

Engaging in the EU Regulatory Network: Member State Journeys

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Slovenia



Population: 2,1 mio

Health expenditure per capita: 2186 PPP € (EU 27: 2552 PPP €)

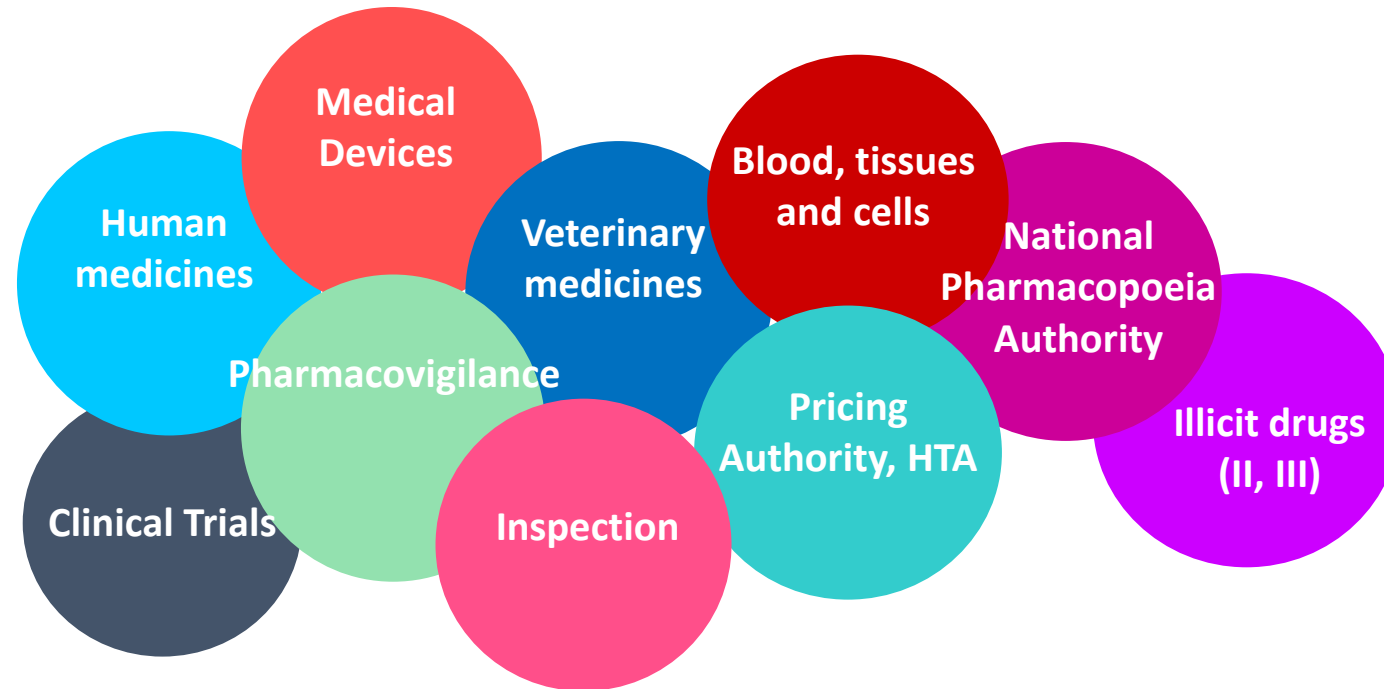
Life expectancy: 81,6 yrs

- The first **Green Country** in the World
- Slovenia the **hottest destination** in 2019 by Virtuoso
- European Region of **Gastronomy** 2021



- Source: The Health Insurance Institute of Slovenia Annual Report 2020; Available at: [https://api.zzs.si/ZZZS/info/egradiva.nsf/0/a998991f0f548b4bc125868c0040ba61/\\$FILE/Letno%20poro%C4%8Dilo%20ZZS_2.3.2020.pdf](https://api.zzs.si/ZZZS/info/egradiva.nsf/0/a998991f0f548b4bc125868c0040ba61/$FILE/Letno%20poro%C4%8Dilo%20ZZS_2.3.2020.pdf)
- Source: Eurostat, March 2021

**AGENCY FOR MEDICINAL PRODUCTS AND
MEDICAL DEVICES OF THE REPUBLIC OF
SLOVENIA**



Contribution to the EU network

Centralized procedures



Product	Start of procedure	JAZMP
Zalasta	2006	Rapp
Grepid	2008	Rapp
Clopidogrel Teva	2008	Rapp
Clopidogrel Apotex	2008	Rapp
Clopidogrel Ratiopharm	2014	Rapp
Clopidogrel / Acetylsalicylic acid Mylan	2018	Rapp



