Advice on Regulatory Improvements in Ukraine's Pharmaceutical Sector.

Phase III. Institutional Capacity Building Plan

Presentation for the EBRD Steering Committee, Kyiv, 26 April 2017

European Bank
for Reconstruction and Development

Content

- Part I: Status of Consortium work
- Part II: Reform of medicines registration administration (Polish experience)
- Part III: Consultants' vision reform of medicines registration administration

Part I.
Status of Consortium work

Status of Consortium work

Since the recent Steering Committee meeting the Consortium:

- issued Final Report (officially published on the MoH website)
- proposed amendments to the National Drug Strategy and Action Plan (4 out of 11 recommendations were taken into account)
- proposed remarks during the public consultations of the National Drug Strategy
- had several meetings with MoH representatives on the future steps within the Project

Status of Consortium work (2)

Impact of Consortium work

- SEC increased salaries to its experts (according to the information provided by SEC)
- SEC promotes and supports e-health implementation
- SEC holds seminars for applicants on the regular basis
- SEC increased slightly prices for its services. New prices came into force February 15, 2017

Scope of Phase III

The scope of Phase III is the following:

- preparation of the Institutional capacity building plan (organizational structure and general principles of functioning) for a new model of drug registration authority (HR, transparency and decision-making)
- preparation of the related legal step-plan
- outlining what changes in existing laws are required to ensure a successful transfer from current institutional framework and organization of medicines registration process to the new one

Duration of Phase III is 12-14 weeks.

Part II.
Reform of medicines registration administration – Polish experience

Establishment of the Office (2001)

- Reasons for establishment of the Office
- Act of 27 July 2001 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL)
- URPL as a state budgetary unit, subordinated to MoH, assisting MoH in issuing decisions of registration
- Started operations on 1 October 2002
  - Coordinated with fundamental reform of pharmaceutical law in all areas (implementation of EU legislation)
  - From „day one" the new Office taken over all competence of previously competent authorities
- New Office was based on selected property and staff resources of several state institutions, including:
  - Bureau for Registration of Pharmaceuticals and Medical Materials (part of Institute of Medicines, a state-owned scientific institute), which provide expert advice in registration procedure)
  - Centre for Medical Technology (state-owned R&D unit)

Reform of the Office (2011)

- Reasons for reform
- Act of 18 March 2011, entry into force on 1 May 2011
- President of the Office became a „central body of government” (function in many ways similar to a minister of cabinet), with a right to grant marketing authorizations by way of individual marketing decision.
- The Office (URPL) became a structure supporting the President of the Office in performing its competences.
- MoH retained general supervision, and hears appeals in individual cases.

Polish experience

- Name of the agency
- Scope of competence (types of products)
- Position in the structure of state administration
- Philosophy of building the institution (scientific vs managerial)
- Challenges in the field of HR
  - employee turnover
  - reputation of the Office
- Public image
  - media
  - industry

Polish experience (2)

- Sources of financing
- Harmonization of registration dossiers with EU standards as a challenge and as an opportunity
- Collaboration with EU institutions
  - Trainings
  - Scientific residency
- Conferences and trainings for the industry
- Regular meetings/conferences for journalists and non-experts
- Scientific magazine „Almanach”
- Changes to remuneration scheme
- Reinforcement of internal audit, subordinated directly to the President of the Office
- Creation of PhV and CT inspections within URPL

Part III.
Consultants' vision of reform

New medicines registration authority
Tasks

- Tasks of medicines registration agency – European perspective:

	Poland	Germany	France	UK
Clinical Trials	URPL	BfArM / PEI	ANSM	MHRA
Marketing Authorizations	URPL	BfArM / PEI	ANSM	MHRA
Pharmacovigilance	URPL	BfArM / PEI	ANSM	MHRA
Manufacturing and Import Licensing	GIF	regional governments	ANSM	MHRA
Wholesale and Retail Licensing	GIF	regional governments	ANSM	MHRA/ GPhC
Promotion and Advertising	GIF	regional governments	ANSM / CEPS	MHRA + self-regulatory bodies
Quality control	GIF	regional governments	ANSM	MHRA
Pricing, Reimbursement, HTA	MoH + HTA agency (AOTMiT)	MoH + health funds + HTA agency (IQWiG)	MoH + CEPS + health fund	health fund + HTA agency (NICE)

