

New Agency for medicines registration

Key issues

Presentation for the meeting in the Ministry of Healthcare of Ukraine
Kyiv, 8 June 2017



European Bank
for Reconstruction and Development

New Agency Tasks

- Building a „Big Agency” brings more risks than advantages.
- Integration of all functions in one structure could be considered in the future, when the New Agency becomes operative and stable.
- Proposed model:

Clinical Trials	Yes
Marketing Authorizations	Yes
Pharmacovigilance	Yes
Licensing – Manufacturing, Import	Not recommended
Licensing – Wholesale, Retail	Not recommended
Advertising	Not recommended
State Quality Control	Not recommended
Pricing, Reimbursement, HTA	Yes*

** At least in the initial period, as a part of a „competence center”.*



New Agency

Products covered

- Proposed model:

Medicinal products – human	Yes
Medicinal products – veterinary	Not recommended
Medical devices	Yes
Borderline products	Yes (by default)
Biocidal products	Possible in the future
Functional foods	Possible in the future
Cosmetics	Possible in the future



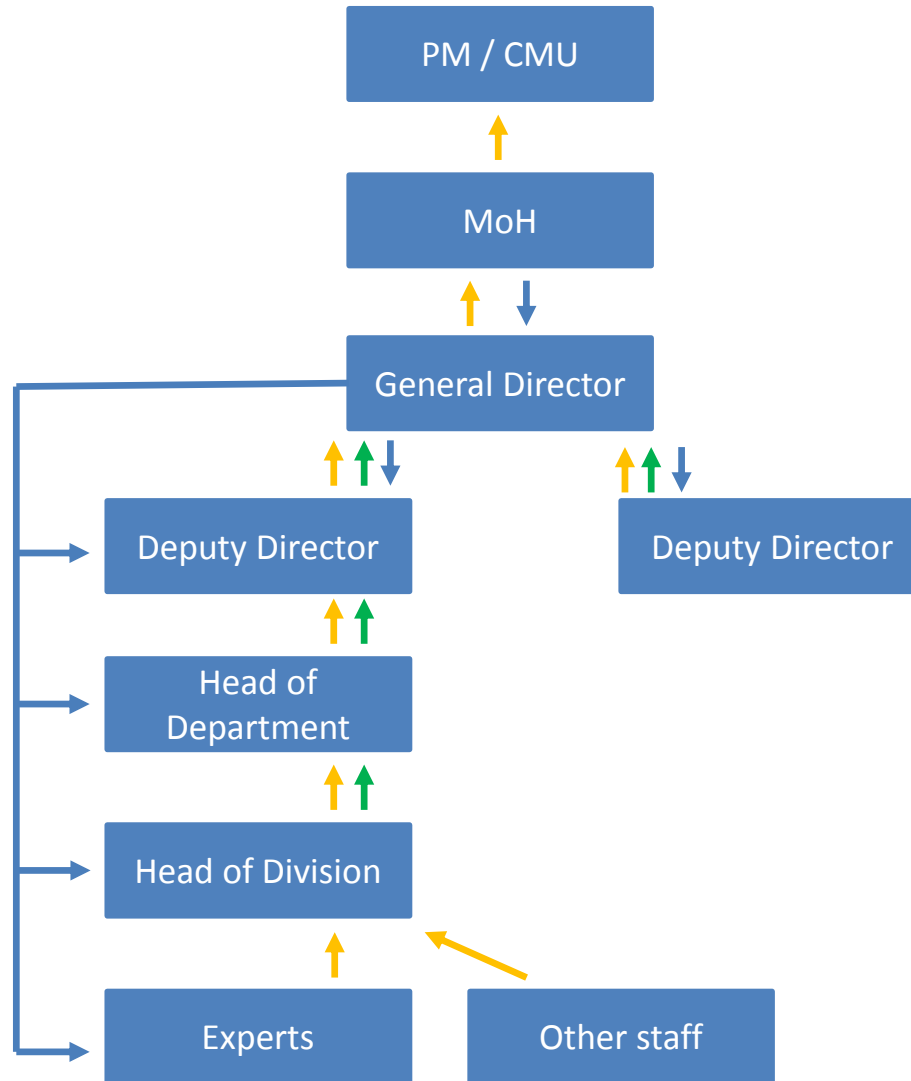
Position in the system (subordination)

Key:

