Workshop Radiopharmaceuticals, Bern, 12. September 2018

What is the focus of clinical review?

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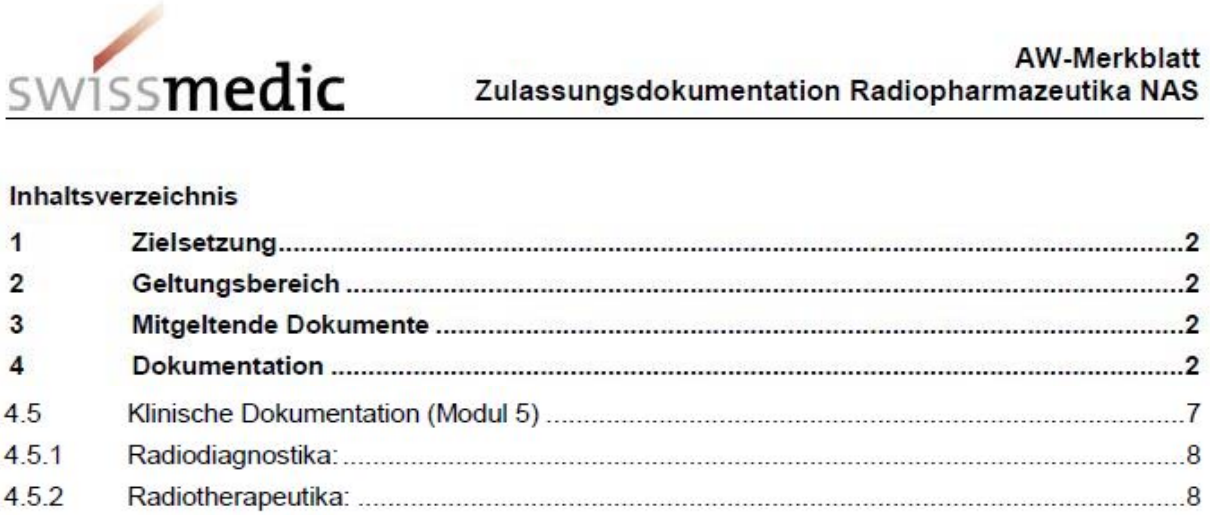
Submission of clinical information

- Package insert (Fachinformation),
  Swissmedic does not require a patient information sheet
- Clinical documentation (Modul 5. Swissmedic information sheet)



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AW-Merkblatt
Zulassungsdokumentation Radiopharmazeutika NAS

Inhaltsverzeichnis

All details can be found in the Swissmedic information sheet, documentation for authorization of radiopharmaceuticals.

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Focus of clinical review

I. Clinical efficacy — benefit

II. Unwanted effects — risk

III. Contraindications — risk

IV. Warnings and Precautions — risk

V. Interactions — risk

VI. Overdose — risk

VII. Indication — risk

VIII. Activity dose/Administration — risk

IX. Procedures (imaging and therapy)

X. Pharmacokinetics/pharmacodynamics

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Focus of clinical review

Benefit-risk assessment – FDA's benefit-risk framework

Benefit-Risk Integrated Assessment		
Benefit-Risk Dimensions		
Dimension	**Evidence and Uncertainties**	**Conclusions and Reasons**
Analysis of Condition		
Current Treatment Options		
Benefit		
Risk and Risk Management		

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Focus of clinical review

I. Clinical efficacy - benefit

Always justification of the design of the clinical trial

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Focus of clinical review

IV. Warnings and Precautions

The packet insert must include specific instructions for

- **patients of child-bearing age;**
  pregnancy test is mandatory in these patients especially before receiving therapeutic activities of radiopharmaceuticals

Dosage Card (Version 5.7.2016)

Multiple of Baseline Activity

Weight kg	Class A	Class B	Class C	Weight kg	Class A	Class B	Class C
3	1	1	1	32	3.77	7.29	14.00
4	1.12	1.14	1.33	34	3.88	7.72	15.00
6	1.47	1.71	2.00	36	4.00	8.00	16.00
8	1.71	2.14	3.00	38	4.18	8.43	17.00
10	1.94	2.71	3.67	40	4.29	8.86	18.00
12	2.18	3.14	4.67	42	4.41	9.14	19.00
14	2.35	3.57	5.67	44	4.53	9.57	20.00
16	2.53	4.00	6.33	46	4.65	10.00	21.00
18	2.71	4.43	7.33	48	4.77	10.29	22.00
20	2.88	4.86	8.33	50	4.88	10.71	23.00
22	3.06	5.29	9.33	52-54	5.00	11.29	24.67
24	3.18	5.71	10.00	56-58	5.24	12.00	26.67
26	3.35	6.14	11.00	60-62	5.47	12.71	28.67
28	3.47	6.43	12.00	64-66	5.65	13.43	31.00
30	3.65	6.86	13.00	68	5.77	14.00	32.33

$$A[MBq]_{\text{Administered}} = BaselineActivity \times Multiple$$

Administration

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Always justification of the proposed activity dose
- only as much as necessary -

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Focus of clinical review

IX. Procedures (imaging and therapy)

The packet insert must include specific instructions for

- **scanning the patient;**
  e.g. specific preparation before scanning, recommended scanning time, instructions for reading the scans etc.

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Focus of clinical review

Objections in the clinical review - Period 2016 until now

I. **Clinical efficacy**

II. **Unwanted effects**

III. **Contraindications**

IV. **Warnings and Precautions**

V. **Interactions**

VI. **Overdose**

VII. **Indication** — 1 x correction of indication

VIII. **Activity dose/Administration** — 3 x missing justification of dosage

IX. **Procedures (imaging and therapy)** — 4 x adding information about scan protocol/scan reading instructions

X. **Pharmacokinetics/pharmacodynamics**

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Questions?