Workshop Radiopharmaceuticals, Bern, 12. September 2018

Presentation of the Expert Commission Radiopharmaceuticals, the FOPH and Swissmedic

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Dr. Annette Mollet, President of the Commission, Dr. Rolf Hesselmann, FOPH, Dr. Andreas Fürer, Swissmedic

Swissmedic • Swiss Agency for Therapeutic Products • Hallerstrasse 7 • 3012 Berne • Switzerland • www.swissmedic.ch

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ECRP (Expert Commission for Radiopharmaceuticals)
FOPH (Federal Office of Public Health)
SMC (Swissmedic)

Legal Basis for the collaboration:

- Federal Act on Medicinal Products and Medical Devices (TPA)
- Radiation Protection Act and Ordonance (RPA / RPO)

Radiopharmaceuticals are the only medicinal products which cannot be authorized by SMC alone but in collaboration with the FOPH and ECRP

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Expert Commission Radiopharmaceuticals (ECRP):

- Appointed by the Federal Council
- Members:
- Dr. Annette Mollet, President, Preclinic Expert
- Dr. Peter Koch, Vice-President, Quality Expert
- Dr. Frank Assenmacher, Radioprotection Expert
- Dr. Anass Johayem, Preclinic Expert
- Prof. Dr. Niklaus Schäfer, Clinic Expert
- Dr. Marietta Straub, Quality Expert
- Prof. Dr. Damian Wild, Clinic Expert
- Secretary: Dr. Esther Wullimann, Swissmedic
- https://www.admin.ch/ch/f/cf/ko/gremium_10407.html

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Duties of the Expert Commission Radiopharmaceuticals

- 6 Meetings in a year (about every 2 months)
- Review on Quality (radiochemistry), Preclinic, *Clinic* and Radioprotection for Radiodiagnostics (new applications, variations and temporarily limited authorisations)
- Review on Quality (radiochemistry) and Radioprotection for Radiotherapeutics (new applications and variations)
- Peer Review on Preclinic and Clinic for Radiotherapeutics (new applications and variations)
- The ECRP Review is the basis for the decision for an approval or rejection of a new application.

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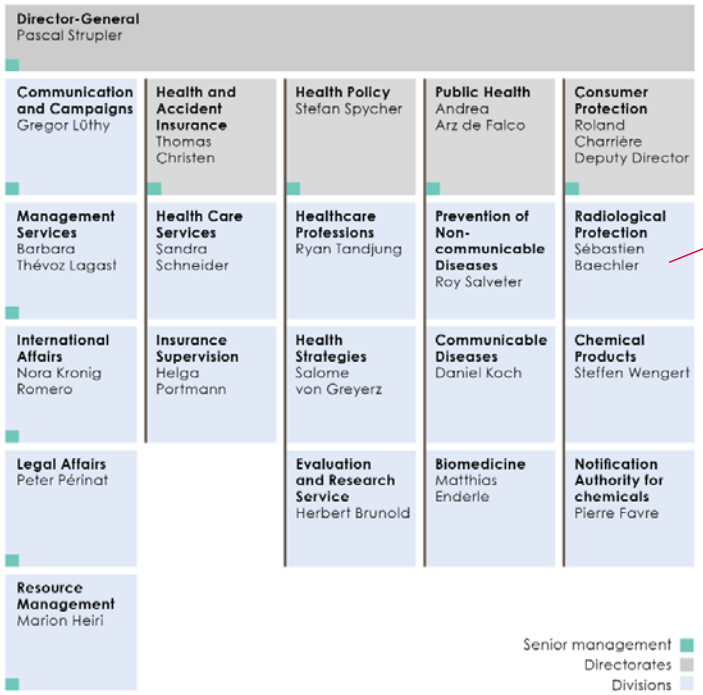
Federal Office of Public Health (FOPH)



