



# Engaging in the EU Regulatory Network: Member State Journey

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# Estonia – what country is this?

Population: 1.3 million.

System of government: Parliamentary republic

Member of: EU, NATO, UN, OSCE, OECD & WTO

Number of islands: 1 521

Estonia is a country of thousand of lakes

Highest point: Great Egg Hill, 318 m

Estonia is a green land, forests cover 55% of the country

Temperature range: -30°C to + 30°C

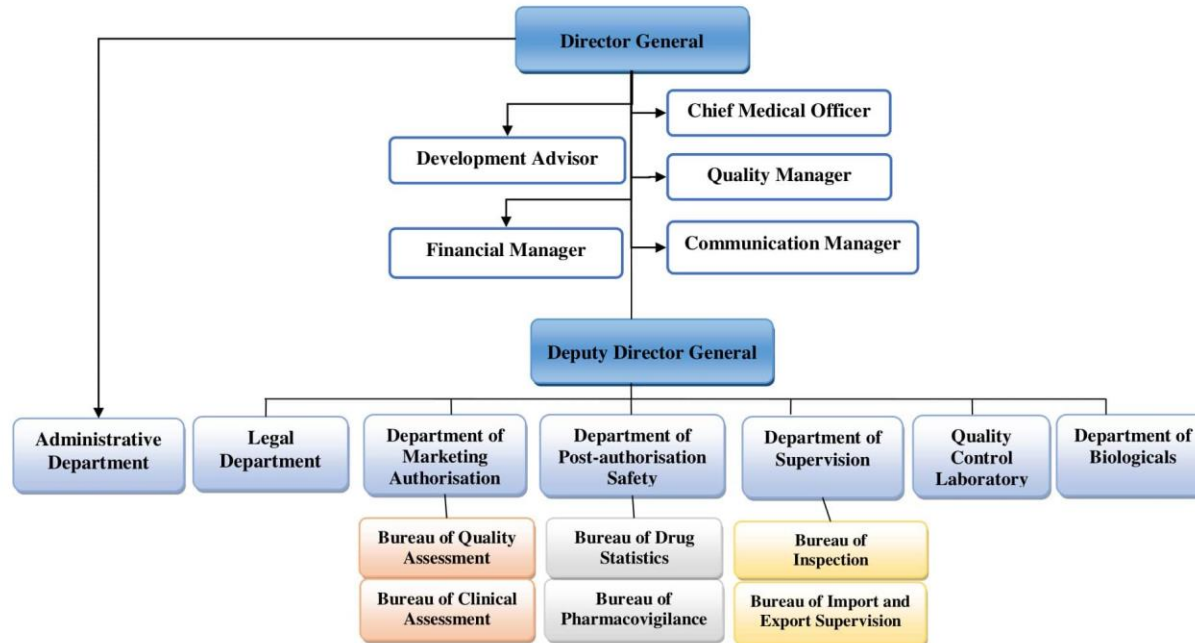
Country of Skype, e-services (declaration taxes online, check children's grades in the e-school, vote in e-elections. We have e-government, an e-health system, an e-system for border crossing, mobile parking and etc.)





# REPUBLIC OF ESTONIA AGENCY OF MEDICINES 30

Estonian State Agency of Medicines  
Structure



Competence  
Efficiency  
Reliability  
Cooperation

103 employees  
76 FTE

# Participation in the EU regulatory procedures

- Since 2005 - RMS in MRP and DCP with 275 procedures in total
- Since 2006 - rapp/ co-rapp for 96 initial marketing authorisation applications in CP
- 27 substances for signal detection
- 21 substances for PSUSA Lead MS
- In average 4 GCP inspections in the EU system per year

# Estonian State Agency in the EU Network – centralised procedure (since 2006)



# Assessment area (originators)

## Antiinfectives:

- doripenem
- iclaprim
- tseftarolin
- sofosbuvir
- sofosbuvir/velpatasvir
- imipenem-cilastatin-relebactam
- delafloxacin

## Cardiovascular drugs:

- azilsartan
- cangrelor
- vorapaxar
- evolocumab
- alirocumab
- different combinations

# Multinational teams

- Initiated by the Baltic Consortium which allowed Denmark, Estonia, Finland, Iceland, Latvia, Lithuania, Norway, Poland, and Sweden to collaborate on the assessment
- The concept was broadened to all MS for Co-Rapporteurships
- Maximises the use of available resources and expertise within the network and enables smaller MSs to participate in areas where we have limited expertise
- In total for 6 assessment EE as a leading MS
  - Quality data – biologicals in cooperation with FI and PEI
  - Pre-clinical data – in cooperation with MPA, BFARM, PEI, FI

# The State Agency of Medicines strategy 2019-2022

## Digital supervision capability

- By 2022, have at least five innovative digital services and a plan for further development.

## Biotechnological medicines, innovative technologies

- We have undertaken to assess three MA applications for biotechnological medicines and review applications for clinical trials using the common EU-wide procedure.
- We have developed expertise to give scientific advice on biological, biotechnological, and innovative drugs as well as novel health technologies

## Stakeholders' awareness of medicines and the Agency

- We have become the main centre of drug information for the general public and stakeholders, and by 2022 we provide information in a more user friendly manner

## More effective procedures

- We only collect and process information that can be used for the benefit of public health. We only engage in activities that are essential and contribute to the protection of public health. We know which regulations should be worded more clearly and which should provide
- a wider margin for discretion. Our workload is distributed more evenly and staff members have time available for self-development.



