

**GUIDANCE DOCUMENT  
ON THE RELATIONSHIP BETWEEN  
THE GENERAL PRODUCT SAFETY DIRECTIVE (GPSD)  
AND CERTAIN SECTOR DIRECTIVES WITH PROVISIONS  
ON PRODUCT SAFETY**

**(Directives on Medical Devices, Construction Products,  
Machinery, Medicinal Products and Motor Vehicles)**

**SECOND CHAPTER**

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**Annex 1: Table overview of relationship between the GPSD and sectoral Directives**

# 1. INTRODUCTION

The Commission's Directorate General Health and Consumer Protection (DG SANCO) in the autumn 2003 published a first chapter of an informal guidance document<sup>1</sup> (The Guideline), clarifying the relationship between the General Product Safety Directive 2001/95/EC (GPSD) and four key sectoral directives applying to certain consumer goods (the Toys Directive, the Directive on Low Voltage Equipment, the Directive on Personal Protective Equipment and the Directive on Cosmetic Products).

Several Member States had requested an extension of the analysis to several additional sectoral directives that may cover consumer goods: the Directives on medical devices, the Construction Products Directive (CPD), the Machinery Directive (MD), the Medicinal Products Directive (MPD) and the Motor Vehicles Directive (MVD). Since the general principles on the relationship are already explained in the first guidance document, these are not repeated in this document. Instead the analysis in the following is summarised and focuses on those articles of the GPSD that *apply* to consumer products falling under sector directives.

This document has been drafted in close contact with DG Enterprise, Member States' experts and stakeholders.

It is recalled that the general scope of the GPSD is limited to "consumer products", as defined in its article 2(a). "*Consumer products*" are products that are intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them. What are "reasonably foreseeable conditions" must be judged in the individual case and will change with market developments as consumers increasingly use complex products, for example medical devices and machinery.

It should be noted that for the sector Directives covered by this second chapter, the majority of products are not consumer products.

For example, the Directive on Construction Products is to a large part focussed on the professional Construction sector. Still some Do-it-yourself products and other construction products migrate to the consumer market and are therefore relevant in this context.

As regards the Medical Devices Directive, examples of products that would fall under the scope of the GPSD are band aids, crutches, condoms, glasses, contact lenses, hearing aids or *in vitro* diagnostica for self-testing. Medical devices supplied to health care professionals and intended to be used by them – even if used on a consumer – generally would not qualify as consumer products. Examples include cardiovascular catheters, laboratory equipment, scalpels, and x-ray equipment.

There is no legal definition of a "consumer" in the GPSD or in the EC Treaty as such. The essential concept is however widely accepted to be individuals acting in a personal capacity in the market as opposed to individuals or legal persons acting in their professional capacity. In other pieces of consumer legislation the term has been defined. For example a "consumer" in the Directive on Consumer Credit (87/102/EC) and the Directive on Doorstep Selling (85/577/EC) means "*a natural person who, in transactions covered by this Directive, is acting*

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<sup>1</sup> [http://europa.eu.int/comm/consumers/cons\\_safe/prod\\_safe/gpsd/revisedGPSD\\_en.htm](http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/revisedGPSD_en.htm)

*for purposes which can be regarded as outside his trade or profession*". The recent Directive on Unfair Business-to-Consumer Commercial Practices (2005/29/EC) provides a similar definition of "consumer" in its article 2 a). The definition is not directly applicable to the GPSD, but may be used as a basis for the interpretation.

The starting point for this assessment of the relationship between the GPSD and the concerned sectoral Directives is article 1.2 of the GPSD which states that '*[t]his Directive shall apply to all products defined in article 2(a) [...] in so far as there are no specific provisions with the same objective in rules of Community law governing the safety of the products concerned*'.

Also Recital 13 of the Preamble specifies that '*[t]he provisions of this Directive relating to the other obligations of producers and distributors, the obligations and powers of the Member States, the exchanges of information and rapid intervention situations and dissemination of information and confidentiality apply in the case of products covered by specific rules of Community law, if those rules do not already contain such obligations*'.

This guidance document is intended to be used as an informal guide to assist the public authorities of the Member States and interesting stakeholders when applying the Directives covered.

Only the text of the directives is authentic in law. The text of the directives is applicable where there are differences between the provisions of a directive and the contents of this Guide. The interpretation of Community law is ultimately the responsibility and privilege of the European Court of Justice. The analysis set out in this Guide does not in any way preclude a different interpretation by the ECJ in a particular case, and does not in any way commit the European Commission.