New medicines registration authority
Tasks (2)

- Proposed model:

Clinical Trials	Yes
Marketing Authorizations	Yes
Pharmacovigilance	Yes
Licensing – Manufacturing, Import	?
Licensing – Wholesale, Retail	?
Advertising	?
State Quality Control	?
Pricing, Reimbursement, HTA	Possible, but additional safeguards needed

- Possible models:
  - registration agency + separate enforcement agency („Scientific Agency" + „Pharma-Police")
  - scientific and enforcement concentrated in one agency, but relatively independent, with separate deputy directors, budget planning etc. („Big Agency")

New medicines registration authority
Tasks (3)

- „Big Agency" or separate agencies?
  - Respective agencies should serve as tools for MoH to create and implement drug policy of the state. From this perspective several specialized institutions would be probably more operative and controllable than one big conglomerate.
  - Mission/vision of the new agency + desired management culture would be easier to develop and implement in separate structures than in „Big Agency" (due to different background and history of original institutions).
  - Higher risk of organizational failure of „Big Agency" (= potential risk to public health)
- Pricing, reimbursement, HTA
  - Usually separated from registration

  BUT
  - Possible opportunity to create „competence center" in Ukrainian healthcare administration

New medicines registration authority
Products covered

- Other products covered by medicines registration agencies – European perspective:

	Poland (URPL)	Germany (BfArM)	France (ANSM)	UK (MHRA)
Medicinal products – human				
Medicinal products – veterinary				only where the company undertakes both human and veterinary activities
Medical devices		competences divided with regional government		
Biocidal products				
Functional foods				
Cosmetics				

New medicines registration authority
Products covered (2)

- Proposed model:

Medicinal products – human	Yes
Medicinal products – veterinary	No
Medical devices	Recommended
Biocidal products	Possible (disinfectants, chemical sterilizers)
Functional foods	Only borderline
Cosmetics	Possible („cosmeceuticals”)

