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Regulation of Oncology Biologics in Switzerland

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Bern, Switzerland

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Oncology Biologics include

- Monoclonal antibodies, recombinant proteins
- Cancer vaccines
- Gene therapy products
- Transplantation products

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Legal Basis

- Swiss Law on Therapeutic Products
- Swiss Law on Transplantation
- European Pharmacopoeia

Guidelines

- Swiss Guidelines
- International Guidelines (e.g. ICH* Guidelines)

*ICH: International Conference on Harmonisation; www.ich.org

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Regulation of Oncology Biologics

- Not different from other medicinal products
- Notification/approval of clinical trials
- Marketing authorization of products
- Accelerated approval possible
- Orphan drug status if requirements fulfilled
- Scientific advice

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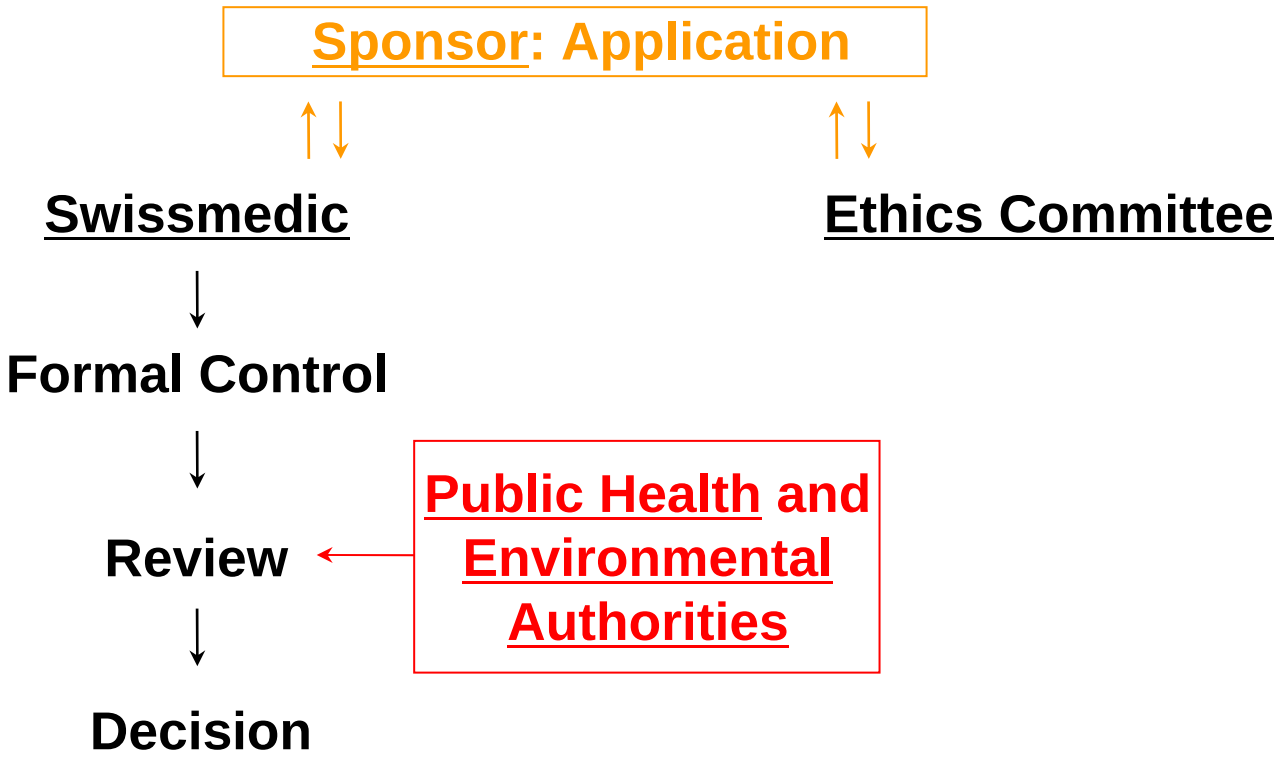
Approval of Clinical Trials (90 days)

(Gene therapy and investigational products containing GMOs)



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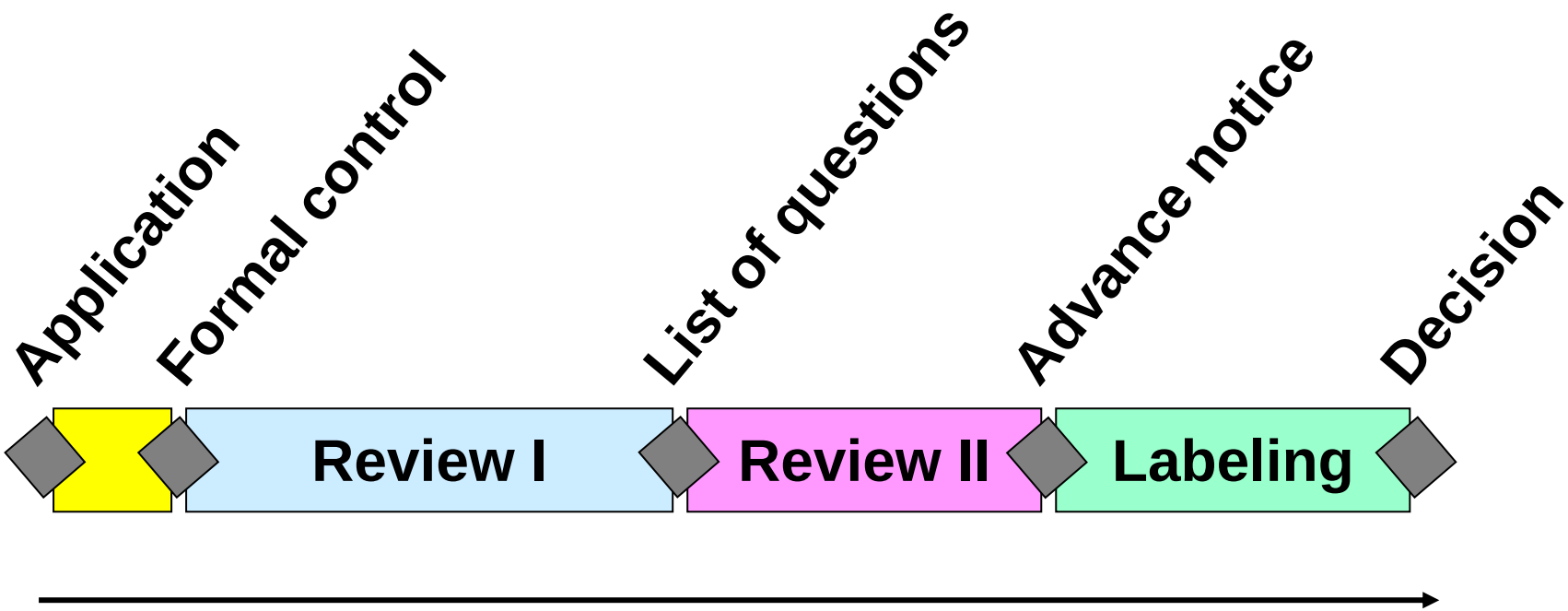
Marketing Authorization



Time to approval 130 – 300 days

(Swissmedic evaluation time)