



***Position paper on a patient-centred,  
affordable and sustainable system for  
incontinence\* aids***

\*does not refer to children under 5 years of age

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## Summary

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Incontinence currently affects millions of Europeans and, as our populations grow older, it will touch the lives of millions more. While Member States are responsible for the funding and delivery of health services, the EU can play an important role in improving patient care in this field by embedding key principles in health systems across Europe.

These include recognising incontinence as a set of diseases, ensuring that all patients affected by incontinence get the care they need, supporting the provision of information to patients about the condition and its treatments, and fostering a patient-centred approach to incontinence care which values transparency and patient choice.

The purpose of the paper is to raise awareness, initiate and facilitate constructive dialogues amongst all stakeholders including patients, clinicians, payers, policy makers, the industry, and promote efficient collaboration in finding the best potential solutions.

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## What is incontinence?

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Incontinence is one of humanity's most strongly tabooed topics, it may affect individuals of all ages, and there is a wide range of severity and symptoms. It is not a life-threatening disease, but the different symptoms may seriously influence physical, psychological, and social well-being.

### **Urinary incontinence**

Urinary incontinence is defined as "*any involuntary leakage of urine*" by the International Continence Society (ICS).

### **Faecal and anal incontinence**

Faecal Incontinence (FI) is the involuntary loss of faeces – solid or liquid. Anal Incontinence (AI) includes these events as well as the involuntary loss of flatus, which is felt by many patients to be an equally disabling disorder<sup>1</sup>. Anal incontinence in most cases co-exists with urinary incontinence, and is usually a consequence of surgical intervention, dementia or other degenerative conditions.

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<sup>1</sup> 4th International Consultation on Incontinence, 2008

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## Who is affected?

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There are currently no exact estimates on the numbers of people who live with chronic incontinence, but European studies estimate that between 4% and 8% of the total population are affected. The following prevalence figures combine the number of people who suffer from temporary and chronic<sup>2</sup> incontinence.

### Urinary incontinence

The estimated prevalence of urinary incontinence (UI) in middle-aged and older women in the general population appears to be in the range of 30% to 60% and the percentage increases with age. For example, recent studies reported that one quarter of young women, half of middle-aged and post-menopausal women, and three quarters of elderly females in nursing homes, experienced some degree of involuntary urine loss.

The prevalence of daily UI ranges from 5% to 15%. It is estimated that one in seven women aged over 70 who are institutionalised experience daily UI. The burden of incontinence in Europe is expected to grow due to the ageing population and increasing life expectancy.

Age is associated with a steady increase in prevalence among women. The epidemiology of UI in men has not been investigated to the same extent as for females, but it appears that incontinence is at least twice as prevalent in women as in men.<sup>3</sup>

### Anal incontinence

The prevalence of anal incontinence also increases with age, but is present in all age groups and in both genders ranging from 1.5% in children to more than 50% in nursing home residents.<sup>4</sup>

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## Medical devices available

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There are two distinct ranges of medical devices available for individuals affected by urinary incontinence: absorbent products and appliances

The indication for the use of both absorbent products and appliances depends on

- the type/nature of incontinence
- the severity of the incontinence
- the patient's personal circumstances (physical condition, size, mobility care situation etc.)
- the patient's and carer's skills and abilities

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<sup>2</sup>Chronic: Incontinence which lasts over a sustained period and is not directly linked to a certain event in the patient's life. (e.g.: pregnancy, surgery, infections)

<sup>3</sup>4th International Consultation on Incontinence, (2008)

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The absorbent products are developed for the purpose of absorbing urine and faeces. Main types are:

- Female products (for urine only)
- Male products (for urine only)
- Inserts (for urine and faeces)
- All in one products (for urine and faeces)
- Belted briefs (for urine and faeces)
- Pants or “pull on” products (for urine and faeces)

Appliances are categorized into:

- indwelling bladder drainage devices (suprapubic catheters and transurethral catheters)
- intermittent transurethral catheters and intermittent self-catheterising systems (ISC)
- urinary condoms with leg bags / night bags
- external urine drainage devices for men and women
- anal irrigation devices

For more detailed description of product categories, see Annex I & II.