Annex I to this document gives an overview of the applicability in table format.

## **2. MEDICAL DEVICES<sup>2</sup>**

### ***2.1. Producers' obligations***

#### ***2.1.1 General safety obligation***

The definition of the 'producer' in the GPSD is broader than the definition of the 'manufacturer' in the Directives on medical devices, as it also covers other professionals in the supply chain, insofar as their activities may affect the safety of a product. In this regard the GPSD may apply.

Article 1.2 of the GPSD states that the general safety requirements of the GPSD shall not apply to those products for which the risks or categories of risks are covered by the specific Community legislation.

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<sup>2</sup> The three main Directives in the regulatory framework for medical devices are: Council Directive 90/385/EEC of 20 June on the approximation of the laws of the Member States relating to active implantable medical devices, 20.07.1990, OJ L 189/17. Council Directive 93/42/EEC on medical devices of 14 June 1993, 12.07.1993, OJ L 169/1. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. They are referred to in the text as 'Community Directives on medical devices'. For the appropriate provisions see the annex.

This rule is clarified in recital 12 of the preamble:

*“If specific Community legislation sets out safety requirements covering only certain risks or categories of risks, with regard to the products concerned the obligations of economic operators in respect of these risks are those determined by the provisions of the specific legislation, while the general safety requirement of this Directive should apply to the other risks.”*

Following the objectives of the GPSD it is unambiguous that the nature of the risks and categories of risks must relate to human health and safety. The Community Directives on medical devices set out safety requirements covering health and safety risks. These articles all refer to the Annexes of the respective Directive which use the notion “safety of patients”, “the safety and health of users or other persons”.

Therefore, the general rule applies: the general safety requirements of the GPSD are not relevant for medical devices as these requirements are set out in specific Community legislation on medical devices.

### ***2.1.2 Other obligations for producers***

The Community Directives on medical devices cover most of the obligations for producers set out in the GPSD. GPSD articles 5.1 and 5.3 may however apply as regards the general obligation for producers to follow-up product safety after placing on the market and to inform public authorities of dangerous products and action to prevent risk in relation to custom-made devices, in those cases where they are considered as consumer products.

Furthermore the Community Directives on medical devices do not have a specific provision on the aspect covered in GPSD article 5.4 regarding co-operation between producers and the competent authorities, although co-operation is foreseen as a pre-condition for the functioning of the Community Directive on medical devices. Thus the GPSD applies. Co-operation in line with this article is taking place and will be pursued at the level of competent authorities in view of the provisions applicable to medical devices.

## ***2.2. Distributors’ obligations***

The Community Directives on medical devices has no provisions related to distributors’ obligations. Therefore, all aspects of GPSD article 5 relevant for distributors apply to medical device consumer products.

## ***2.3. Obligations and powers of Member States***

Although it is not stated explicitly anywhere in the Community Directives on medical devices that competent authorities shall be organised and designated (GPSD article 6), some provisions envisage a national competent authority. These are specific provisions dealing with the market surveillance aspect and have the same objective. Because of the relatively limited scope of the sector directive provisions, the corresponding GPSD provisions should serve as an example and a model for market surveillance of medical devices.

Furthermore articles 7, 9 and 10 of the GPSD on the Member States’ obligation to adopt rules on penalties and to follow-them up, to put in place a market surveillance strategy and to establish administrative co-operation between competent authorities apply since there are no specific provisions in the Community Directives on medical devices covering these aspects. It

should be noted however that under the Community Directives on medical devices, MS have the obligation to ensure effective implementation of the Directives, which includes the imposition of penalties, market surveillance activities and co-ordination as a matter of fact. Administrative co-operation is carried out through the Medical Devices expert group already established.

The Community Directives on medical devices deal with powers of national authorities. These provisions cover several aspects contained in the GPSD article 8, but not the power to require recall of products. In this specific context the GPSD applies when the safety requirements of the Community Directives on medical devices are not fulfilled.

## **2.4. Notification, rapid intervention and administrative provisions**

Community rapid intervention is covered by the Community Directives on medical devices. In combination with the vigilance procedure (i.e. information on incidents occurring following placing devices on the market) RAPEX notification (article 12) is not required since the existing “vigilance system” covers the obligations under the RAPEX system.<sup>3</sup>

In addition, article 8 and article 14b of the Medical Devices Directive provide for an intervention system by the Commission in cases of health and safety risks. However, since this provision can only be triggered by Member States intervention, article 13 of the GPSD may apply in urgent cases.