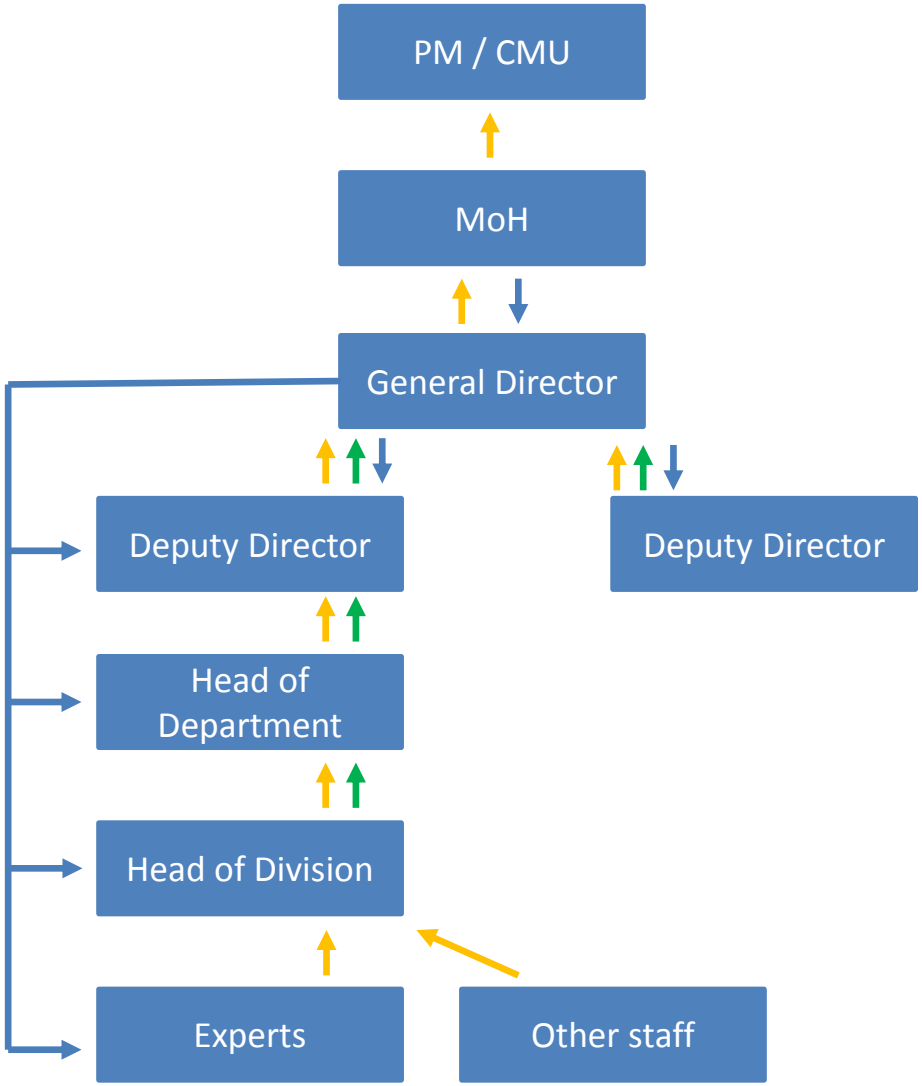
- Why medical devices?
  - integrated approach to clinical trials, post-authorization safety, potentially also to pricing/HTA
- Borderline products
  - New authority would have competence „by default” to decide on the status of a bordeline product
