

# Advice on Regulatory Improvements in Ukraine's Pharmaceutical Sector

## Phase III. Institutional Capacity Building Plan

Presentation for the EBRD Steering Committee, Kyiv, 25 July 2017



**European Bank**  
for Reconstruction and Development

# Agenda

## **Recent Developments:**

- 1) Meeting with MoH
- 2) MoH current expectations regarding the registration system development
- 3) Modification of Consortium's proposal

## **Options of New Agency:**

- 1) New State enterprise to replace SEC
- 2) New Central body in the form of State Service + Pros and Cons
- 3) New Central body with special status + Pros and Cons
- 4) Consistence with models applied in selected EU jurisdictions

## **Discussion**



# RECENT --- DEVELOPMENTS

# Meeting with MoH

- Meeting with Acting Minister of Health, Dr. Ulana Suprun on June 8, 2017
- Experts presented initial view on reform of medicines registration agency (presented at Steering Committee Meeting held on April 26, 2017)
- MoH opted for more drastic changes



# MoH current expectations regarding reform

- Fundamental reform of the medicines registration authority
- New registration agency shall have state body status
- New state body shall have new structure
- New state body shall be, if possible, subordinated to MoH
- MoH shall be policy-maker, but not the registration authority



# Modification of Consortium's proposal

- Previous Consortium's proposal:
  - create new registration body on the basis of SEC
  - leave new body with the status of state enterprise
  - change organizational structure of new state enterprise
  - separate functions between few institutions instead of creating a Big Agency
  - change approaches, but not the whole system fundamentally
- Based on the outcome of the Meeting with MoH, Consortium modified its proposal accordingly



# OPTIONS OF NEW AGENCY

# New State enterprise to replace SEC – Initial proposal

- Creation of new registration body on the basis of SEC
- Leaving new body with the status of state enterprise
- Changing the structure of new state enterprise
- Separation of functions in the sphere of MPs registration between few institutions instead of creating a Big Agency
- Changing approaches and practices, but not the whole system fundamentally





# MoH current expectations regarding reform

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NEW OPTION 1

# New Central Body in form of State Service (1)

- CMU creates **Ordinary Central Bodies** to implement certain functions of the state policy and approves their statutes
- Ordinary Central Bodies are **guided and coordinated by the CMU through one of the ministers**
- Ordinary Central Bodies (depending on the main functions) are created in form of (a) Agency, (b) State Service, (c) Inspection
- If the main function of the newly created Ordinary Central Body is provision of administrative services, it is established **in the form of State Service**



## New Central Body in form of State Service (2)

- Employees of Ordinary Central Bodies have status of civil servants: salaries are regulated based on Law On Civil Service
- CMU appoints and dismisses Heads of Ordinary Central Bodies based on the proposal of Commission on Senior Civil Service
- Minister of Health may:
  - a. Adopt work plan of Ordinary Central Body/ initiate its audit
  - b. Issue regulations, obligatory for Ordinary Central Body
  - c. Adopt its organizational structure



# Pros and Cons of Central body in form of State Service

- **Pros:**

- Easier amendments at the level of laws (compared to the new option 2)
- Greater flexibility regarding further transformation (if needed) of the Central Body (compared to the initial option)

- **Cons:**

- Restricted below-market level salaries for leadership and employees
- May one day become similar to SAUMP



NEW OPTION 2

# New Central Body with special status (1)

- **Central Bodies with special status** are established to regulate important spheres of state policy (e.g. economic competition)
- Main feature: flexibility in subordination, financing, status of employees etc.
- CMU creates Central Bodies with special status and sometimes adopts their statutes
- In other cases their status is determined in special Laws (e.g. Antimonopoly Committee of Ukraine, Asset Recovery Agency)



## New Central Body with special status (2)

- Employees of Central Bodies with special status are civil servants unless otherwise established by law. However:
  - a. top officials of the Central Body with special status may have no status of civil servants (e.g. Antimonopoly Committee)
  - b. Law regulating Central Body with special status may establish salary level for civil servants, different from the one established in the Law On Civil Service (e.g. Asset Recovery Agency)
- Specific rules on appointment and dismissal of the Head of such body may be determined in the relevant law
- No general restrictions on subordination (may be subordinated to MoH)





# Examples of Central Bodies with special status (1)

- **National Agency on Corruption Prevention**
- **Asset Recovery Agency**
- **Antimonopoly Committee of Ukraine**
- **State Committee for Television and Radio Broadcasting of Ukraine**
- **State Property Fund of Ukraine**
- **National Agency of Civil Service of Ukraine**



# Examples of Central Bodies with special status (2)

- **Antimonopoly Committee of Ukraine**



**Controlled by the President, reports to Verkhovna Rada**



**Regulated by a special Law**



**All employees are civil servants, except for Head and State Commissioners**



**Head is appointed/dismissed by the President upon consent of Verkhovna Rada**



**Financed from State budget**



# Examples of Central Bodies with special status (3)

- **National Agency of Civil Service of Ukraine**



**Guided and coordinated by the Cabinet of Ministers**



**Created by a resolution of the Cabinet of Ministers**



**All employees are civil servants**



**Head is appointed/dismissed by the Cabinet of Ministers**



**Financed from State budget**



# Examples of Central Bodies with special status (4)

- **Asset Recovery Agency**



**Controlled by and responsible to the Cabinet of Ministers, reports to Verkhovna Rada**



**Created by a special Law**



**Employees are (1) civil servants (with higher salaries, established by a special law) + (2) on the basis of labor contracts**



**Head is appointed/dismissed by the Cabinet of Ministers on a competitive basis**



**Financed from State budget**



# Pros and Cons of Central Body with special status

- **Pros:**

- More stability to the system, should serve as a safeguard against de-reforming
- Flexibility in part of financing and salaries, subordination, functions

- **Cons:**

- Greater political effort and will to adopt more complex changes to the legislation



# Consistence with models applied in selected EU jurisdictions

- Subordination models of medicines registration agency – EU perspective:

	Poland (URPL)	Germany (BfArM)	France (ANSM)	UK (MHRA)
<b>Position in a government administration</b>	Central government administration authority	An independent specialised federal higher authority within the portfolio of the Federal Ministry of Health	Public administrative authority of the state	An executive agency of the Department of Health
<b>Supervision</b>	the Ministry of Health	the Ministry of Health	the Ministry of Health	Department of Health
<b>Appointment of the head</b>	Prime Minister at the request of the Minister of Health	Council of Ministers at the request of the Minister of Health	President	The Secretary of State for Health
<b>Financing</b>	It is financed by the state budget („health” section administered by the Ministry of Health)	Its budget is described in the federal budget.	It is financed by a public service subsidy received from the State.	Activities of the agency, relating to medicinal products, are financed from the fees paid by applicants.  Activities relating to medical devices financed from Government’s donation.



# DISCUSSION

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