GPSD article 11 on notification of national measures is covered by the Community Directives on medical devices via safeguard clause procedures and mechanisms for invoking the particular health monitoring procedure. These procedures all include a notification procedure for measures taken. Consequently, this provision of the GPSD is not applicable.

## **3. CONSTRUCTION PRODUCTS<sup>4</sup>**

### **3.1. Producers’ obligations**

#### **3.1.1 General safety obligation**

The general obligation in GPSD article 3.1 for producers to place only safe products on the market apply, since article 2 and 3 of the Constructions Products Directive (CPD) provide the obligation to place on the market products, which are fit for the intended use and which have such characteristic that the works in which they are to be incorporated, applied or installed can satisfy the essential requirements (such as safety in use, protection against noise, hygiene, health and the environment, etc). These essentials requirements (Annex I of the CPD) concern construction works in which the product will be used and not the product as such.

#### **3.1.2 Other obligations for producers**

GPSD article 5.1, subparagraph 1 on producers’ obligation to inform consumers on risks applies since there are no specific provisions in the CPD. Furthermore article 5.1, subparagraphs 3, 4 and 5 and article 5.3 relating to the follow-up of the safety of consumer

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<sup>3</sup> See: Medical Devices: Guidance Documents: Guidelines on a medical device vigilance system, MEDDEV 2.12-1 Rev 4., April 2001.

<sup>4</sup> Council Directive 89/106/EEC of 21 December 1988, amended by Council Directive 93/68/EEC OF 22 July 1993

construction products placed on the market [only factory control foreseen under Annex III.2 therefore not relevant] and the obligation to inform authorities on dangerous products and action taken to prevent risks apply because there are no provisions on these aspects in the CPD. The obligation in article 5.1 subparagraph 3 as regards sample testing is in most cases not necessary due to stringent product processes employed by manufacturers.

Finally, article 5.4 of the GPSD also applies because there is no specific provision in the CPD referring to the producers' obligation to co-operate with the competent authorities, although co-operation is foreseen as a pre-condition for the functioning of the Directive. Co-operation in line with this article will be established by sector authorities in view of the provisions applicable to construction products.

In those situations where there are no technical specifications for a consumer construction product and it therefore to be placed on the market without the CE-marking, the provisions in GPSD article 5.1 on identification of the producer and traceability of the product also apply.

It should be noted that GPSD provisions covering safety warnings and recall under article 5.1 only apply to products before they are incorporated into the works, after which the CPD provisions will apply.

### ***3.2. Distributors' obligations***

All provisions in article 5 of the GPSD relevant for distributors apply, because the CPD does not have specific provisions on this aspect.

### ***3.3. Obligations and powers of Member States***

Although it is not stated explicitly anywhere in the CPD that competent authorities shall be organised and designated (GPSD article 6), several articles and Annex IV, represent specific provisions that envisage a national competent authority. Because of the relatively limited scope of the sector directive provisions, the corresponding GPSD provisions should serve as an example and a model for market surveillance of construction products.

GPSD article 7 on an obligation to adopt and follow up rules on penalties, article 8.1 (a) – (f) on the power of Member States to make checks and take samples, to set conditions for marketing and to recall, article 9 on a market surveillance strategy and article 10 on co-operation between Member States' competent authorities also apply as there are no provisions in the CPD on these aspects. The CPD has some specific provisions on market surveillance in articles 15 and 21, but they do not deal with the overall approach. Administrative co-operation is carried out through the Administrative co-operation Group for construction products already established.

### ***3.4. Notification, rapid intervention and administrative provisions***

The CPD does not contain any provision related to rapid exchange of information (RAPEX) or on Community rapid intervention measures. Therefore, articles 12, 13, 14 and 15 of the GPSD apply.

GPSD article 11 on notification of national measures is covered in most cases by CPD article 21 on safeguard measures. In those cases where a measure concerning health and safety does not fall under CPD article 21 or under the RAPEX notification procedure, it should be notified under GPSD article 11.

In addition the administrative provisions in GPSD articles 16 and 18 apply.

## **4. MACHINERY<sup>5</sup>**

### **4.1. Producers' obligations**

#### **4.1.1 General safety obligation**

The general safety obligation in GPSD article 3.1 does not apply since article 2, ref. Annex I of the Machinery Directive (MD) covers all risks.

#### **4.1.2 Other obligations for producers**

The MD covers most of the obligations for producers set out in the GPSD. However, GPSD articles 5.1 and 5.3 contain obligations for producers to follow up product safety after placing their products on the market and to inform public authorities of dangerous products and action to prevent risk. These aspects are not covered by the MD so the GPSD will apply.

