

HERCA

Multi-Stakeholder Workshop (MSW) Accidental and unintended exposures of individuals subject to medical exposure – notification and recording of events

26-27 October, ASN, Paris

**Presentation of HERCA discussion paper on accidental and
unintended exposures and significant events**

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Accidental and unintended exposures – discussion paper

Background:

2012 – 1st HERCA WGMA survey on notification of events relating to diagnostic medical exposures

2014 – 2nd HERCA WGMA survey extended to include therapeutic medical exposures

2014 – Board of Heads agreed an Action Plan relating to key areas of the Basic Safety Standards Directive 2013/59/Euratom

2015 – 3rd HERCA WGMA survey

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Background:

3rd HERCA WGMA survey (14 countries) provided a range of general conclusions:

- Graded approach to notification of events is evident in most countries but approaches varied
 - all events included
 - high dose procedures only
- Many countries had good cooperation with Medical Device Authorities
- Common principles can be identified and similar frameworks developed
- Unlikely that a single descriptive approach can be achieved for all Member States

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Background:

Work Package on Notification of Accidental and Unintended Exposures

Chair

Marc Valero (France)

Members

Ritva Bly (Finland)

Torsten Cederlund (Sweden)

Isabelle De Pau (Belgium)

Cecile Etard (France)

Eva Friberg (Norway)

Juergen Griebel (Germany)

Steve Ebdon-Jackson (UK)

Petr Papirnik (Czech Republic)

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Structure of the paper:

1. Introduction
2. Possible limitations of the Euratom Treaty and BSSD, Definitions and Purpose of Article 63
3. Interrelation between BSSD, MDR and their respective and other enforcement authorities
4. HERCA WGMA surveys, discussions and conclusions
5. Requirements of Article, current provisions and options for future transposition
6. Conclusions

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1. Introduction

- background of the BSSD
- Articles 96 and 63
- background of HERCA involvement
- content and aim of the paper

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2. Possible limitations of the Euratom Treaty and BSSD, Definitions and Purpose of Article 63

- possible legal restrictions relating to exposures less than intended
 - narrow
 - unhelpful in clinical context
 - International BSS
- formal definitions
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- RP 181
- relevance of article retrospectively to individuals and prospectively to safety culture

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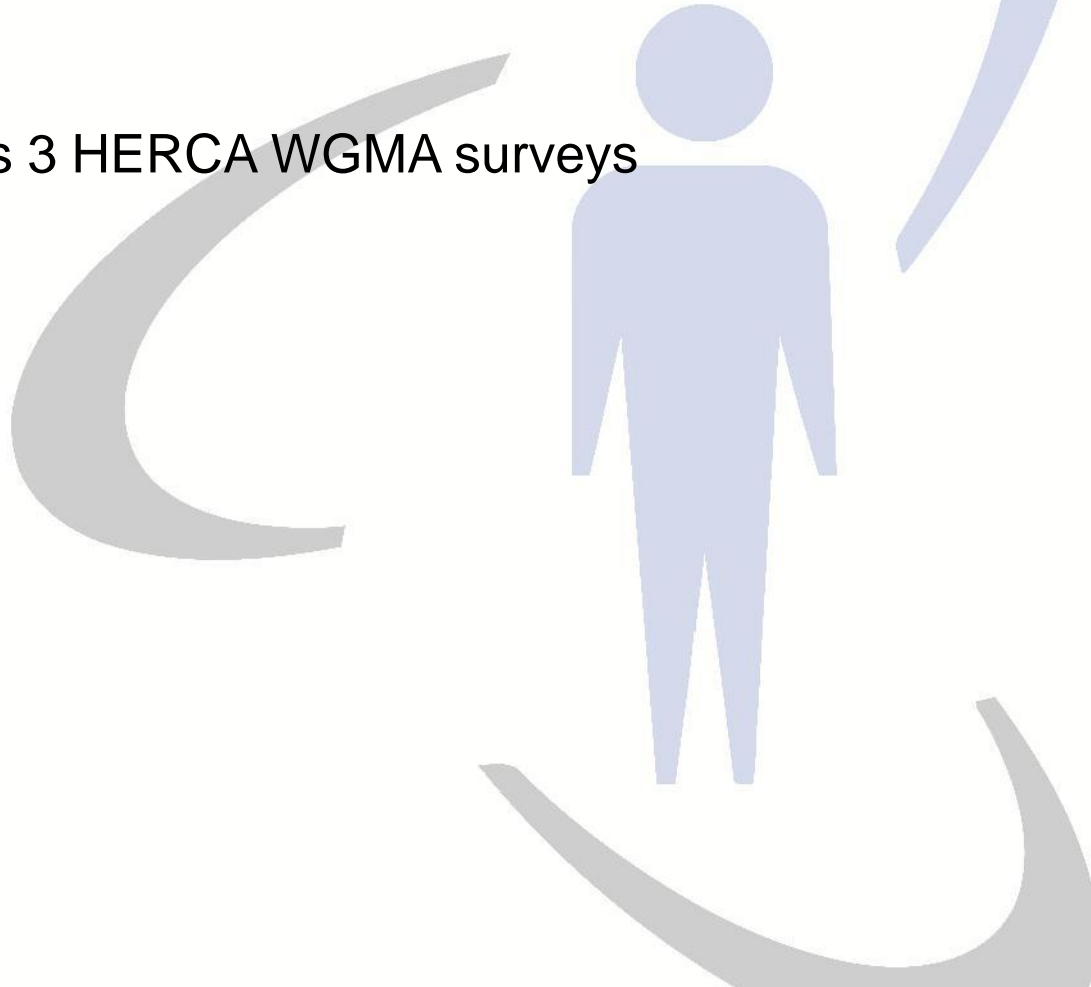
3. Interrelation between BSSD, MDR and their respective and other enforcement authorities

