

Eucomed-SBA Position Paper Sterile Barrier Systems and the Packaging Waste Directive

Executive Summary

This Eucomed-SBA Position Paper addresses the question of whether or not sterile barrier systems (hereafter referred to as SBS) should be considered “packaging” under the PPWD. Eucomed and SBA conclude that SBSs should not be treated as packaging for the following key reasons:

- SBS should be considered as an integral part of, or ‘accessories’ to, medical devices, as defined under Directive 92/42/EC concerning Medical Devices (‘MDD’). They are required by the MDD to perform an ongoing function - safeguarding the sterile environment of the medical device up until the moment that it is finally exposed for use. Although the MDD does not define the term ‘packaging’ there are a number of references to packaging which indicate that it is conceptually distinct from SBS. Whilst the term ‘packaging’ need not have the same legal definition under the MDD and the PPWD the fact that SBS are conceived as performing a function/constituting something other than packaging is important under the terms of the PPWD.
- The definition of packaging under the PPWD is exhaustive. Of the three categories of packaging included in the definition it is only the first - ‘sales packaging or primary packaging, i.e. packaging *conceived so as to constitute a sales unit to the final user or consumer at the point of purchase*’ - that could arguably cover SBS. However, it is apparent from the MDD that SBS are not *conceived* as the sales unit. Rather, SBS exists to perform a specific regulatory requirement ensuring the sterility of medical devices. On the mere facts alone, SBS do not constitute the ‘sales unit’ since medical devices, together with their integral SBSs, in very many cases are not purchased individually but rather in containers/cartons that deliver to the customer/user a number of medical devices. It is this container/carton which is conceived as and actually forms the unit of sale i.e. constitutes the sales packaging, likewise in instances where a single high-value sterile medical device is purchased.
- At a practical level, the context in which SBS are used mitigates against it being considered packaging. SBS often becomes contaminated during the course of a medical procedure - rendering it medical waste. It is not reasonable to assume that this contamination could always be avoided. Unsuccessful attempts to segregate the SBS from any medical contamination present a real health risk to those charged with collecting and recovering them. A contaminated SBS, if not treated as such, could pass a serious or even fatal disease to the handler. For these reasons, it is recognized, as the safe and common practice, to dispose of the SBS together with the medical device as if it were an integral part of or an accessory to the device (both fall under the scope of the Medical Device Directive, 93/42/EEC). These considerations - particular to conditions of working in a medical environment - mitigate against an overly literal reading of the PPWD and provide additional grounds to conclude that SBS are not - and cannot be intended to be treated as - packaging. Treating SBS as packaging would also be contrary to the objective in the 6th Environmental Action Programme that ‘hazardousness should be reduced’ and wastes ‘should present as little risk as possible’ because treating SBS as packaging would actually risk increasing the risks associated with treatment of waste. Finally, given the significant number of SBS disposed of in the EU per year it would be surprising if these items, which cannot safely or practically be treated as required under the PPWD, were to be counted in assessing whether Member States satisfied the required ‘recovery targets’ under the PPWD.
- Finally, Directive 2004/12/EC, amending Directive 94/62/EC on PPW, summarizes the position of SBSs as outlined above and thus excludes them from being considered as packaging under Article 1 i) with the wording as follows: “items shall be considered to be packaging if they fulfil the above definition without prejudice to other functions which the function might also perform unless the item is an integral part of the product throughout its lifetime and all elements are intended to be used, consumed or disposed of together.

Technical annex to Eucomed-SBA Position on Sterile Barrier Systems and the PPW Directive

1. Introduction

Eucomed and SBA are concerned by the fact that Member States are taking contradictory approaches to the treatment of SBS, as regards whether it constitutes 'packaging' under the PPWD. The treatment of SBS as packaging by some Member States has substantial costs for industry and seriously impedes its ability to market products throughout the EU in a consistent manner with regulatory certainty. There is an apparent contradiction between the objective of the MDD - to 'guarantee the free movement of such devices within the internal market'¹ - and the application of differing standards to SBS which hinder this objective. This Position has been drafted to assist in clarifying the sometimes contradictory approaches taken concerning the treatment of SBSs.

2. Understanding SBSs

Before examining the regulatory requirements applicable to SBSs (below) it is necessary to understand, in practical terms, how they perform and are employed. SBSs provide a secure and sterile environment for medical devices. SBSs remain with the medical device up until just before the device is used in a medical procedure. Up until that moment it is an integral part of the sterile medical device and is manufactured with the medical device to ensure the sterility of the medical device is maintained up to the *point of use*. The medical device must be sterile up until the moment of use or cannot be safely employed without compromising the health of the patient. As soon as the SBS is opened, the essential sterile environment that it provides no longer exists. The device must be used immediately and must not come into contact with anything posing a risk to its sterility (and thereby a patient's health). The SBS is placed out of range of the patient once the medical device is released. Similarly, once the medical device has been used it is placed out of range from the patient and third parties (since it is now contaminated). The medical device is typically placed with the SBS, thereby contaminating it (if not already contaminated by contact with other items/substances resulting from the medical procedure).