↓ - appoint/dismiss

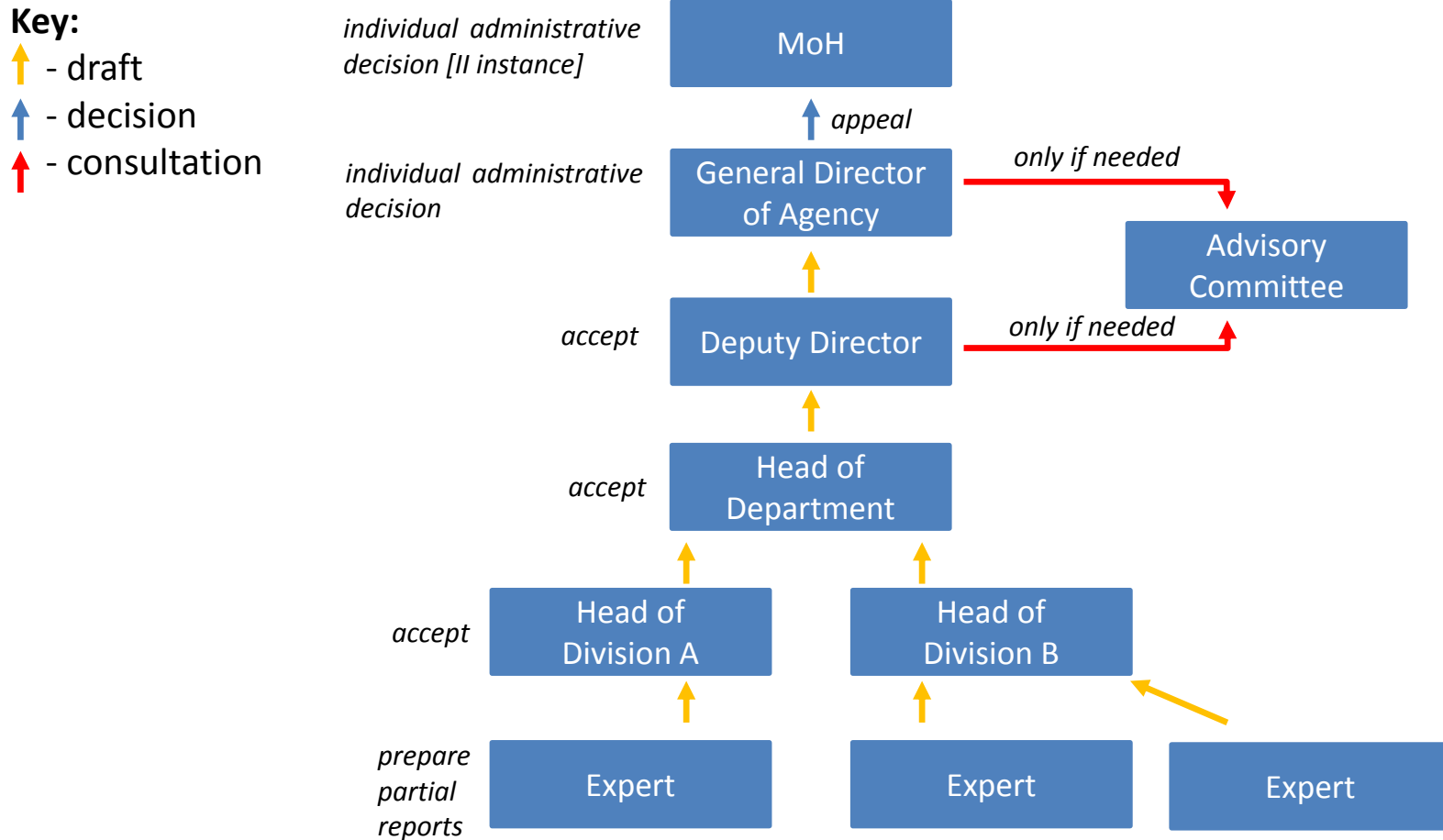
↑ - report

↑ - recommend



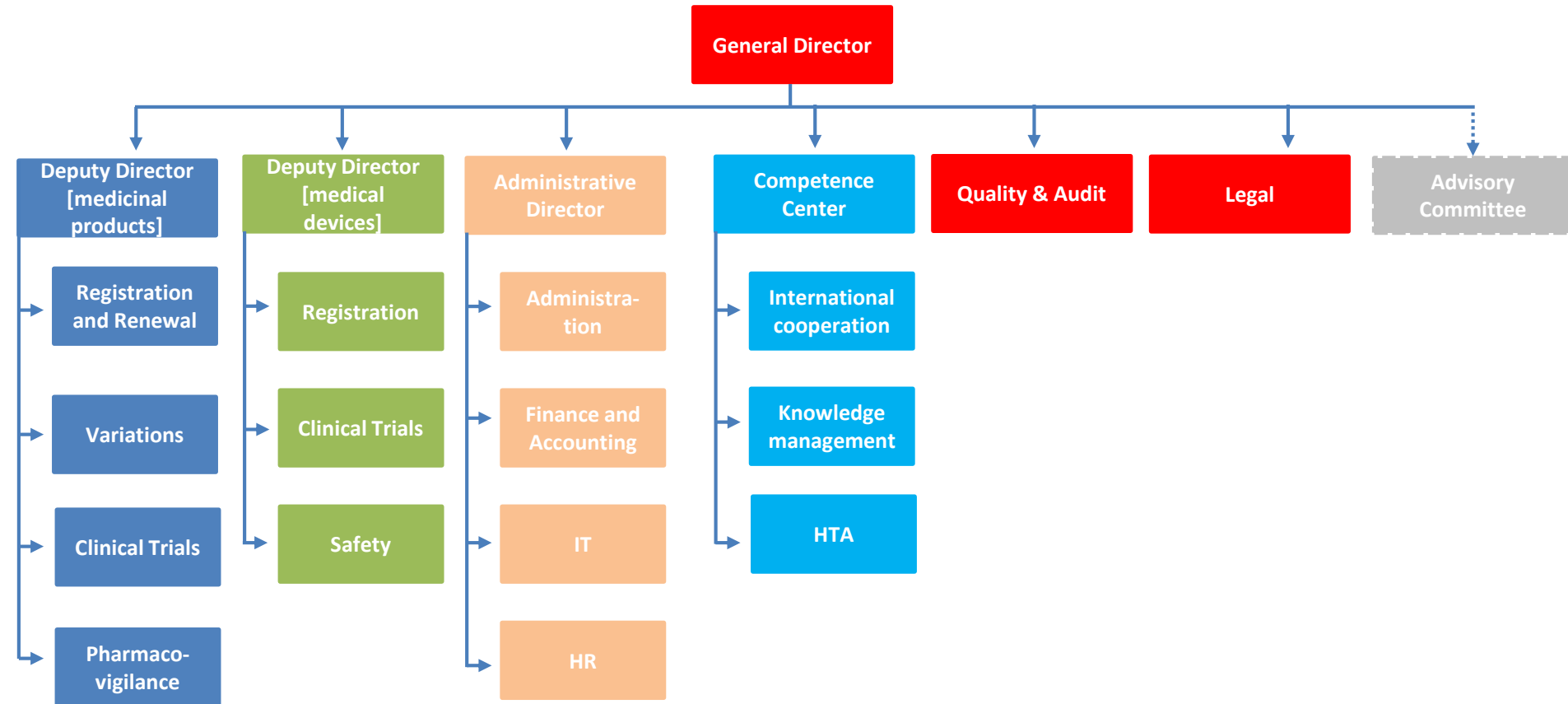
New Agency

Position in the system (procedure)



New Agency

Internal structure



New Agency Transparency

- New website, including:
 - internal procedures
 - CVs of experts
 - **up-to-date patient information leaflets**
- New declarations on conflict of interests



