Legal requirements and practice of the transport of healthcare waste within European Union

Karine Brück & Pedro Ramalho

The Athisa Group, Granada, Spain & Biotask, Lisbon, Portugal

Abstract

This article analyses the main characteristics of the legal system set up to transport hazardous healthcare waste by road within the European Union. It is based mainly on the "European Agreement on Transport of Dangerous Goods by Road" (ADR) and on the „Basel Convention on the Control of Transboundary Movements of Hazardous Waste andtheir Disposal", which have been incorporated to European and Members' States law.

The article explains how in practice transfers between Spain and Portugal function and the effective working of the whole system, even though the administrative divisions of Spain complicate the system.

Keywords

Healthcare waste transport – ADR - Basel Convention – transfer of waste

1 Introduction

Transport of healthcare waste moves enormous quantities within European Union every year and is regulated by European and international legislation on the transport of hazardous goods, according to the classification established internationally by UNO. From a legal point of view, two international instruments have been incorporated in European Law to regulate this sector. The first is the "European Agreement on Transport of dangerous goods by road", known as ADR according to its French initials, incorporated into European Law by the means of the "Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road". This legal instrument establishes safety requirements that transport, loading and unloading of this kind of merchandise must respect and is applied in 46 countries. It entered into force in 1957 and is subject to biennial review. For international road transport, the current version is 1 January 2009 and from July 1, 2009 it has been applied to transportation within the members states of the European Union. The second is the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal which came in force in 1992 and which has been incorporated into European Law by the means of Council Regulation (EEC) Nº 259/93 of 1 February 1993 on the supervision and control of shipments of waste within, into and out of the European Community. This Convention has been adop-

ted by 173 countries around the world and its main aims are to avoid illegal shipping of hazardous waste, mainly to developing countries and to Eastern Europe, to minimize the transboundary movement of hazardous waste, ensure that such wastes are controlled and disposed of respecting the environment, as close as possible to their source of production and to minimize production of hazardous waste at source.

2 The "European Agreement on Transport of dangerous goods by road" (ADR)

This agreement has a much broader implementation than just the European Union territory and its main concern is to ensure the safety of transport of dangerous goods by road. It also implements the transport of hazardous waste in general and the transport of healthcare waste within European Union, in particular in accordance with the principles of environmental protection and standardization of existing rules allowing free movement within the EU of this type of waste. Security requirements to promote safe transport of hazardous waste can be grouped into 3 categories: requirements regarding packaging and labelling of this waste; conditions relating to vehicles and finally conditions about drivers. Moreover, some general precautions according to the type of roads used and speed must be respected and the „traceability" of waste must be fulfiled. **Fehler! Es ist nicht möglich, durch die Bearbeitung von Feldfunktionen Objekte zu erstellen.**

2.1 Requirements regarding packaging and labelling

The classification system of ADR dangerous goods is based on the Recommendations on the Transport of Dangerous Goods drafted by the United Nations Committee of Experts on the Transport of Dangerous Goods and published in a document known as the "Orange Book" (colour of its cover.) This system, designed to be applied globally to all modes of transport, categorises goods into nine different classes according to the main type of danger that may arise during transport (explosive, toxic, flammable, infectious, etc.). Each class corresponds to a series of specific protection measures. Among these are:

Class 6.1 Toxic substances: Toxic substances which are liable to cause death or serious injury to human health (solid toxic disinfectants, toxic liquids, pesticides, etc.)

Table 1 Classification of Hazardous Waste

	Hazardous Materials
	**Class 6.1**: Poison

Class 6.2: Biohazardous substances; the World Health Organization (divides this class into two categories: **Category A**: Infectious; and **Category B**: Samples (virus cultures, pathology specimens, used intravenous needles)

Table 2 Classification of Hazardous Waste

	Hazardous Materials
	**Class 6.2**: Biohazard

In healthcare waste sector, these 2 classes correspond to the 2 main types of hazardous medical waste that exist: chemical waste (class 6.1.) which represent less than 10% of the dangerous healthcare waste generated into the hospitals (basically expired medicines, formol, xylol, etc.) and biohazardous waste which represent approximatively 90% of the hazardous medical waste. Moreover, hazardous substances to be legally transported must be identified by their UN number and the trailers which transport these goods must be marked using this four-digit UN number. This identification enables competent authorities in the different countries to know the material transported and how to act in case of accident because these goods must be transported with their specific Safety Data Sheet. Medical waste with number UN 3291 (Waste or reusable material derived from medical treatment of animals or humans, or from biomedical research, which includes the production and testing of biological products) and moreover must have a specific packaging. The marking and labelling must be indicated on all packages containing dangerous goods.