The MDD establishes the regulatory requirements applicable to 'medical devices and their accessories'. Accessories are 'treated as medical devices in their own right'. (Both are referred to as 'devices'.²)

A 'medical device' is defined, in so far as is material, as:

'...any instrument, apparatus, appliance, material or other article, whether used alone or in combination...to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means...'³

An 'accessory' is defined, in so far as is material, as:

'...an article which whilst not being a device is intended specifically by its manufacturer *to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device*;⁴ (Emphasis added.)

A device may only be placed on the market and put into service if it does not 'compromise safety and health of patients, users and, where applicable, other persons when properly installed, maintained and

¹ Recitals.

² Article 1(1).

³ Article 1(2)(a).

⁴ Article 1(2)(b).

used...⁵. Devices must meet certain 'essential requirements' (in order for a device to enter the EU market):

*'Devices delivered in a sterile state must be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions laid down, until the protective packaging is damaged or opened.'*⁶ (Emphasis added.)

The 'pack' is what is called, by the industry, a SBS. It is apparent from the foregoing that the MDD requires that SBS perform a function (safeguarding the sterile environment up until the moment that the medical device is finally exposed for use) and that they must not be re-used.

As with other 'New Approach' Directives, the MDD provides that in order to '...demonstrate conformity with the essential requirements and to enable conformity to be verified, it is desirable to have harmonised European standards *to protect against the risks associated with the design, manufacture and packaging of medical devices...*' The European Committee for Standardisation (CEN) and the European Committee for Electromechanical Standardisation (CENELEC) are the competent bodies for the adoption of these harmonised standards (on a mandate from the Commission)⁷. To date, no standards have been adopted by CEN or CENELEC concerning the issue of SBS/devices and packaging waste.⁸ We note however, that as early as 1995, the CEN/BTS⁹ "healthcare" meeting resolved - on the advice of the Commission - that 'packaging materials and systems' were:

'To be considered as

- Part of the device itself for devices labelled and supplied "STERILE".¹⁰

It follows from the foregoing, that SBS may be properly considered as an 'accessory' under the MDD. SBS perform an integral function supporting the medical device to enable it to be used as conceived - as a safe and sterile item for medical use. Indeed, we note that DG Enterprise has reached the same conclusion in correspondence with Eucomed:

'A sterile barrier system has two functions: it is the means used in order to enable the sterilisation of a medical product intended to be delivered in a sterile state, and secondly, it is intended to preserve the integrity of the sterile product in order to enable its use in accordance with the manner intended by its manufacturer. Consequently, *a sterile barrier system is to be considered, in the framework of 93/42/EEC Directive on medical devices, as an accessory to a medical device*'.¹¹

3. Packaging under the MDD

The MDD does not define the term 'packaging'. However, there are a number of references to packaging in its provisions:

- The '*packaging and/or label* of the device must distinguish between identical or similar products sold in both sterile and non-sterile condition'.¹²
- The CE marking 'must appear in a visible, legible and indelible form *on the device* or its *sterile pack*, where practicable and appropriate, and on the instructions for use. Where applicable, the CE marking must also appear on *the sales packaging*'.¹³ This last point is particularly significant in that it makes an implicit distinction between: (a) the device; (b) the SBS; and (c) sales packaging, i.e. indicating that, conceptually, the SBS and the sales packaging are *distinct* items.

⁵ Article 2.

⁶ Annex I para. 8.3

⁷ Recital.

⁸ Harmonized standards EN 13428 and EN 13432 concerning packaging have been published in the Official Journal of the EU. 5 draft standards were issued for consultation (which closed 28 February) on the issue of packaging alone, with the aim of adoption in spring 2004.

⁹ BTS stands for 'Technical Sector Board'.

¹⁰ 9th CEN/BTS 2 "Healthcare" meeting, BTS 3H N 423, 1995-04-24/25/26.

¹¹ ENTR/G/4/PT/an D(2001) 845532, 21.11.2001.

¹² Annex I para. 8.7

¹³ Article 17(2).