  - Control over de-registration (switches of registration status from medicinal product to other categories: functional food, medical device, cosmetic)

New medicines registration authority

Position in the system (subordination)

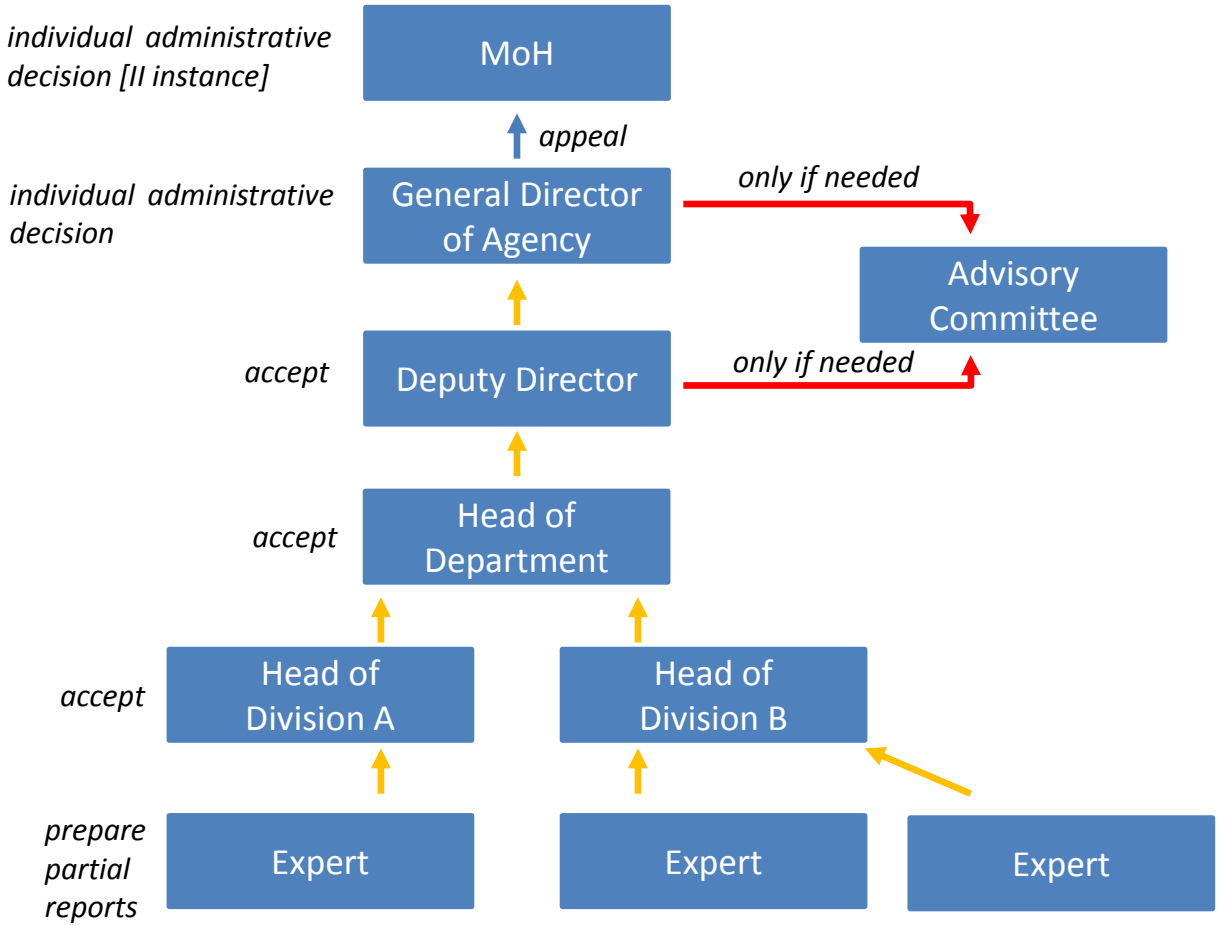
Key:

- ↓ - appoint/dismiss
- ↑ - report
- ↑ - recommend



New medicines registration authority
Position in the system (procedure)

Key:
- ↑ - draft
- ↑ - decision
- ↑ - consultation



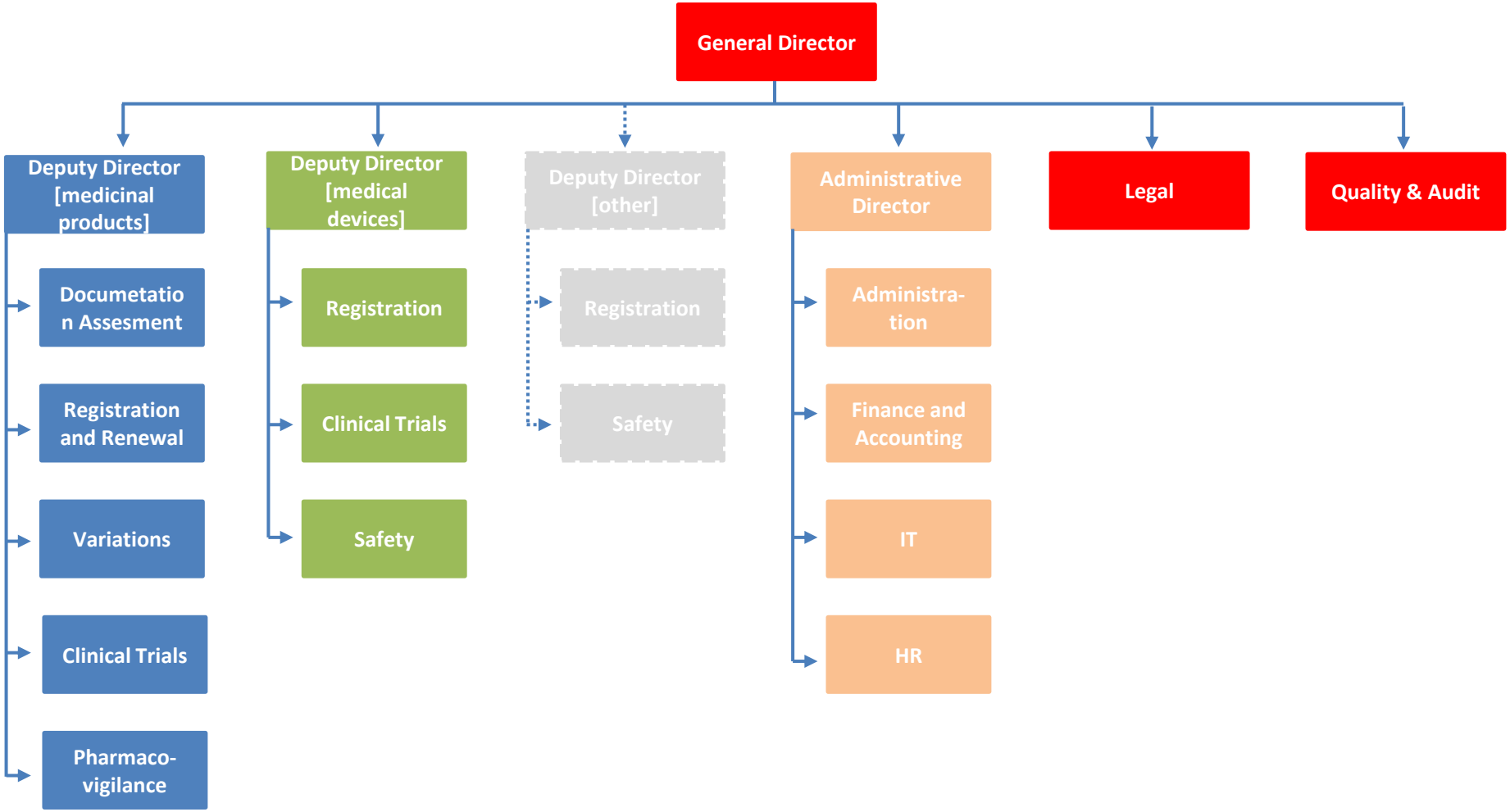
New medicines registration authority
Position in the system (3)