Product	Start of procedure	JAZMP
Fingolimod Mylan	23. 5. 2019	Rapp
Fingolimod Accord	23. 5. 2019	Peer review
Fampridine Accord	15. 8. 2019	Rapp
Conf.	2020	Rapp
Conf.	2020	Rapp
Conf.	2020	Rapp
Conf.	2020	Rapp
Conf.	2020	Rapp
Enyglid	Brexit redistribution	Rapp
Cetrotide	Brexit redistribution	Co-Rapp
Ledaga	Brexit redistribution	Rapp
Conf.	2020	MNAT
Conf.	2021	MNAT
Conf.	2021	MNAT
Conf.	2021	MNAT
Conf.	2021	MNAT

Contribution to the EU network

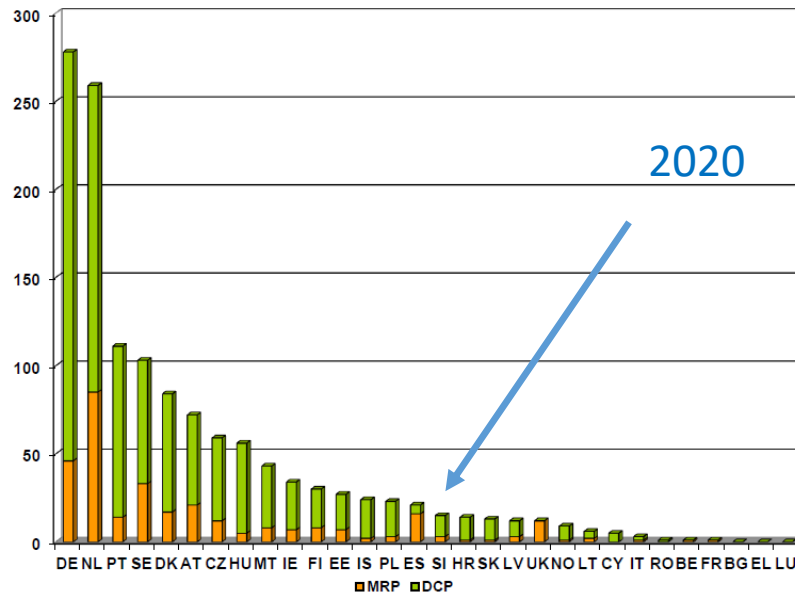
MRP/DCP New applications



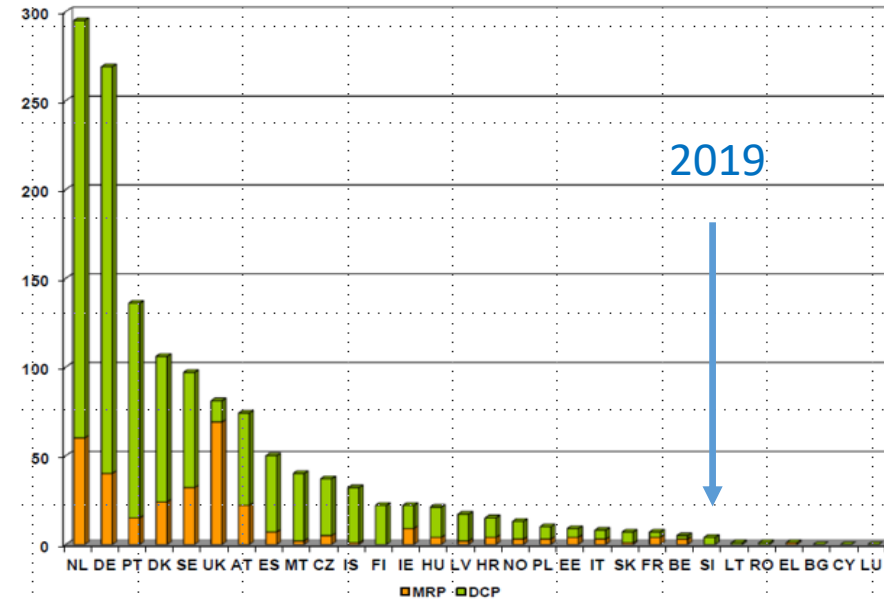
STARTED Procedures – MRP/DCP per RMS

New MA - SI as RMS in MRP/DCP

- 2004 – 2018: 105
- 2019 - 2021: 39



Total 310 MRP and 1006 DCP
(regarding 615 and 1996 products respectively)



Total 318 MRP and 1062 DCP
(regarding 584 and 2145 products respectively)

