

# 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:

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

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



# New Agency

## Products covered

- Proposed model:

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



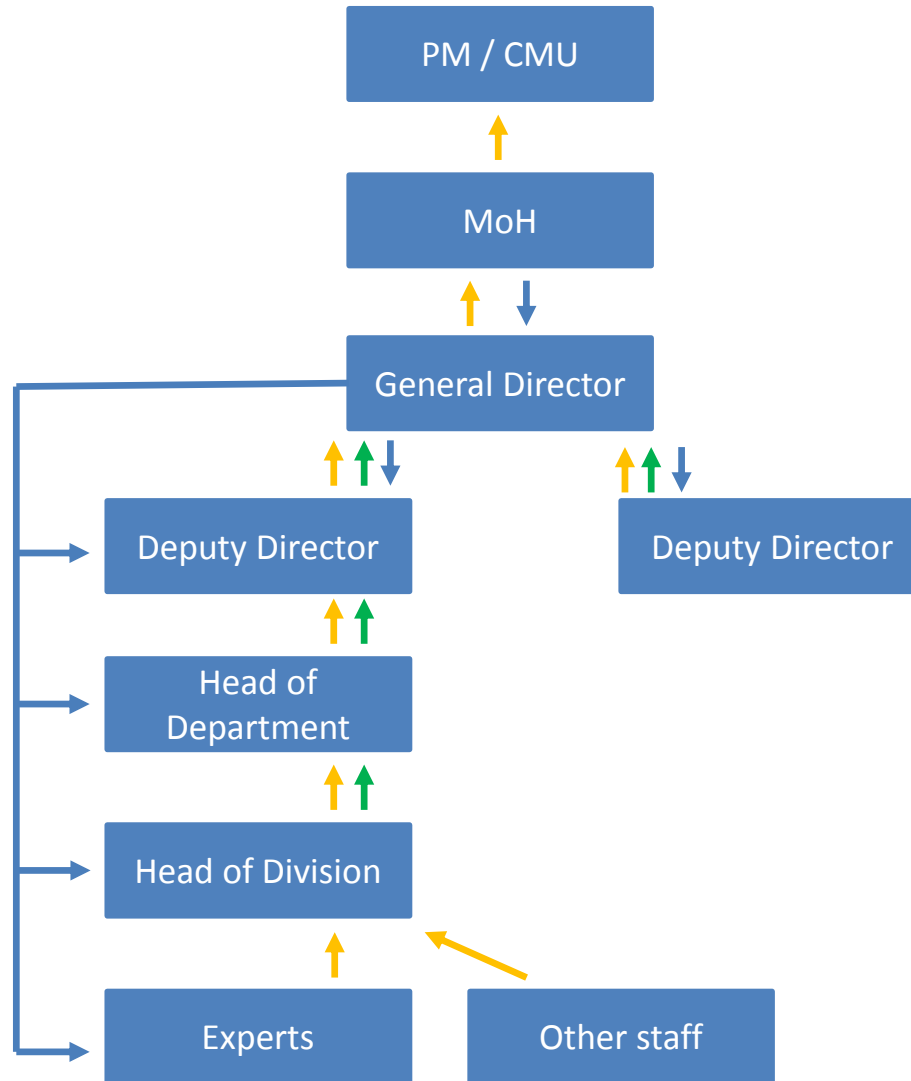
## Position in the system (subordination)