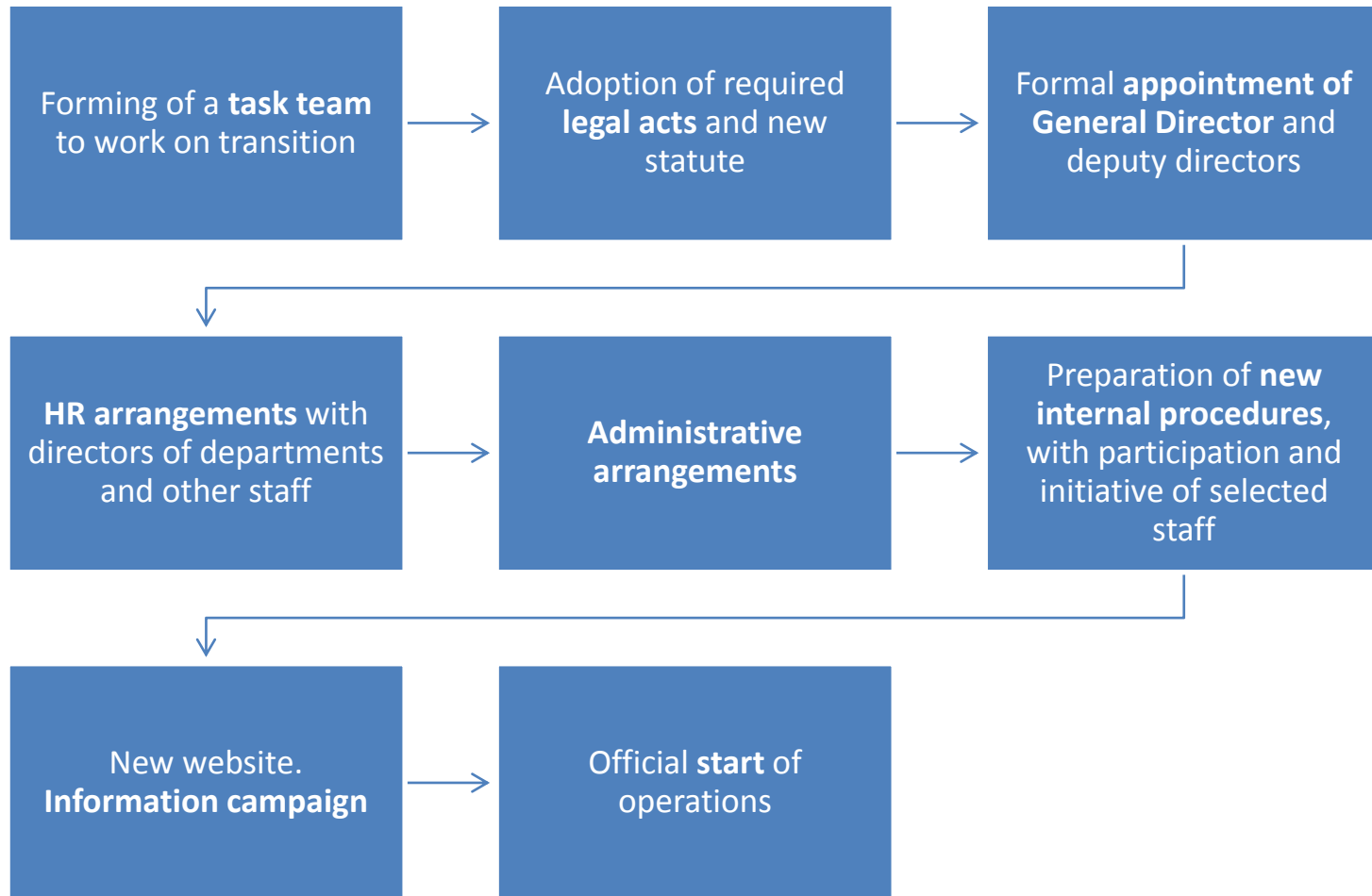
New Agency

Recruitment / HR

- Building the structure top-down.
- In general, all experts are welcome
 - subject to General Director's consent and
 - signing new declaration on conflict of interests.
- Only gradual changes / replacements, with a view to promote internal experts.
- Possibility to employ foreign experts, on a supplementary / temporary basis.
- New remuneration policy.

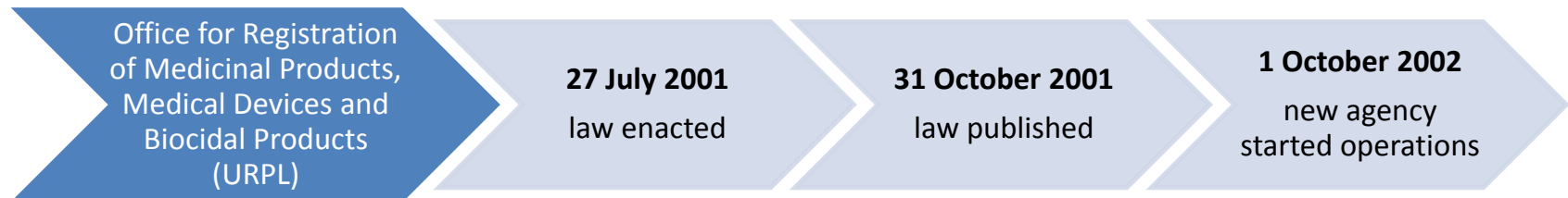


New Agency Transition



New Agency

Timeframe – Polish example



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