- A similar distinction is repeated later where it is stated that ‘Each device must be accompanied by the information needed to use it safely and to identify the manufacturer...As far as practicable and appropriate, the information needed to use the device safely must be set out *on the device itself* and/or *on the packaging for each unit* or, where appropriate, *on the sales packaging*.¹⁴ If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices. Instructions for use must be included *in the packaging for every device*...’¹⁵ i.e. indicating that, conceptually, the device (both the medical device itself and any accessory to it, such as the SBS) is *distinct* from (a) the sales packaging or (b) the packaging for each unit).
- As a final example, the label must bear certain particulars including ‘the name or trade name and address of the manufacturer...the label, or *the outer packaging*, or instructions for use, shall contain in addition the name and address of either the person responsible...’¹⁶

4. Analysis

In assessing whether SBS are packaging under the PPWD it is necessary to consider: (a) the MDD; (b) the body of the PPWD itself; (c) the recitals to the PPWD; (d) the Explanatory Memorandum to the PPWD, Parliamentary statements on the same and the 6th Environmental Action Programme¹⁷; (e) the objective pursued by the PPWD; and (f) any relevant decisions of the European Court of Justice (ECJ) (none at present).

(a) The MDD

The term ‘sales packaging’ need not necessarily, as a strict matter of law, have the identical definition in the MDD as in the PPWD. Nonetheless, the fact that the MDD distinguishes between devices/their accessories and their packaging is persuasive in reaching the conclusion that SBS are not packaging. This is because the PPWD includes in its definition of ‘packaging’ (examined below) the notion of whether the packaging is *conceived* as constituting a unit of sale. It is apparent from the requirements of the MDD that the SBS does not perform the function of defining the unit of sale. It performs a specific - legally prescribed and regulated - function in relation to each device, not each sales unit.

(b) The Body of the PPWD

The Directive covers:

‘...*all* packaging placed on the market in the Community and all packaging waste, whether it is used or released as industrial, commercial, office, shop, service, household or any other level, regardless of the material used.’¹⁸ (Emphasis added.)

It applies, ‘*without prejudice to existing quality requirements for packaging* such as those regarding safety, *the protection of health* and the hygiene of the packaged products or...the provisions of Council Directive 91/689/EEC of 12 December 1991 on hazardous waste’.¹⁹ The foregoing provision means that the requirements of the PPWD apply irrespective of any specific measures addressing packaging quality requirements in the fields specified. We consider that the MDD, properly construed, is not primarily concerned with quality requirements for packaging addressing the protection of health. Rather, it addresses the free movement of medical devices and their accessories (including SBS) and the essential requirements that these must satisfy. The MDD cannot, in our view, be properly construed as a measure substantially addressing quality requirements for packaging - indeed, as noted above, the term is not defined in the MDD but is only referred to in terms which distinguish it from the medical device and the SBS.

¹⁴ Annex I para.

¹⁵ Annex I para 13.1.

¹⁶ Annex I para 13.3.

¹⁷ L 242/1 O.J. 10,09,2002.

¹⁸ Article 2(1).

¹⁹ Article 2(2).

Packaging is defined in the PPWD as:

'...all products made of any materials of any nature to be used for the containment, protection, handling, delivery and presentation of goods...from producer to user or the consumer'. Non-returnable items' used for the same purposes shall also be considered to constitute packaging.

'Packaging' consists *only* of:

- (a) sales packaging or primary packaging, i.e. packaging *conceived* so as to *constitute a sales unit to the final user* or consumer at the point of purchase;
- (b) grouped packaging or secondary packaging, i.e. packaging conceived so as to constitute at the point of purchase a grouping of a certain number of sales units whether the latter is sold as such to the final user or consumer or whether it serves only as a means to replenish the shelves at the point of sale; it can be removed from the product without affecting its characteristics; and
- (c) transport packaging or tertiary packaging, i.e. packaging conceived so as to facilitate handling and transport of a number of sales units or grouped packagings in order to prevent physical handling and transport damage. Transport packaging does not include road, rail, ship and air containers'.

It is hard to conceive of SBS falling within categories (b) and (c). SBS are, *prima facie*, neither grouped packaging or transport packaging because by their very nature they perform an integral function relating to only *one* medical device. This leaves only category (a) as requiring consideration. Since the definition of packaging in the PPWD is exhaustive, if it does not fall under this provision then it is not packaging under the PPWD. The following considerations indicate that it does not fall under this category:

- Firstly, a SBS cannot reasonably be conceived as the unit of sale. The packaging containing single or multiple sterile medical devices, *together with their integral SBSs*, is properly described as the sales/primary packaging.
- Secondly, a SBS is an integral part of or accessory to the medical device and as such does not perform a conventional sales packaging function (mere containment, protection etc.). Rather, the SBS is a compulsory element/accessory to the medical device providing an ongoing essential medical function and is legally required to fulfil this function. The medical device cannot be sold without a SBS - clearly not the case for most sales packaging. In contrast with most sales packaging the SBS also remains with that which it contains almost to the end of its life - performing a continuing function.

Article 20 of the PPWD provides:

'The Commission, in accordance with the procedure laid down in Article 21, shall determine the technical measures necessary to deal with any difficulties encountered in applying the provisions of this Directive in particular to primary packaging for medical devices and pharmaceutical products, small packaging and luxury packaging.'