**Key:**

↓ - appoint/dismiss

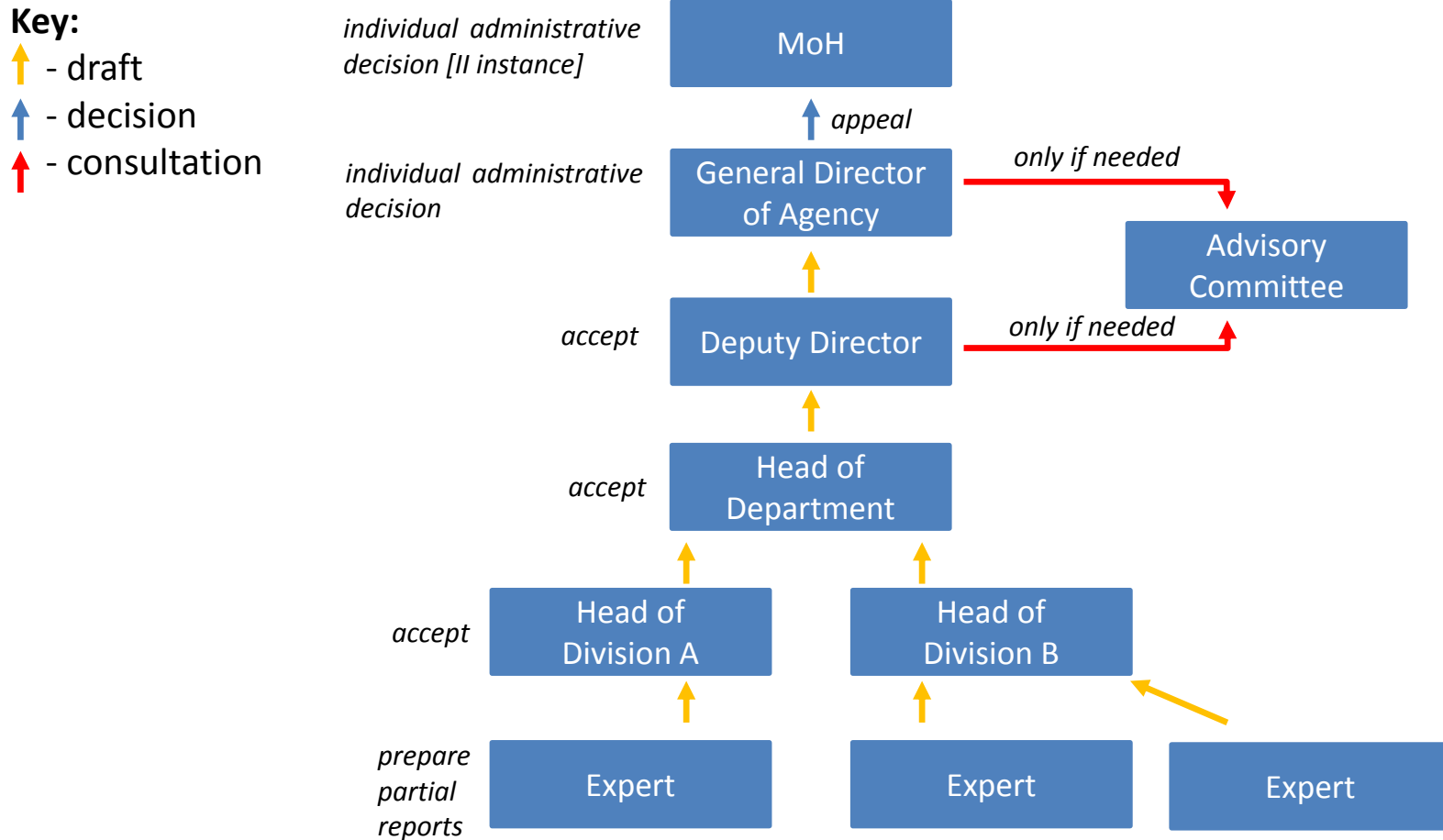
↑ - report

↑ - recommend



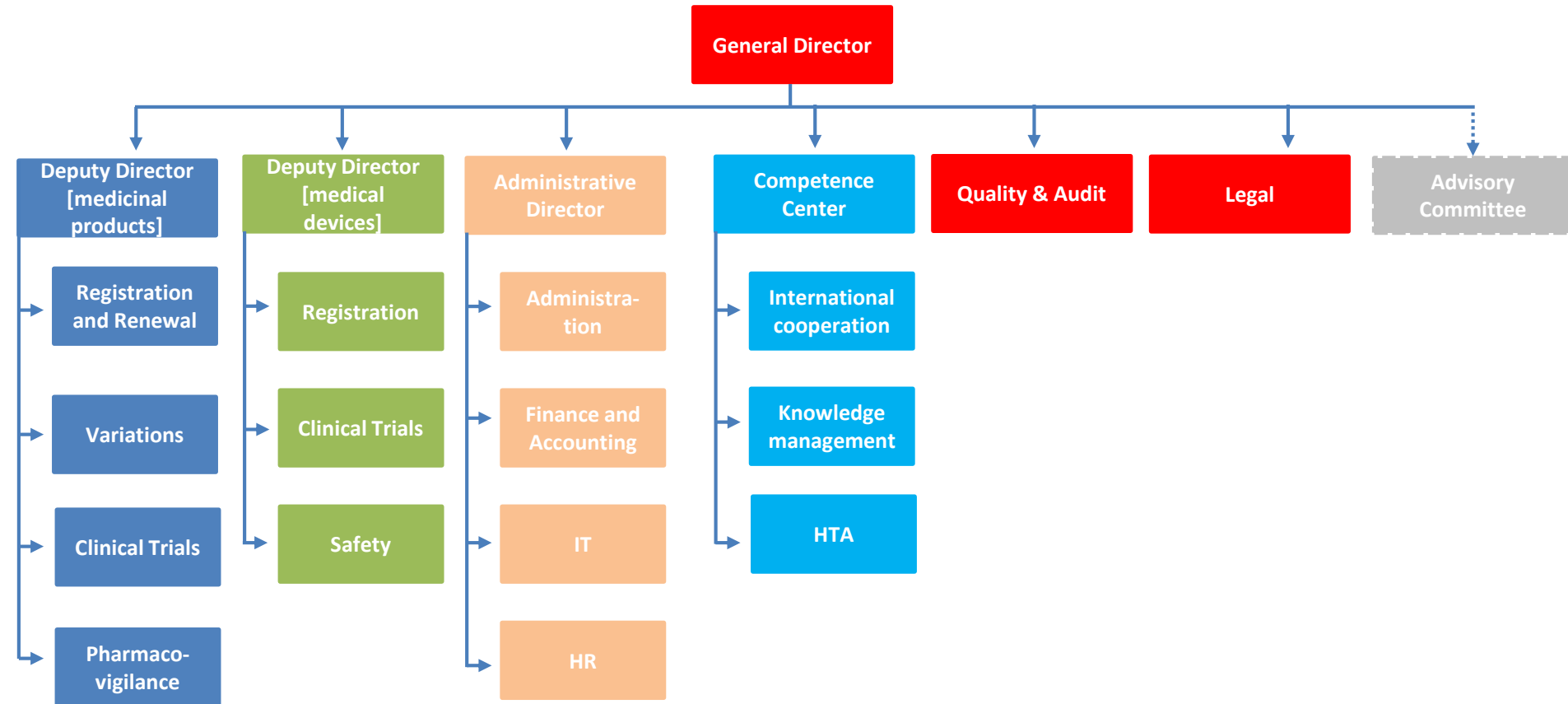
# New Agency

## 