Furthermore the MD does not have a specific provision covering the aspect in GPSD article 5.4 on co-operation between producers and the competent authorities, although co-operation is foreseen as a pre-condition for the functioning of the MD. Thus the GPSD applies. Co-operation in line with this article will be established by sector authorities in view of the provisions applicable to machinery.

### **4.2. Distributors' obligations**

The MD does not contain provisions on distributors' obligations; therefore the GPSD provision in article 5 on this aspect applies also to distributors of consumer machinery products.

### **4.3. Obligations and powers of Member States**

Although it is not stated explicitly in the MD that competent authorities shall be organised and designated (GPSD article 6), several specific articles, including articles 2, 7 and 9 as well as Annex VII, point 7, foresee the existence of a national competent authority. Because of the relatively limited scope of the sector directive provisions, the corresponding GPSD provisions should serve as an example and a model for market surveillance of consumer machinery products.

GPSD article 7 on the obligation to adopt rules on penalties and to follow them up, article 9 on a Market Surveillance Strategy and the obligation to establish administrative co-operation between national authorities (GPSD article 10) apply to consumer machinery products since

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<sup>5</sup> Council and European Parliament Directive 98/37/EC of 22 June 1998, amended by Council and European Parliament Directive 98/79/EC

there are no provisions in the MD. Administrative co-operation is carried out through the Administrative co-operation Group for machinery already established.

Finally, with regard to GPSD article 8, as there is no provision in the MD on powers to make checks, take samples and require information, article 8.1 (a) of the GPSD would apply. The other aspects of GPSD article 8 are covered in the MD.

#### **4.4. Notification, rapid intervention and administrative provisions**

The MD does not contain any provision related to rapid exchange of information (RAPEX) or on Community rapid intervention measures. Therefore, articles 12, 13, 14 and 15 of the GPSD apply.

The obligation to notify national measures restricting the marketing of products in GPSD article 11 is in most cases covered by MD article 7 on safeguard measures for CE marked products. But in those cases where a measure concerning health and safety does not fall under the MD article 7 or under the RAPEX notification procedure, GPSD article 11 applies.

Finally GPSD articles 16 and 18 containing administrative provisions on access to information and motivation of decisions apply as far as MD article 11 and 7 do not cover this aspect.

## **5. MEDICINAL PRODUCTS<sup>6</sup>**

The Directive on Medicinal products (MPD) sets out a detailed framework for the safe provision of medicinal products in the EU. The analysis shows that almost all aspects of the GPSD are covered by specific provisions in the MPD. However, the general safety obligation in GPSD article 3.1 may apply to certain risks that are not covered by MPD article 6, ref articles 8, 9 and 10.

In addition, the GPSD provisions apply to these medicinal products which are not covered by the MPD and which are supplied to consumers. For instance, these would include medicinal products neither prepared industrially nor manufactured by a method involving an industrial process.

## **6. MOTOR VEHICLES<sup>7</sup>**

### **6.1. Producers' obligations**

#### **6.1.1 General safety obligation**

The general safety obligation in GPSD article 3.1 does not apply since the Motor Vehicles Directive (MVD) articles 4.2, 7.1, and 7.2 cover all risks relating to construction and functioning of motor vehicles. (Article 7.1 and 7.2 of the MVD require that all vehicles, components and separate technical units comply with the type approval requirements.)

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<sup>6</sup> Council 2001/83/EC on the Community Code relating to medicinal products for human use, amended at the latest by Council Directive 2004/27/EC of 31 March 2004

<sup>7</sup> Council Directive 70/156/EEC of 6 February 1970, amended, at the latest by Council regulation (EC) No 807/2003 of 14 April 2003

### **6.1.2 Other obligations**

The MVD covers most of the obligations for producers set out in the GPSD. However, GPSD articles 5.1 and 5.3 contain obligations for producers to follow up product safety after placing their products on the market and to inform public authorities of dangerous products and action to prevent risk. Article 30 of the Commission proposal for a Framework Directive on the approval of motor vehicles, which will replace the current MVD once adopted (“the draft Framework Directive”)<sup>8</sup>, will require producers to inform the appropriate authorities if they have to operate a recall of their products. In addition, manufacturers are required to inform of remedial measures taken in the context of vehicle emissions, which may include recalls.<sup>9</sup>

To the extent that these provisions do not fully address the requirements of the GPSD, the GPSD will apply.

The MVD does not cover the aspect in GPSD article 5.4 of co-operation between producers and the competent authorities in a specific article, although co-operation is provided for throughout the type-approval procedure.