• Source: CMDH Statistics accessed at <https://www.hma.eu/87.html>

Contribution to the EU network

Surveillance 2019



Inspection Division

EMA and EDQM GMP inspections: 4

local GMP inspections 20 (including MRA)

Third countries GMP inspections

GDP inspections: 21

GVP: 12



Pharmacovigilance

EMA GMP inspections: 4

PSUSA Lead MS: 9 substances (10 in total before 2019)

Signal detection: 9 substances (10 in total before 2019)

3172 new reports on suspected ADRs (1526 reports/mio)

1068 follow-up reports

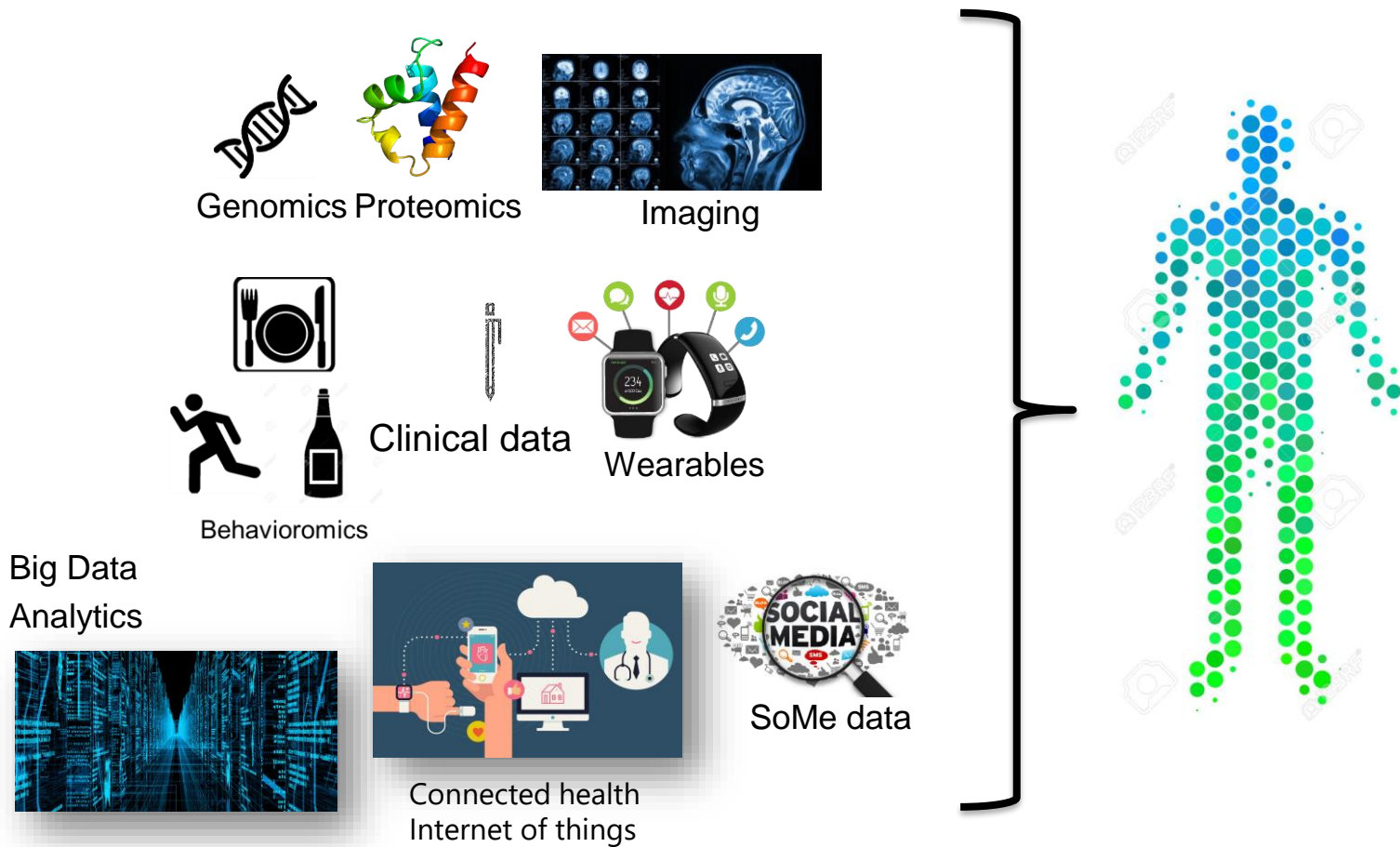
- more than 150 of adverse reaction reports per 100.000 inhabitants in 2019



