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Regulatory environment and peculiarities for radiopharmaceuticals in Switzerland

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Revision of the therapeutic products act (TPA)

- TPA revision started in November 2012 and was completed in March 2016
- Ordinances have to be revised as a consequence
- In-depth view & explanation:
  - Ordinance on the fees of the Swiss Agency for Therapeutic Products
  - Ordinance on medicinal products (VAM/Oméd) – annex 1

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Application fees

Application Type	Fee at present (reduction incl.)	Fee acc. to revised ordinance
New acitve substance	7'000.- CHF	80'000.- CHF
New indication	2'000.- CHF	15'000.- CHF
Known acitve substance	1'500.- CHF	50'000.- CHF
Label variation (major)	2'500.- CHF	5000.- CHF
Quality variation (major)	2'000.- CHF	5000.- CHF
Label variation (minor)	750.- CHF	1'500.- CHF
Quality variation (minor)	750.- CHF	1'500.- CHF
Hospital preparations (Art. 14 para. 1 let. d TPA)		**2'000.- CHF**

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Fee reducing actions

- Fees will be charged according to expenditure
- Only the scientific review will be charged
- No charges for:
  - Administrative activities
  - Peer review
  - Expert Commission Radiopharmaceuticals (ECRP)
- Cost-cap for each variation, according to regular fee of (HGebV/OEPT)
- Art. 12 HGebV/OEPT – Fee reduction for the public benefit
  - Can and will be used

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Future application fees - estimation

- Fees were calculated using data from already approved applications of the last two years

Application Type	Fee at present (reduction incl.)	Future fees (reducing actions incl.)
New acitve substance	7'000.- CHF	10'500.- CHF (6'000 to 15'000.- CHF)
Variations (all Types)*	750 - 2'500.- CHF	Ø 2000.- CHF

* Not enough data to estimate the fee for every type of variation, therefore only an average for future fees is given

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Future application fees

- Swissmedic is aware of the special situation with radiopharmaceuticals
  - essential preparations with complex production and handling
  - commercial interest in radio pharmaceuticals compared to other drug groups in many cases is lower
  - administrative burden during the review is usually lower than for a conventional pharmaceutical

- Art. 13, Art. 14 (TPA) as well as orphan drug status is also applicable to radiopharmaceuticals

- Review of applications with high-quality supporting documentation will be cheaper

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Temporary distribution licenses

- No temporary distribution licenses with the new TPA
- Annex 1 para. 3 (VAM/Oméd)
  - Includes all active pharmaceutical ingredients with a limited marketing license by 31.12.2018
  - Annex applies to hospitals and contract manufacturers
- For new active pharmaceutical ingredients to be included in annex 1 an application has to be sent to Swissmedic
- SOP-Draft for annex 1 will be published by 30.09.2018

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Anhang 1 Ziffer 3 VAM - excerpt

Active ingredient	Limitations	Quality requirements
[^{68}Ga]Gallium-PSMA-HBED-CC Also known as: [^{68}Ga]-PSMA-11, ^{68}Ga-Labelled GLU-Urea-LYS(AHX)-HBED-CC	Labelling of tumors in patiens with prostate adenocarcinoma	[^{68}Ga]-PSMA-11 ≥ 95 % of total radioactivity at release [^{68}Ga]Galliumchloride-solution for radio-labelling conforms to Ph. Eur. PSMA-11 and its metal complexes: ≤ 30 µg per dose
[^{68}Ga]Gallium-Oxodotreotidum Also known as: [^{68}Ga]-DOTATATE, [^{68}Ga]-DOTA-Octreotate	Labelling of neuroendocrine tumors	[^{68}Ga]-DOTATATE ≥ 95% of total radioactivity at release ^{68}Ga-Labellingsolutions conforms to Ph. Eur. DOTATATE and its metal complexes: ≤ 50 µg per dose

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Swissmedic information events on the revision of the Therapeutic Products Act (TPA)

- Swissmedic will hold two different information events to provide information on the revision of the Therapeutic Products Act (TPA)

- Date: **Thursday 25 October and Friday 9 November 2018**

  https://www.swissmedic.ch/swissmedic/en/home/services/veranstaltungen/events/info-event-rev_hmg.html

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Thank you for your attention!

Questions?