- BSSD relates to practices
- no potential overlap with other European Directives and regulations
- close cooperation with Medical Device Authorities is advantageous for patient safety

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4. HERCA WGMA surveys, discussions and conclusions

- outlines 3 HERCA WGMA surveys



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5. Requirements of Article, current provisions and options for future transposition

- discusses each paragraph of Article 63
- identifies existing and new requirements
- main focus is on Article 63(e)(i)
 - significant events
 - reporting to the competent authority

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Article 63(a)

“Member States shall ensure that all reasonable measures are taken to minimise the probability and magnitude of accidental and unintended exposures of individuals subject to medical exposure”

Similar to previous Directive 97/43/Euratom

- *are current regulatory requirements adequate ?*
- *is the balance between diagnostic and therapeutic exposures appropriate ?*

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Article 63(b)

“Member States shall ensure that for radiotherapeutic practices the quality assurance programme includes a study of the risk of accidental or unintended exposure”

Simple transposition possible with potential reference to prior risk assessment etc

- *is this consistent with good medical practice ?*
- *would this provide difficulties for stakeholders ?*

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Article 63(c)

“Member States shall ensure that for all medical exposures the undertaking implements an appropriate system of record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice”

Requires a system of record keeping and analysis of all medical exposure events but allows for graded approach

- *are current regulatory requirements adequate ?*
- *is the balance between diagnostic and therapeutic exposures appropriate ?*

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Article 63(d)

“Member States shall ensure that arrangements are made to inform the referrer and the practitioner, and the patient, or their representative, about clinically significant unintended or accidental exposures and the results of the analysis”

Introduces the term “clinically significant” but this is not defined and does not require the competent authority to define it.

- *can/should/will the professional bodies define clinically significant ?*
- *is guidance already available?*
- *can this be at European level or is it a national issue ?*

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Article 63(e)(i)

“Member States shall ensure that the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority”

Significant events and reporting criteria can be defined, and based on the risk to the individual(s) exposed.

- do existing criteria, where available, have credibility within the radiological community as reporting criteria of significant events?*
- should events which do not require immediate reporting be considered as events which are not significant events ?*

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Article 63(e)(i)

“Member States shall ensure that the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority”

Some events may not be considered clinically significant, based on risk to the individual, They may however have real value as an indicator of the safety culture of the undertaking.

- *should events carrying low risk to the individual(s) be reported as significant events, but not immediately on an individual basis ie such events could be collected and reported to the competent authority on a periodic basis ?*

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Article 63(e)(i)

“Member States shall ensure that the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority”

Some significant events, as defined by the competent authority, will need to be reported as soon as possible. All clinically significant accidental or unintended exposures could be included within this category of significant events.

- *should there be a direct link between clinically significant accidental or unintended exposures and significant exposures (see options 1-6 in the paper) and from this arequirement for reporting of all such clinically significant exposures to the competent authority?*

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Article 63(e)(i)

“Member States shall ensure that the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority”

Other criteria for significant events may also need to be developed by the competent authority.

- *what criteria developed for individuals do stakeholders feel might be appropriate and acceptable to the radiological community?*
- *what criteria developed for large numbers of patients do stakeholders feel might be appropriate and acceptable to the radiological community?*

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Article 63(e)(ii)

“Member States shall ensure that the results of the investigation and the corrective measures to avoid such events are reported to the competent authority within the time period specified by the Member State”

There is recognition that thorough investigations and corrective measures can take time.

- *who should be making the investigations /*
- *should maximum time periods be specified in regulations and specific time periods specified on a case by case basis ?*

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Article 63(f)

“Member States shall ensure that mechanisms are in place for the timely dissemination of information, relevant to radiation protection in medical exposures, regarding lessons learned from significant events”

Sharing information on significant events may reduce the likelihood of similar events happening elsewhere, but the information will need to be of sufficient detail to allow meaningful analysis.

- *who should do this ?*
- *what is the experience and value and can sufficiently detailed information be provided without violating the wishes of patients ?*