## **6.2. Distributors’ obligations**

The MVD has no provisions on distributors’ obligations, thus the relevant provisions in article 5 of the GPSD applies to consumer products covered by the MVD.

## **6.3. Obligations and powers of Member States**

There is no provision in the MVD dealing explicitly with the obligation to adopt rules on penalties and to follow them up or to establish a strategy for market surveillance. However, the MVD contains a safeguard provision (article 7.3) that allows Member States to ban the sale for six months of a new motor vehicle if it presents a risk to road safety, even if the vehicle was correctly type-approved and complies with all the requirements of the MVD. This implies that Member States may carry out market surveillance activities. In practice, most recalls at present are taken on the manufacturer’s initiative. Articles 7 and 9 of the GPSD will therefore apply in a complementary way to the MVD.

There is no provision in the MVD equivalent to that in GPSD article 8.1(f) on Member States having the power to recall products. However, the draft Framework Directive empowers Member State authorities to withdraw European type approval in case a producer takes insufficient measures to address a serious risk or if the relevant measures are not implemented quickly enough. This is tantamount to a withdrawal of the authorisation to put vehicles on the market.

Apart from this, all aspects relevant for Member States authorities are covered by specific provisions in the MVD.

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<sup>8</sup> COM (2003) 418 and COM (2004) 738.

<sup>9</sup> See section 6, "plan of remedial measures", of Appendix 3 to Annex I of Directive 98/69 and 2002/80 (both amendments to 70/220/EEC). Similar provisions are introduced in the Commission draft proposal recasting Dir. 88/77, in section 7 of Annex XII.

#### **6.4. Notification, rapid intervention and administrative provisions**

The MVD does not contain any provision related to rapid exchange of information (RAPEX) or on Community rapid intervention measures. Therefore, articles 12, 13, 14 and 15 of the GPSD apply.

The obligation to notify national measures restricting the marketing of products in GPSD article 11 is in most cases covered by MVD article 7.3 on safeguard measures for type-approved products. The draft Framework Directive (Art. 30) provides for the obligation on the part of the manufacturers to inform the approval authorities of any recall they may have been required to undertake in application of the GPSD and also requires Member State authorities to inform other authorities without delay and to effectively implement appropriate remedies within their respective territories. But in those rare cases where a measure concerning health and safety does not fall under these MVD articles or under the RAPEX notification procedure, GPSD article 11 applies.

Finally the MVD does not have any provisions governing access to information as set out in GPSD article 16, therefore this provision applies also to consumer products covered by the MVD.

## ANNEX I

### Overview of relationship between GPSD and certain sector directives<sup>10</sup>

(Where no sector provisions are indicated in the table the GPSD provision applies)

<b>GPSD</b>	<b>Medical Devices<sup>11</sup></b>	<b>Construction Products</b>	<b>Machinery</b>	<b>Medicinal Products</b>	<b>Motor Vehicles</b>
<b>Article 3.1 – Obligation for producer to place only safe products on the market</b>	IVDD: Articles 2 and 3, Annex I MDD: Articles 2 and 3, Annex I AIMDD: Articles 2 and 3, Annex 1	Articles 2 and 3, ref. Annex I, §1 to §5 – cover only construction works in which the product will be used and not the product as such.	Article 3, ref. Annex I, in particular paragraph 1.1.2.a)	Article 6, ref. articles 8, 9, 10. These provisions may not necessarily cover all risks.	Articles 4.2, 7.1 and 7.2  Articles 3 and 4 re. Annexes III, IV and XI, ‘technical requirements of relevant separate Directives in Annexes IV and XI’ (but just in relation to authorisation system)  Article 6 (Certificate of Conformity)  Article 7.3
<b>Article 5.1, subparagraph 1 – Obligation for producer to inform consumers on risks</b>	IVDD: Article 3, ref. Annex I, Section 8 MDD: Article 3, ref. Annex I, Section 13 AIMDD: Article 3, ref. Annex 1, Section 15	NO PROVISION	Article 3, ref. Annex I, 1.1.2 (b), 1.7.2, 1.7.3 and 1.7.4	Articles 54 (f), (g), (i) and (n), 59 (c), (d) and (e), 63.2, 66, 68 and 69.1	Article 6.4
<b>Article 5.1, subparagraph 3 and 4 –</b>	IVDD: Article 3, ref. Annex I, Section 8 MDD: Article 3, ref. Annex I,	Article 14, ref. Annex III, § 4.1, fifth indent, but only where technical specifications	Annex I, point 1 of the preliminary observations, last paragraph, ref. 1.7.3	Articles 54 (k), 59.1(f), fifth dash, 66.3, fourth dash, 69.1, second dash	Articles 6.1 and 6.3

<sup>10</sup> The overview of the sector directives’ provisions in this table are for illustration of the application of the GPSD only; the cited provisions of the sector directives are not intended to give an exhaustive account of the obligations under these directives.