In daily practice, healthcare waste managers use a colour code to identify easily the type of medical waste in the containers used, similar to the picture below. As containers are normally found in the different services of the health centres and hospitals, the training and use for staff in segregation of the waste is simplified to ensure correct and efficient management.

Figure 1 Coloured containers for medical waste

In Portugal and parts of Spain, containers normally used for receiving healthcare waste and for transporting it according to all European and international standards are 60-litre-reusable containers used for all hazardous health care waste, except sharp objects for which “one-use specific containers” of different capacities are used. Reusable green, yellow or red 60-litre-containers (the coloured code normally used in Spain and Portugal) are certified for Class 6.2. of ADR and for classes 18.00.00 of the European Waste List. They are totally cleaned and disinfected and can be put into the different services of the hospitals and/or in the central deposit (according to the waste characteristics and production in the services). Their manufacture is subject to E.C. rule (DIN-V-30739) and they are rigid, leak-proof containers, capable of retaining liquids and passing the following tests: falls, leak-proof, internal (hydraulic) pressure, stacking, perforation resistant.

These containers are disinfected in the treatment plant where wastes are sterilized. Waste which has normally to be incinerated must be transferred to France or Germany where the process is carried out; the choice of the country depends basically on the price of this service.

Figure 2 Container for medical waste

Packaging for use with clinical waste has to comply with the requirements of P621. Dangerous goods shall be packed in good quality packaging and healthcare waste is included in Group II Packaging, specific for materials presenting moderate danger. The containers must be strong enough to withstand any normal shocks during transport, including transhipment between transport devices or between transportation and warehousing as well as the removal of the pallet or overpack with a view to a subsequent manual or mechanical handling . Packaging shall be constructed and closed when waste is prepared for shipment in order to prevent any loss of content that might be caused under normal conditions of transport, by vibration or temperature variations, humidity or pressure (due to, for example, the altitude). Packaging shall be closed in accordance with information provided by the manufacturer. These provisions apply, as appropriate, to new packaging, reused, reconditioned or remanufactured and new, reused, repaired or rebuilt and new packaging.

Except as otherwise stated in the ADR, the UN number corresponding to the goods, preceded by the letters "UN“ must appear clearly and durably marked on each package transported. In the case of unpackaged objects, the mark must appear on the object itself in its cradle or on its handling, storage or release device.

Figure 3 Barcode and label for identification of the packages

Besides all the information required for transport, waste managers add a label with a barcode on all the containers. This label allows the service where waste has been produced, production date, weight of waste, etc to be identified. With the labelling of the containers, it is possible to identify the “quality” of the segregation in production sites (afterwards, it is possible to know the exact origin of one specific container) and it is possible, with the training of the health care professional to improve segregation and to reduce the production of hazardous health care waste directly at its origin.

2.2 Requirements regarding vehicles

The regulation requires a physical separation between the driving cockpit and the cargo area, parking lights, fire extinguishers in the cabin and outside, a deposit of water to allow hand washing, a system for securing the load, a protected electrical system: all connections in a box, battery isolator switch (in the cabin and the engine), an independent lighting in the loading area, orange number plates, a box of tools, etc...technical requirements are numerous. From a practical standpoint, the vehicles must meet all the conditions imposed, have passed the technical inspection to receive the approval to transport dangerous goods under ADR. So a first examination of this authorization is sufficient to determine if a vehicle meets the standards set out in the transport of hazardous medical waste.

2.3 Requirements regarding drivers

They must possess a professional certificate for driving dangerous goods issued by the competent authority following the completion of a technical course and practical exercises. The crew must know how to use fire-extinguishing apparatus. During transport, smoking is prohibited in vehicles and their vicinity. It is forbidden to carry passengers except the crew in vehicles carrying dangerous goods. Again, the accent is on safety.

2.4 General precautions and "traceability" of waste

Precise speed limits, time restrictions, mandatory routes using the prevailing motorways and ring roads, parking restrictions, restrictions on movement in road tunnels ... are imposed by the legislation.

All these elements must be taken into account when the integral healthcare waste manager is elaborating the circuit to collect the waste produced in the different hospitals and healthcentres to transport them to the treatment plant and final disposal. Moreover, in practice, we must stress the importance of management in real time with satelite location of the lorries working to choose the itineraries. These new technologies permit immediate optimization based on the variable parameters that may occur during the transport circuit. This new management tool can be very important and to help disminish risks, problems and costs.

