label prescriptions is allowed and from time to time is useful, but if exaggerated can lead to non-negligible problems [25–26].

The comparative analysis between the "Annex II of the Directive (92/29/EEC)" and the WHO Essential Model List confirms the presence on board ships of active substances, which are considered to be lifesaving such as penicillin, hydrocortisone, adrenaline, furosemide, anti-tetanus immunoglobulin. These are all included in the ship medicine

chest, although a greater possibility of choice in terms of formulation for these active principles would be desirable. In general there is a good correspondence between essential medicines recommended by the WHO Model List, those required by the European Directive – Annex II 92/29/EEC (see Table 5) and the contents of the 12 medicine chests studied. However, the lack of antimalarial medications in some flag states regulations remains an issue, taking into account that merchant ship may sail in areas identified as epidemiological outbreaks of this parasitosis.

Seafarers should benefit of both preventive and therapeutic health care approaches. This requires the ability to identify and assess risks in workplaces and the systematic recording of environmental stress and their pathological, pathophysiological and psychological effects. To ensure an adequate level of medical care, the appropriate stocks of drugs and medical equipment is necessary. From this availability depends on much of the opportunity to provide quality medical assistance to seafarers. An adequate provision of drugs, together with enough quality telemedical assistance, may guarantee health/life protection of seafarers at sea [27].

CONCLUSIONS

The results of this work suggest the need of a revision of national and international regulations, aimed at the development of a universal ship's medicine chest, based on dedicated pharmacoepidemiologic studies. Another issue that should be considered is the periodic and frequent update of these lists. In this way, thanks to technological evolution we will be able to shorten distances and take advantage of a high quality medical assistance at sea. The best solution to the problem of medicine chest standardization is to homogenize them to ensure that any ship sailing in international waters carries well-equipped and standardized

medicine chest. This will be helpful for seafarers and those from ashore are treating them.

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CONFLICT OF INTEREST

The authors declare no conflicts of interest with respect to the research, authorship, and/or publication of this article.

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