<sup>11</sup> There are three main Directives in the regulatory framework for medical devices which are: Council Directive 90/385/EEC of 20 June on the approximation of the laws of the Member States relating to active implantable medical devices, 20.07.1990, OJ L 189/17 (referred to as AIMDD), Council Directive 93/42/EEC on medical devices of 14 June 1993, 12.07.1993, OJ L 169/1 (referred to as MDD) and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (referred to as IVDD)

<b>GPSD</b>	<b>Medical Devices<sup>11</sup></b>	<b>Construction Products</b>	<b>Machinery</b>	<b>Medicinal Products</b>	<b>Motor Vehicles</b>
<b>identification of producer</b>	Section 13 AIMDD: Article 3, ref. Annex 1, Section 12	have been developed, as a additional information on CE label § 4.2. certificate of conformity shall contain information about producer, and § 4.3 declaration of conformity shall contain information about producer			
<b>Article 5.1, subparagraph 3 and 4 – identification of product</b>	IVDD: Article 3, ref. Annex I, Section 8 MDD: Article 3, ref. Annex I, Section 13 AIMDD: Article 3, ref. Annex 1, Section 12	Article 14, ref. Annex III, § 4.1, fifth indent, but only where technical specifications have been developed, but only indications to identify the characteristics of the product on the basis of the technical specifications § 4.2. certificate of conformity shall contain more information about product, and § 4.3 declaration of conformity shall contain more information about product	Annex I, point 1 of the preliminary observations, third last paragraph, ref. 1.7.3	Articles 54 (a) to (d), (l) and (m), 59.1(a), 66.3, , 69.1,	Articles 6.1 (certificate of conformity), 6.3 and 6.4
<b>Articles 5.1, subparagraph 3, 4 and 5 – Obligation for producers to follow-up product safety after the placing on the market of their products</b>	IVDD: Article 9, ref Annex III, § 5 ; Annex IV, § 3.1 ; Annex VI, § 3 ; Annex VII, § 3.1. MDD: Article 11 (Conformity assessment procedures), ref. Annex II, § 3.1 seventh dash and § 3.2.e); Annex IV, § 3; Annex V, § 3.1 eighth dash and § 3.2.d); Annex VI, § 3.1 eighth dash; Annex VII, § 4 except for custom made medical devices However, the revision of the MDD foresees the introduction of an obligation to follow-up product safety for custom made devices.	NO PROVISION [only factory control foreseen in Annex III.2]	NO PROVISION	Articles 103 and 104	Draft Framework Directive Article 30 (direct reference to GPSD)  See also section 6, "plan of remedial measures", of Appendix 3 to Annex I of Directive 98/69 and 2002/80 (both amendments to 70/220/EEC). Similar provisions are introduced in the Commission draft proposal (not still officially adopted),

GPSD	Medical Devices <sup>11</sup>	Construction Products	Machinery	Medicinal Products	Motor Vehicles
	<p>Article 15.5 and Annex X §2.3.5 for devices for clinical investigation AIMDD: Article 9, ref Annex 2, § 3.1; Annex 4, § 3.</p>				<p>recasting Dir. 88/77, in section 7 of Annex XII.</p>
<p><b>Article 5.3 – Obligation for producers to inform the authorities of dangerous products and action taken to prevent risk</b></p>	<p>IVDD: Article 9, ref Annex III, § 5; Annex IV, § 3.1; Annex VI, § 3; Annex VII, § 3.1. except for in medical devices for performance evaluation. MDD: Article 11 (Conformity assessment procedures), ref. Annex II, § 3.1 seventh dash, last paragraph, (i) &amp; (ii); Annex IV, § 3 (i) &amp; (ii); Annex V, § 3.1 eighth dash, (i) &amp; (ii); Annex VI, § 3.1 eighth dash, (i) &amp; (ii); Annex VII, § 4 (i) &amp; (ii); Article 10 ref. Annex X § 2.3.5 (for clinical evaluation MD) except for custom made medical devices Article 15.5 and Annex X §2.3.5 for devices for clinical investigation AIMDD: Article 9, ref Annex 2, § 3.1; Annex 4, § 3. Article 10 (for clinical evaluation) Annex 7, § 2.3.5. Adverse events must be recorded, but it does not say how or if they should be notified.</p>	<p>NO PROVISION</p>	<p>NO PROVISION</p>	<p>Article 104</p>	<p>Draft Framework Directive Article 30 (direct reference to GPSD)</p> <p>See also section 6, "plan of remedial measures", of Appendix 3 to Annex I of Directive 98/69 and 2002/80 (both amendments to 70/220/EEC). Similar provisions are introduced in the Commission draft proposal (not still officially adopted), recasting Dir. 88/77, in section 7 of Annex XII</p>
<p><b>Article 5.4 – Obligation for producers to cooperate with the</b></p>	<p>NO PROVISION. Co-operation in line with this article undertaken by sector authorities in view of the provisions applicable to</p>	<p>NO PROVISION. Co-operation in line with this article undertaken by sector authorities in view of the</p>	<p>NO PROVISION. Co-operation in line with this article undertaken by sector authorities in view of the provisions</p>	<p>Articles 103 and 104</p>	<p>Co-operation in line with this article undertaken by sector authorities in view of the provisions</p>