- General Director of the Agency personally and individually responsible for the decision
  - scientific background needed
  - encouragement to build and retain trusted team of experts

New medicines registration authority
Internal structure

- General principles:
  - Expert-oriented
  - General Director sub-delegates tasks (only selected area, like legal and audit, directly subordinated)
  - Structure organized by sectors, by reference to types of products (Medicinal Products, Medical Devices, etc.)
  - Non-scientific functions concentrated in Administrative sector

New medicines registration authority
Internal structure (2)



New medicines registration authority
Internal structure (3)

- Separate specialized unit(s) (in „Administration” sector or subordinated directly to General Director) for:
  - international cooperation, including:
    - monitoring of developments of EU pharmaceutical legislation
    - international exchange of experts
  - knowledge management – external, including:
    - information center for applicants and start-ups
    - conference and trainings for applicants
    - certification of regulatory managers
    - paid scientific advice
  - knowledge management – internal
  - [optionally] HTA analysis for technologies with the dominant use of medicinal products and medical devices
- Advisory bodies to be replaced by one Advisory Committee for Medicinal Products
  - + optionally Advisory Committee for Medical Devices (if covered)

New medicines registration authority
Transparency

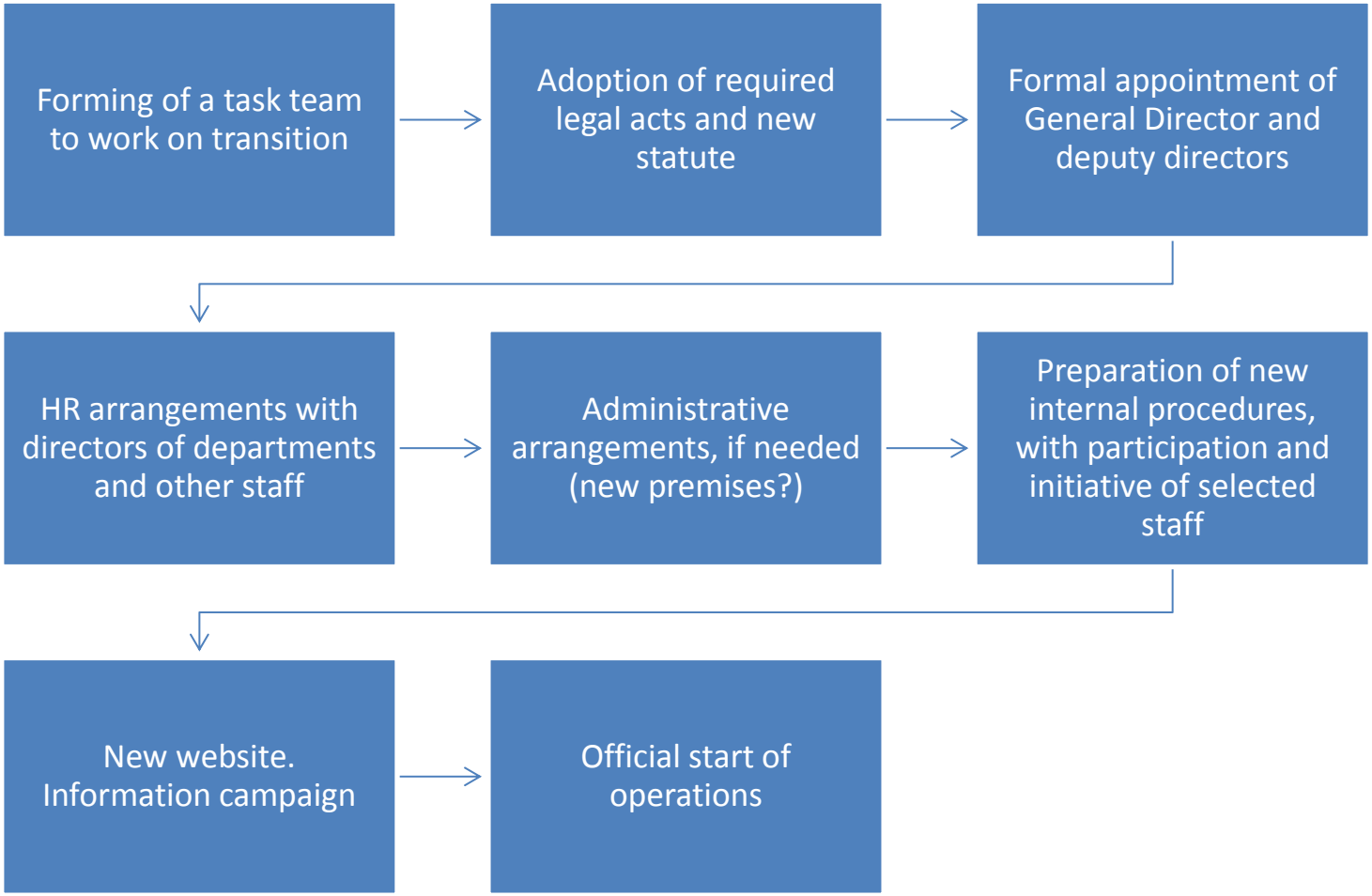
- New website
  - internal procedures
  - CVs of experts (external, advisory committees, possibly also internal)
  - status of the application (access restricted to the applicant)
  - up-to-date patient information leaflets
  - public assessment reports
- New declarations on conflict of interests

New medicines registration authority
Recruitment / HR

- General principles:
  - Building of the structure top-down
  - Obligation to sign the new declaration on conflict of interests (for internal and external experts)
  - New remuneration policy
  - External experts shall be gradually replaced by internal experts but in the initial phase the proportions shall generally remain as they are
- Internal experts
  - Mainly those currently employed by SEC
  - Only limited additional recruitment (if necessary and feasible)
- External experts
  - Mainly those currently used by SEC, subject to review of the list by the new General Director
  - Only limited additional recruitment (if necessary and feasible)

New medicines registration authority

Transition



European Bank
for Reconstruction and Development