EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Section 7 to 10 related to the Marketing Authorisation

Section 11 and 12 related to radiopharmaceuticals

SmPC training presentation

Note: for full information refer to the European Commission's Guideline on summary of product characteristics (SmPC)

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Sections 7 and 8

7. Marketing authorisation holder

- ✓ Name + address +/- Telephone, fax numbers or e-mail addresses
- ✘ Not websites* or emails linking to websites

8. Marketing authorisation number(s)

Item to be completed by the competent authority or by the Marketing Authorisation Holder once the Marketing Authorisation has been granted. For medicinal products for which the European Commission is the Competent Authority, the number to be included in this section is the number in the Community Register

* Note: Public Assessment Reports provide detailed information on medicinal products and are available on the website of the European Medicines Agency, Heads of Medicines Agencies or other National Competent Authorities. A link to the relevant website should be included in SmPCs when a public assessment report is available

Section 9

9. Date of first authorisation/renewal of the authorisation

Item to be completed by the competent authority or by the Marketing Authorisation Holder once the Marketing Authorisation has been granted or renewed. Both the date of first authorisation and, if the authorisation has been renewed, the date of the (last) renewal should be stated; the date should correspond to the actual date of the European Commission decision on the (conditional) renewal.

Section 10

10. Date of revision of the text

- Leave blank in case of a first Marketing Authorisation
- For medicinal products for which the European Commission is the Competent Authority: date of approval of latest variation or transfer, e.g. the latest Commission Decision amending the SmPC, implementation date of the Urgent Safety Restriction or date of (European Medicines Agency) notification amending the annexes to the Marketing Authorisation [for more details refer to the QRD annotated template]
- For products for which Member States are the Competent Authorities: date of approval of latest variation or implementation date of the Urgent Safety Restriction resulting in a revision of the SmPC

Item to be completed by the competent authority or by the Marketing Authorisation Holder at time of printing the SmPC

Sections 11 and 12

11. Dosimetry (if applicable)

Example 1

Full details of internal radiation dosimetry should be included in this section for radiopharmaceuticals

Example 2

12. Instructions for preparation of radiopharmaceuticals (if applicable)

For radiopharmaceuticals, additional detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready-to-use pharmaceutical will conform to its specifications

Special instructions relating to the disposal of containers and unused contents should also be included

Further details are provided in the Guideline on core SmPC and package leaflet for radiopharmaceuticals

Example 1-Dosimetry

Target Organ	Absorbed radiation dose µGy/MBq
Adrenals	13.1
Brain	18.1
Breasts	8.0
Gallbladder wall	25.7
Lower large intestine wall	42.4
Small intestine	20.6
Stomach	11.4
Upper large intestine wall	38.1
Heart wall	13.1
Kidneys	11.1
Liver	28.3
Lungs	42.5
Muscle	9.6
Ovaries	17.0
Pancreas	13.2
Bone marrow	9.8
Bone surfaces	17.4
Skin	6.3
Spleen	10.6
Testes	8.8
Thymus	10.3
Thyroid	9.2
Urinary bladder wall	53.5
Uterus	16.3
Total body	11.5
Effective Dose	23.5 µSv/MBq

Iodine-123 has a physical half-life of 13.2 hours. It decays emitting gamma radiation with a predominant energy of 159 keV and X-rays of 27 keV.
The estimated absorbed radiation doses to an average adult patient (70 kg) from intravenous injection of active substance X (123I) are listed. The values are calculated assuming urinary bladder emptying at 4.8-hour intervals and appropriate thyroid blocking (Iodine-123 is a known Auger electron emitter).
Frequent bladder emptying should be encouraged after dosing to minimise radiation exposure.

The effective dose (E) resulting from administration of 185 MBq of active substance X injection is 4.35 mSv (per 70 kg individual). The listed data are valid in normal pharmacokinetic behaviour. When renal or hepatic function is impaired, the effective dose and the radiation dose delivered to organs might be increased.

Example 2-Instructions for preparation of radiopharmaceuticals

Radiopharmaceutical precursor, solution

Before use, packaging and radioactivity should be checked. Activity may be measured using an ionisation chamber. Active substance X is a beta pure emitter. Activity measurements using an ionisation chamber are very sensitive to geometric factors and therefore should be performed only under geometric conditions which have been appropriately validated.
Usual precautions regarding sterility and radioactivity should be respected.

The vial should never be opened and must be kept inside its lead shielding. The product should be aseptically withdrawn through the stopper using sterilised single use needle and syringe after disinfection of the stopper.

Appropriate aseptic precautions should be taken, complying with the requirements of Good Pharmaceutical Manufacturing Practice, in order to maintain the sterility of active substance X and to maintain sterility throughout the labelling procedures.

Any unused product or waste material should be disposed of in accordance with local requirements.

Thank you for consulting this training presentation

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Please note the presentation includes examples that may have been modified to best illustrate the related principle