<b>GPSD</b>	<b>Medical Devices<sup>11</sup></b>	<b>Construction Products</b>	<b>Machinery</b>	<b>Medicinal Products</b>	<b>Motor Vehicles</b>
<b>competent authorities on action to prevent risks</b>	medical devices.	provisions applicable to construction products.	applicable to machinery.		applicable to motor vehicles.
<b>Article 5 – Obligation for distributor not to supply dangerous product, to participate in safety monitoring of products and in tracing dangerous products etc</b>	NO PROVISION	NO PROVISION	NO PROVISION. However, the general provision in Article 2(1) that only safe products may be placed on the market has implications for whoever places them on the market. In practice Member State authorities address distributors as well as manufacturers in case of non-conforming products. See also Art. 8(7). EC case law (Yonemoto case C-40) may affect measures required from distributors in the future.	Articles 76, Article 80 (a), (d), (e) and (f) ( <i>wholesalers</i> ) Article 82 second paragraph ( <i>pharmacists</i> )	NO PROVISION
<b>Article 6, subparagraphs 1 and 2 – Obligation on the Member States to establish or nominate authorities competent for enforcement</b>	NO PROVISION; it is implied in the Directives that such authority is established or nominated	Annex IV, last paragraph	Articles 2, 7 and 9 state duties of Member States Annex VII, point 7 - This is an implicit obligation in order for the Member States to fulfil their enforcement obligations under the Directive. Member State implementation texts give such information. Note that an equivalent obligation to that laid down in Article 6, subparagraphs 1 and 2 of the GPSD has been introduced in the proposal for the revised Directive.	Articles 6.1, 19.1 and others impose duties on Member States' competent authorities.	Article 3.1 ref Article 2, twelfth dash ('approval authority')
<b>Article 7 – Obligation on the Member States to adopt rules on penalties and to</b>	NO PROVISION	NO PROVISION	NO PROVISION. However, note that an equivalent provision to Article 7 of the GPSD has been introduced in the proposal for the revised Directive.	Article 99	NO PROVISION

<b>GPSD</b>	<b>Medical Devices<sup>11</sup></b>	<b>Construction Products</b>	<b>Machinery</b>	<b>Medicinal Products</b>	<b>Motor Vehicles</b>
<b>follow up these rules</b>					
<b>Article 8.1. (a) – power to make checks, take samples</b>	NO PROVISION	NO PROVISION	NO PROVISION. However, such powers fall within the normal scope of enforcement.	Article 19 Article 61 (packaging and leaflet) Article 77.5 (for wholesalers) Articles 111 to 114 (inspection in general by competent authorities)	Annex X Section 3 (especially 3.5)
<b>Article 8.1 (b) – (c) – power to set conditions for marketing</b>	IVDD: Article 8, article 13, article 17 MDD: Article 8.1 (restriction to marketing within the “interim measures”); article 14b (“availability “subjected to particular requirements” within the transitional measures); article 18 (b) AIMDD: Article 7, article 13	NO PROVISION	Article 7, paragraph 1 Article 10.4 (b)	Article 22, Article 32.4(c),	Articles 4.5 and 4.6 Article 7.1 and 7.2 Article 11.2
<b>Article 8.1 (d) – (f) – power to ban or recall</b>	IVDD: Article 8, article 13, article 17 MDD: Article 8 (safeguard clause: 8.1 for interim measures and 8.3 for non-complying devices); article 14b (transitional measures) & article 18 (wrongly affixed CE marking) AIMDD: Article 7, article 13	Articles 15 and 21.1, but not for recall	Article 7, paragraph 1 Article 10.4 (b)	Article 64 (for packaging and leaflet); Article 77.6 (for wholesale) Articles 88.1 and 88.3 (re. ban in advertising) Articles 116 to 118	Article 4.2 (but only in relation to the authorisation system and not for recall) Article 7.3
<b>Art 9 – Market surveillance strategy</b>	NO PROVISION	NO PROVISION	NO PROVISION	Article 97 (re. advertising monitoring) Title IX ‘Pharmacovigilance’ (Articles 101 to 108)	NO PROVISION