This provision only indicates that the definition of primary/sales packaging for medical devices is not a straightforward matter - hence the different positions taken by Member States and Commission services. Article 20 does not indicate, one way or another, whether SBS are primary/sales packaging. This is confirmed by the recitals to the PPWD ('Whereas it is necessary to provide for specific measures to be taken to deal with any difficulties encountered in the implementation of this Directive in accordance, where appropriate, with the same committee procedure'). We understand that the Article 21 procedure (involving a committee of Member State representatives) has not been used to clarify this issue.

As already noted, SBS invariably becomes contaminated and thereby becomes medical waste. This can only be safely used for energy recovery along with other suitable medical waste. DG Environment has indicated that this is 'a definite option for this type of packaging'²⁰. The PPWD establishes 'recovery' targets for the territories of Member States²¹ and requires them to establish 'Return, collection and recovery systems' to provide for, amongst other things, '...recovery...of the packaging

²⁰ ENTR/G/4/PT/an D(2001) 845532, 21,11,2001.

²¹ Article 6.

and/or packaging waste collected'²² which must 'take into account, in particular, requirements regarding the protection of environmental and consumer health, safety and hygiene; the protection of the quality...and the technical characteristics of the packed goods...'²³. Information for users of packaging must be provided so they 'obtain the necessary information about...the return, collection and recovery systems available to them'²⁴.

The separation of the SBS (which is in constant risk of becoming contaminated during the course of a medical procedure) and the medical device (which will always be contaminated through contact with a patient) is impracticable in the course of carrying out (sometimes life threatening) medical procedures. Whilst the true sales/primary packaging can be left outside of an operating theatre (for example) and directed into a separate waste stream, the SBS cannot be separated from the medical device until the moment that the device is used. This also indicates the device is not packaging as normally understood.

Further, unsuccessful attempts to segregate the SBS from any medical contamination present a real health risk to those charged with collecting and recovering them. A contaminated SBS, if not treated as such, could pass a serious or even fatal disease to the handler. These practical considerations - particular to conditions of working in a medical environment - mitigate against an overly literal reading of the PPWD and provide additional grounds to conclude that SBS are not - and cannot be intended to be treated as - packaging. Finally, given the significant number of SBS disposed of in the EU per year, it would be surprising if these items, which cannot safely or practically be treated as required under the PPWD, were to be counted in assessing whether Member States satisfied the required 'recovery targets' under the PPWD.

(c) Recitals to the PPWD

In so far as relevant, the recitals providing guidance on the interpretation of the WPPD have already been referred to above. They confirm our view that SBS are not properly classified as packaging.

(d) The Explanatory Memorandum to the PPWD, Parliamentary statements on the same, the Community Strategy for Waste Management and the 6th Environmental Action Programme

The explanatory memoranda to the original Commission proposal and the amended proposal provide no further clarification.

The difference of opinion amongst Member States has been acknowledged in a recent reply by Commissioner Wallström to a Parliamentary question on packaging.²⁵ No further guidance is to be gleaned from Parliamentary questions or debates.

The 6th Environmental Action Programme includes in its 'Objectives and priority areas for action on the sustainable use and management of natural resources and wastes' that the level of wastes' that 'hazardousness should be reduced and they [wastes] should present as little risk as possible'.²⁶ For the practical reasons already set out above, attempts to treat SBS as packaging would actually risk increasing the risks associated with treatment of waste.

(e) The objective pursued by the PPWD

For all of the reasons previously set out, Eucomed and SBA consider that the conclusion that SBS are not packaging is consistent with the underlying objectives of the PPWD.

²² Article 7(1)(b).

²³ Article 7(2).

²⁴ Article 13.

²⁵ Written Question E-0413/01 by Philip Bushill-Matthews (PPE-DE) to the Commission. European Packaging Directive. O.J. C 235 E , 21/08/2001 p.201.

²⁶ Article 8.

5. Conclusions

It follows from the reasoning set out above that SBS should not be treated as packaging under the PPWD, having regard to:

- (a) the fact that SBS are accessories to the medical device performing a vital ongoing function in respect of it;
- (b) SBS are not conceived of as primary packaging;
- (c) the SBS does not constitute a unit of sale;
- (d) it is impracticable in medical conditions to treat SBS as packaging rather than medical waste; and
- (e) doing so would create an increased risk to handlers of the waste generated (contrary to the objectives in the 6th Environmental Action Programme).

Directive 2004/12/EC, amending Directive 94/62/EC on PPW, summarizes the position of SBSs as outlined above and thus excludes them from being considered as packaging under Article 1 i) with the wording as follows: "items shall be considered to be packaging if they fulfil the above definition without prejudice to other functions which the function might also perform unless the item is an integral part of the product throughout its lifetime and all elements are intended to be used, consumed or disposed of together.