

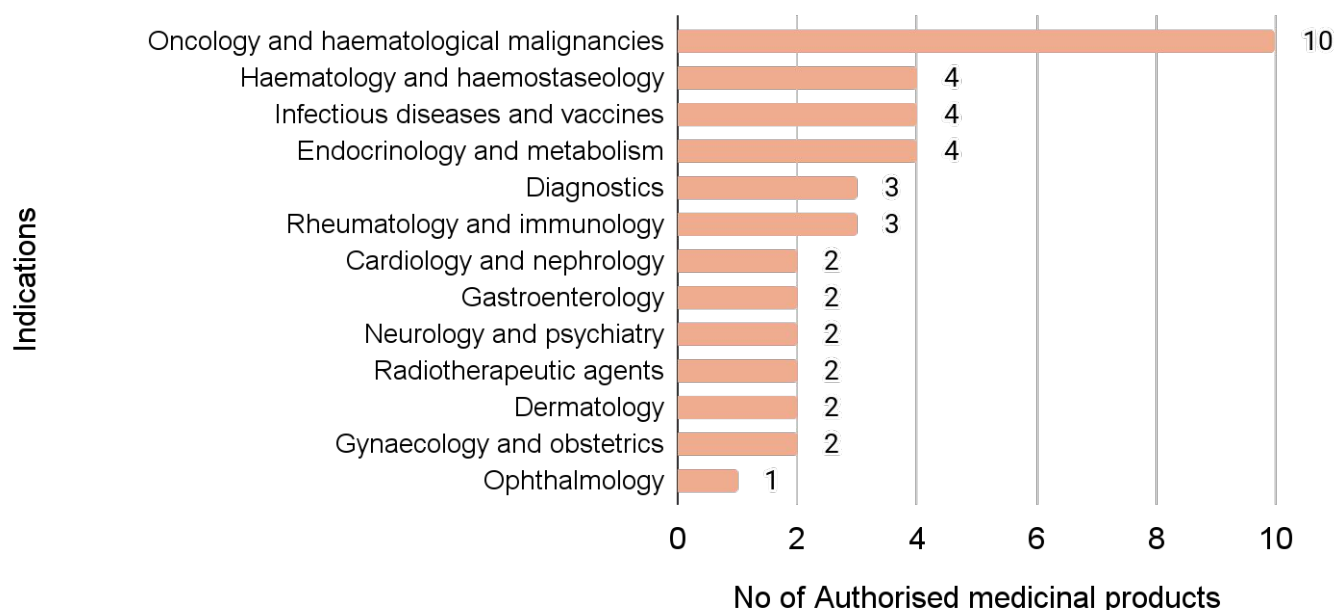
# 2023 insights into Swissmedic authorization of human medicinal products featuring a new active substance and additional indications

Swissmedic-authorized medicinal products may only be distributed in Switzerland. The Swiss Agency for Therapeutic Products is involved in the entire life cycle of a medicinal product

# Swissmedic granted authorization to 41 human medicinal products featuring a new active substance

- In 2023, Swissmedic finalized 49 new authorization applications for human medicinal products with new active substances
  - Of these, 41 (84%) were authorized while in 8 cases (16%), the application was withdrawn by the companies
- Median turnaround time was 441 calendar days ( vs 456 days in 2022)

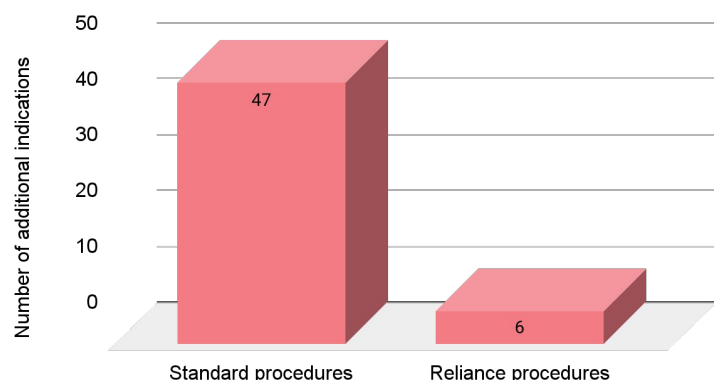
## Newly authorized medicinal products as per the indication (N=41)



## Authorization of additional indications by Swissmedic

- In 2023, Swissmedic finalized 79 applications for additional indications
  - Of these 65 (82%) were authorized, 13 (16%) were withdrawn by the companies and in one case (1%), there was a partial withdrawal
  - Median turnaround time was 352 calendar days (vs 345 in 2022)

### Procedures with standard time limit (N=53)



### Fast-track procedures (N=12)