<b>GPSD</b>	<b>Medical Devices<sup>11</sup></b>	<b>Construction Products</b>	<b>Machinery</b>	<b>Medicinal Products</b>	<b>Motor Vehicles</b>
<b>Article 10 – Establishment of procedures for administrative co-operation between competent authorities of the various Member States</b>	NO PROVISION, but procedures established by sector authorities to be continued in practice.	NO PROVISION, but procedures established by sector authorities to be continued in practice.	NO PROVISION, but procedures established by sector authorities to be continued in practice.	Title III, Chapter 4 ‘Mutual recognition’ (Articles 27 to 39) Articles 77.4 and 77.7 (information re. wholesale authorisation of medicinal products) Article 105.1 and 105.2 (pharmacovigilance) Article 122 and 124	Articles 4.5 and 4.6 Article 5.4, last phrase in fourth paragraph and 5.5 Article 10 Article 11.5 Article 14
<b>Article 11 – Obligation to notify measures which restrict placing on the market of products</b>	IVDD: Article 8, article 13, article 17 MDD: Article 8, article 14b, article 18 AIMDD: Article 7, article 13	Article 21 [safeguard measures, but limited to products in conformity with directive]	Article 7 [safeguard measures – but limited to CE marked products]	Article 107	Article 4.2 (but only in relation to the authorisation system)  Draft Framework Directive Art. 30 (recalls and other measures)  Article 7.3 (safeguard clause)  Article 11.2, 11.5 and 11.6 (conformity with approved type)
<b>Article 12 – Obligation to notify under RAPEX measures and other action concerning products posing serious risks</b>	IVDD: Article 11 MDD: Article 10 AIMDD: Article 8	NO PROVISION	NO PROVISION	Art. 29: Specific mechanism to deal with products posing potential serious risks to public health	NO PROVISION
<b>Article 13 – Powers and procedures for Community rapid intervention measures</b>	Articles 8 and 14b partially cover NO SIMILAR PROVISION	NO PROVISION	NO PROVISION	Articles 31, 32: Referral in case of Community interest to the Committee for Medicinal Products for Human Use, leading to a binding Commission decision	NO PROVISION

<b>GPSD</b>	<b>Medical Devices<sup>11</sup></b>	<b>Construction Products</b>	<b>Machinery</b>	<b>Medicinal Products</b>	<b>Motor Vehicles</b>
<b>Article 14 and 15 – Committee procedures for rapid intervention</b>	NO PROVISION	NO PROVISION	NO PROVISION	Articles 120, 121 (ref to Committee procedure in several provisions, such as Articles 34, 35, 46, 104, etc.)	NO PROVISION
<b>Article 16 – Provisions on access to information on product risks and protection of confidentiality</b>	Partially covered by: IVDD: Article 19 MDD: Article 20, ref Annex XI § 7 AIMDD: Article 15	NO PROVISION	NO PROVISION. Note than an equivalent provision on protection of confidentiality has been introduced in the proposal for the revised Directive.	Articles 102	NO PROVISION
<b>Article 17 – relationship with the directive on liability for defective products</b>	NO PROVISION	NO PROVISION	NO PROVISION	NO PROVISION	NO PROVISION
<b>Article 18 – motivation</b>	IVDD: Articles 8.1, 13 and 18  MDD: Articles 8.1, 14b, 19.1  AIMDD: Articles 7.1 and 14	NO PROVISION]	Articles 11 and 7 [only for safeguard measures]. Note than an equivalent provision to Article 18 of the GPSD has been introduced in the proposal for the revised Directive.	Articles 125	Articles 4.2 (but only in relation to the authorisation system); 5.3 third paragraph and 5.4, third paragraph (motivation of the ‘extension’ of the revised approval certificate) Article 7.3 Article 11.5 Article 12