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

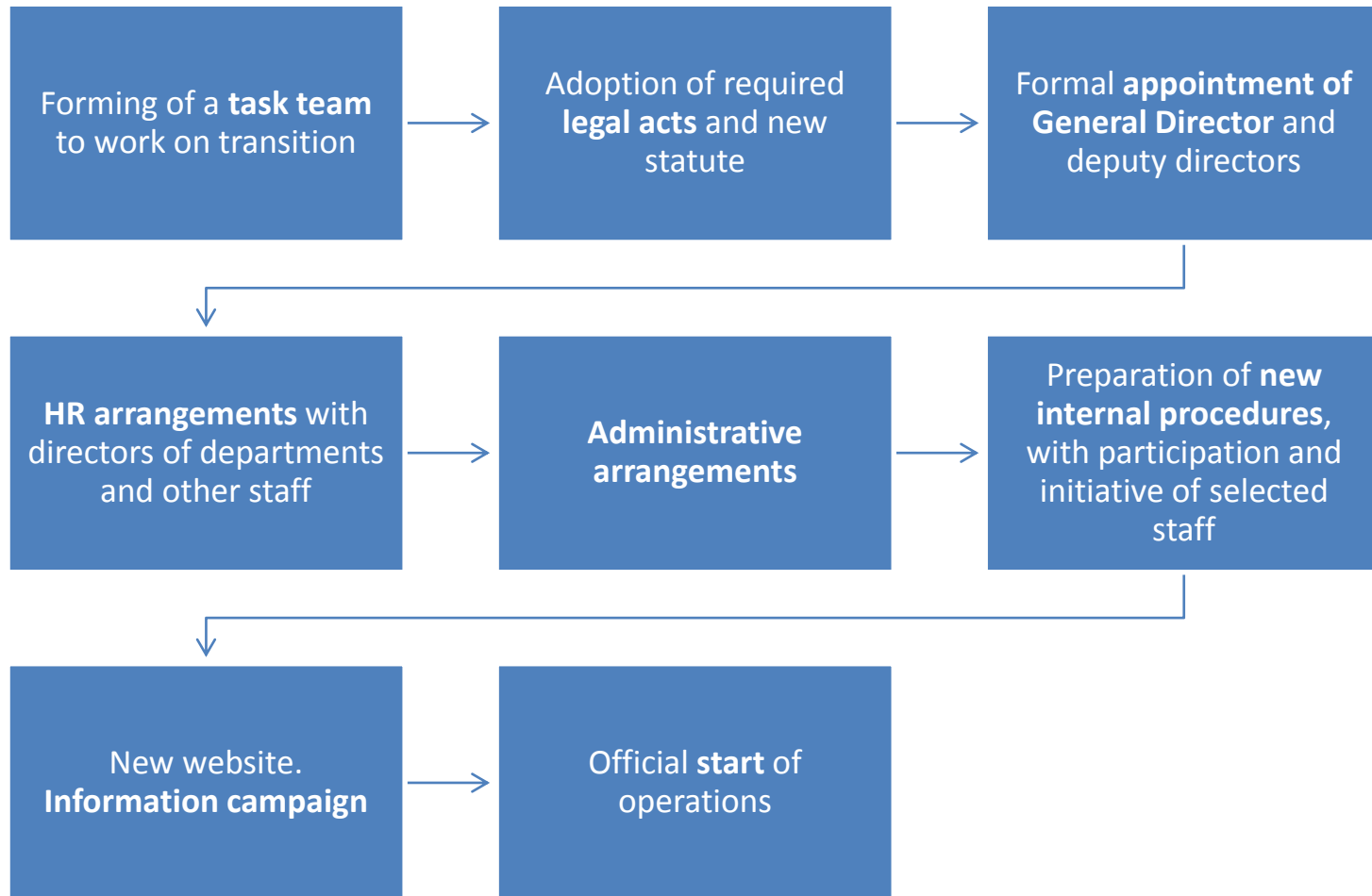
## Recruitment / HR

- 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.



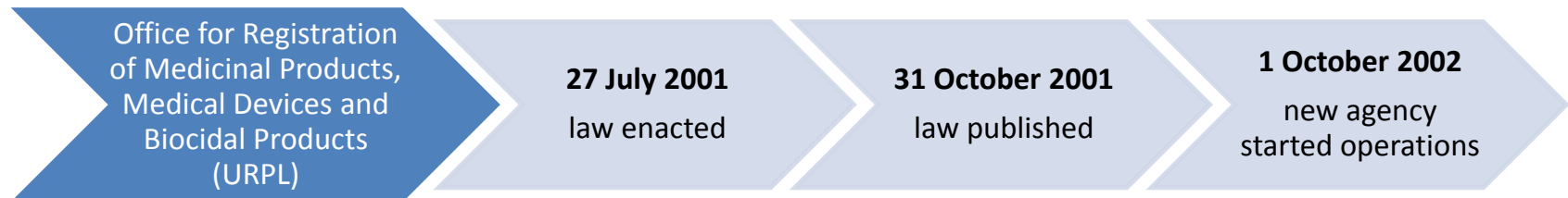


# New Agency Transition



# New Agency

## Timeframe – Polish example



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