Section Research Plants and Nuclear Medicine
Dr. Nicolas Stritt, Head of the Section
Dr. Rolf Hesselmann

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Function of FOPH

- Responsible for the Authorisations of handling radioactive materials (incl. producers and users of radiopharmaceuticals)
- Inspections of producers and users of radiopharmaceuticals
- Co-Review on Regulatory, Quality, Preclinical, Clinical, and Radioprotection for radiopharmaceuticals (new applications and variations)

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Function of FOPH II

- Preparation and Review on Quality, Preclinical, Clinical, and Radioprotection for Radiopharmaceuticals which shall obtain a temporarily limited authorisation.
  Decision of approval for a temporarily limited authorisation
- Decision about approval or rejection of a new application
- Contact to the Federal Council, like elections for the Commission, Appendix 1 of the VAM/OMéd

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Swiss Agency for Therapeutic Products, Swissmedic

Dr. Andreas Fürer
Urs Eugster

Prof. Dr. Oliver Wildner

Dr. Elisabeth Klenke

Dr. Edmund Ehrensperger

Beatrice Blaser, Protocol

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Swiss Agency for Therapeutic Products, Swissmedic

- Inspectorates
- Licencing for the companies
- Special authorisations

Clinical Trials

Pharmacopeia

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Function of SMC Authorizations

- Preparation of the new application/variation documentation for the Review
- Regulatory Review
- Peer Review on Preclinic and Clinic for Radiodiagnostics (new applications and variations)
- Review on Quality (cold Chemistry) and occasionally Pharmacovigilance (PHV) for all Radiopharmaceuticals (new applications and variations)

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Function of SMC Authorizations II

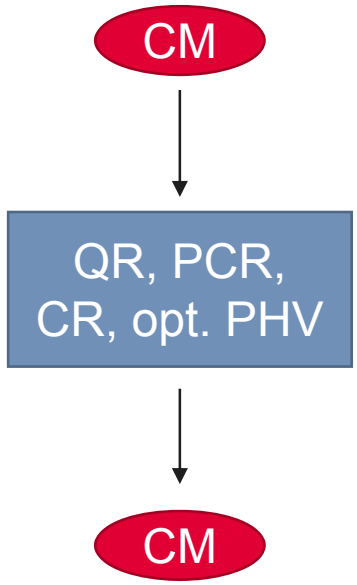
- Review on Preclinic and Clinic for Radiotherapeutics (new applications and variations)
- Correspondence of Questions, preliminary Decisions and final Decisions.
- Documentation Management

Usual Workflow at Swissmedic

Preparation and Admin.

Scientific Review

Communication (LoQ, VB/PA..)