# Biotechnological medicines, innovative technologies – from stated goal to practice

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**2019**

Defined the area (proteins, MAB's, including biosimilars) and hired staff

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In-house trainings (reading peer- reviews, AR's, VHP's, parallel assessment and writing the AR)

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Agreement with PEI for trainings, ongoing discussion with two other agency's and MoU with MEB to strengthen capacity and quality of the medicines regulatory network

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**2020**

EE have been appointed as peer-reviewer for 4 products (biosimilar and 3 monoclonal antibodies)

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Day 100 comments – initial applications, biologicals, biosimilars

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Leading agency (clinical assessment) in the MNT for one biological product (MAB, cardiology; in-house shadow assessment of the Quality documentation)

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# Activity in the Committee of Advanced Therapeutics

2018

- 2 classification procedures, both were gene therapy products

2019

- 3 classification procedures, of which two were gene therapy products and one was a non-ATMP

2020

- 2 classification procedures, both were somatic cell therapy products
- 1 participation in compiling the scientific advice report (quality)
- 1 scientific advice report (quality)

# Objectives for 2021-2022

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We have undertaken to assess at least 3 MA applications for biotechnological medicines

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We have developed expertise to give scientific advice on biological, biotechnological, and innovative drugs as well as novel health Technologies

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**2021**

2 MNAT - participating agency (quality assessment). 1 co-rap for new active substance and rap new pharmaceutical form

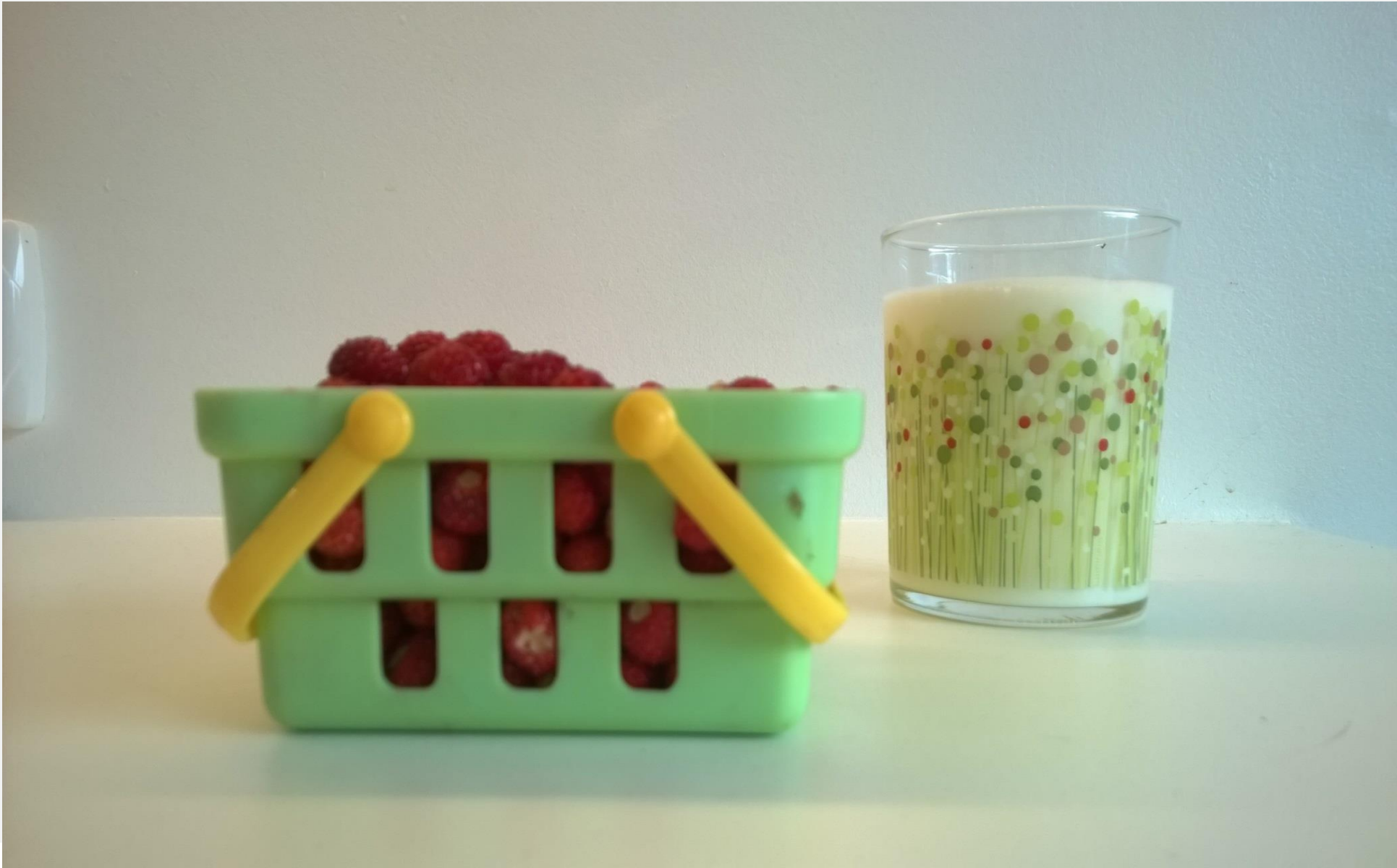
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1 MNAT – leading agency (MAB for COVID-19, Clinical assessment)

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1 sc adv - cell therapy product

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ADVANCING HEALTH PRIORITIES

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