The other important aspect is to be able to follow healthcare waste all the way, not only during transport but also „from the craddle to the grave". For this reason, apart from the specific labelling with barcodes, as we have seen above, the Basel Convention procedure of notification will be used if there is a transfer of healthcare waste which involves 2 countries.

3 The "Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal"

3.1 General principles

We have seen that ADR determines the rules of security mainly for vehicles, packaging and transport and the Basel Convention establishes rules to control, transboundary movements and disposal of hazardous waste for human health and the environment when at least two States are involved in the movement at international level.

The premise of Basel Convention is that no waste can be exported if the importing state has not given consent in writing to the specific import of such wastes.

Information about proposed transboundary movements must be reported to the States concerned by a notification form, so they can assess the implications for human health and the environment of the proposed movement. The principles of proximity, priority for recovery and self-sufficiency at Community and national levels are applied. Regulation (EEC) No 259/93 with effect from 12 July 2007 was replaced by Regulation (EC) No 1013/2006 from European Parliament and the Council of 14 June 2006 on shipments of waste [Official Journal L 190 of 12.07.2006]. The regulation applies to almost all types of waste except mainly radioactive waste that has its own control system. The Regulations set out two different transfer control procedures: The first known as "green list" applies to non-hazardous waste destined for recovery and it requires only that information be given to the competent authority. The second is the notification procedure, which applies to all transfers of waste for disposal and hazardous waste for recovery. When healthcare waste is to be disposed of, the procedure used is notification. This procedure requires that the competent authorities of the countries involved in the shipment (country of origin, countries through which the waste transit and destination countries) give their consent before any transfer. To ensure the proper functioning of the single European market, the notice need to be sent only by the notifier to the competent dispatching authority, which is responsible for transmitting the notification to the competent destination and transit authorities. These authorities must give their consent (with or without conditions) or objections within 30 days. The transfer of waste requires a contract between the person in charge of transfering the waste and the recipient of such waste. This contract must be accompanied by financial guarantees in case of transfer of medical waste as in the case of all waste subject to notification requirement.

3.2 Practice

From the entry into force of the new framework Directive 2008/98/EC, through article 19, this regulation will be applied to transport of dangerous waste within a Member State. This is an innovation for Portugal where competent authorities are centralized in the Portuguese Agency for Environment (Division of Waste and Contaminated Soils) but not so much for Spain because of its administrative organization. Spain is divided into 17 autonomous regions or “communities” which are already obliged to prepare documents for transfer as if each region crossed were an independent country. Regulation on medical waste is different depending on the region. There is no general rule about the classification of medical waste in hospitals or for treatment systems and disposal permits, even though Law 10/1998, of April 21, on Waste (BOE nº. 96, April 22, 1998) apparently standardizes the sector in the country. Some areas accept incineration, some not, single use containers are required, for example, in Catalonia, while the reusable one is the rule in Andalusia. Each different region requires proper transport and management authorisations and each Community has to have its own treatment facilities to

implement the self-sufficency principle. Although there is a national plan on hazardous waste, there are, however, 31 different regional plans related to this matter.

4 Conclusions

Inevitably, the legislation imposes considerable costs on the integrated healthcare waste management. It is therefore essential that managers not only understand the regulation in detail but seek to arrange an efficient and effective system that fulfills the demands that society makes in such a sensitive and important matter. Moreover, private companies involved in this sector have developed a whole strategy to trace the healthcare waste from the moment of its production until its safe final disposal. Further to the framework directive, the European Union, through the implementation of international regulations has developed a whole body of legal requirements which combines obligations that reinforce transport safety, environment and health protection and the functioning of the single market. It succeeds in finding the balance between these apparently antagonistic aims regulating the system throughout Europe to the benefit of us all.

Author's address(es) *:*

Ing. Dipl.-Pedro Ramalho
Biotask, Bio-technology Solutions
Parque Empresarial de Torres Vedras. Lote A1
Ar 9 Paúl
2560-383 Torres-Vedras (Portugal)
Telefon +351 965 00 55 73
Email: pramalho@eco-task.com

LL.B. (Liège), LL.M. (Brussels) Karine Brück
Grupo Athisa
Periodista F.J. Cobos, 18 Edificio Camposol, 1-1ºC
18.014 Granada (Spain)
Tel: + 34 629 90 20 12
Email: karinebruck@yahoo.es
Website: www.athisa.es