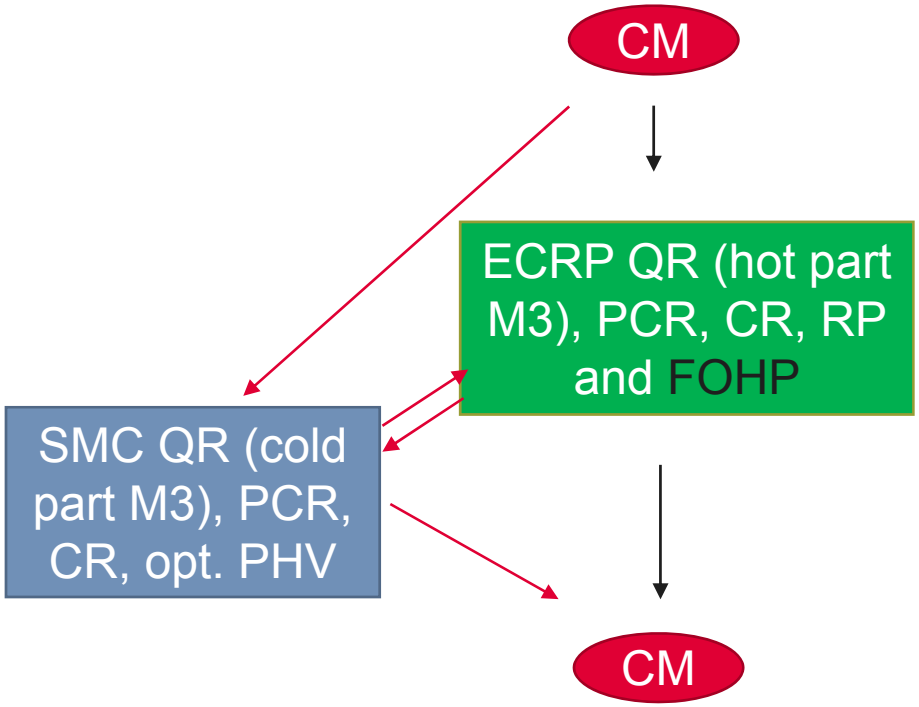
Workflow: Radiodiagnostic

Preparation and Admin.

Scientific Review

Scientific Review and
Peer Review

Communication (LoQ, VB/PA..)

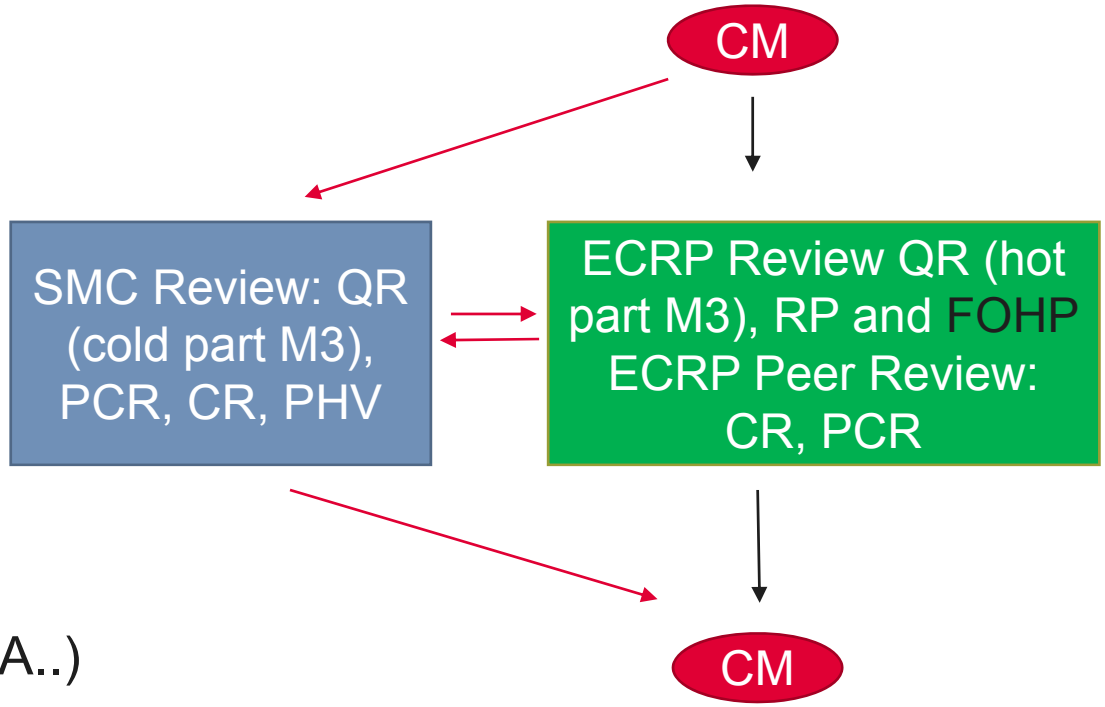


Workflow: Radiotherapeutic

Preparation and Admin.

Scientific Review and Peer Review

Communication (LoQ, VB/PA..)



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Expert Commission RP, the FOPH and SMC

Thank you for your attention!

Questions?