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## Overcoming barriers

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According to Article 129 of the European Union Treaty, the organisation and delivery of health services and medical care are the responsibility of the Member States. Disparities between, and within, Member States lead to inequality in how patients are cared for. This can also make it difficult for patients suffering from incontinence to understand their entitlements and to navigate complex bureaucratic reimbursement systems.

A number of barriers must be overcome if patients are to receive optimal care:

1. Regional differences in the volume of products for which patients are reimbursed, and in terms of incompatibilities between two or more incontinence aids which can arise due to different interpretation of norms
2. Bureaucracy: release and renewal times are not well-suited to patient needs
3. Unsuitability of incontinence aids (low customisation)
4. Low quality incontinence aids, which might lead to other diseases
5. Incontinence aids not suited to patient needs because aids are not technologically advanced
6. Supply interruption
7. No/ little information available about all incontinence aids and about patients' rights

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## What is the industry's perspective?

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By integrating the following principles into systems all over Europe, we would move towards patient-focused, sustainable and affordable systems for quality incontinence care:

- 1) **Incontinence should be recognised as set of diseases.** Until this happens, and until the complexity of incontinence management is understood by decision makers, it will not receive the appropriate level of priority when it comes to allocating health care resources
- 2) **Patients should be provided with products and services that are medically adequate, necessary, and identified based on individual assessment.** Personalised product selection should be granted and (if available) be based on internationally recognised standards (ISO 15621, ISO 16021).
- 3) **Continence care should not be considered a commodity business.** Management of this complex symptom requires interdisciplinary collaboration; beside product related factors, user- and usage related factors should be considered
  - The burden of carers should be relieved, respite care provision, guidelines and good practices should be put in place
  - Care institutions should set up training courses and services to support carers of older people with incontinence, especially when they are discharged from hospital. This would help carers to assess and manage leakages, choosing the right products and thus avoiding bedsores.
- 4) **Patients and carers should have access to product and service information and have freedom to choose the products/care they need.** Patients who live with incontinence and use medical devices are a heterogeneous group because the cause of their incontinence and their individual needs differ greatly. As there is no one-size-fits-all solution, patients must have access to all available information and products. In order to secure freedom of choice, all direct communication channels should be opened for sharing information with patients and carers. Patient information will increase the level of knowledge, appropriate product use and patient adherence; thus leading to a more efficient utilisation of public resources.

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## About Eucomed

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Eucomed represents the medical technology industry in Europe. Our mission is to make modern, innovative and reliable medical technology available to more people. Eucomed promotes a balanced policy environment that enables the medical technology industry to meet the growing healthcare needs and expectations of society.

Eucomed members include both national and pan-European trade and product associations as well as medical technology manufacturers. We indirectly represent 25,000 designers, manufacturers and suppliers of medical technology used in the diagnosis, prevention, treatment and amelioration of disease and disability.

Small and medium sized companies make up more than 95% of this sector. The European medical technology industry generates annual sales of €100 billion, has the most patent applications of all industries and employs around 575,000 highly skilled workers. Eucomed is a member of MedTech Europe, an alliance of European medical technology industry associations.

For more information visit [www.eucomed.org](http://www.eucomed.org)

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# ANNEX

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## Annex I: Types of absorbent incontinence devices

### Female products (for urine only):

- assortment of products of different sizes and absorption levels tailored to women's anatomy



### All in one products(for urine and faeces):

- assortment of one- piece products of different sizes/absorption levels with fixation tapes around the waist area



### Inserts(for urine and faeces):

- assortment of pad- shaped products of different sizes/absorption levels which are held in place by close-fitting underwear or stretch meshbriefs



### Male products (for urine only):

- assortment of products of different sizes and absorption levels tailored to men's anatomy



### Belted briefs (for urine and faeces):

- assortment of "all in one" products with belt around the hip/waist area to secure fixation



### Pants or "pull on" products(for urine and faeces):

- assortment of underwear-like products intended mainly for active/mobile patients and/or patients with dementia



**Annex II: Types of Appliances (NEEDS TO BE COMPLETED)**

Indwelling bladder drainage devices (suprapubic catheters and transurethral catheters):

Intermittent transurethral catheters and intermittent self-catheterising systems (ISC):

Urinary condoms with leg bags / night bags:

External urine drainage devices for men and women:

Anal irrigation devices:

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