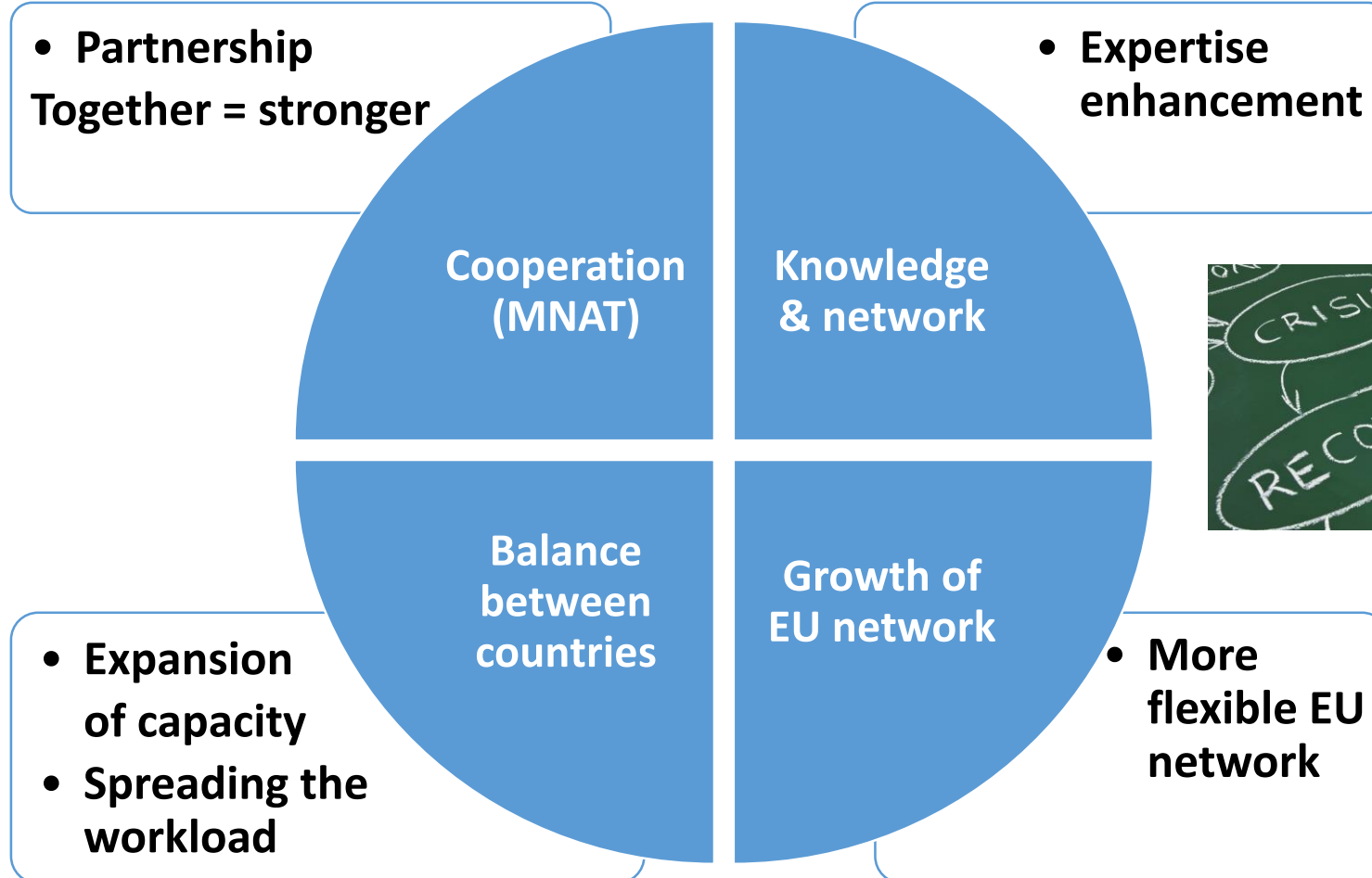
How the future will look like?

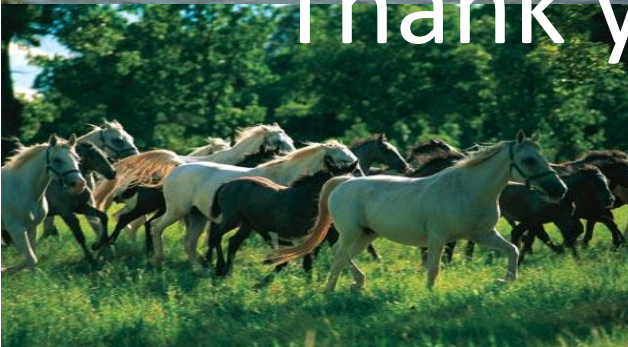
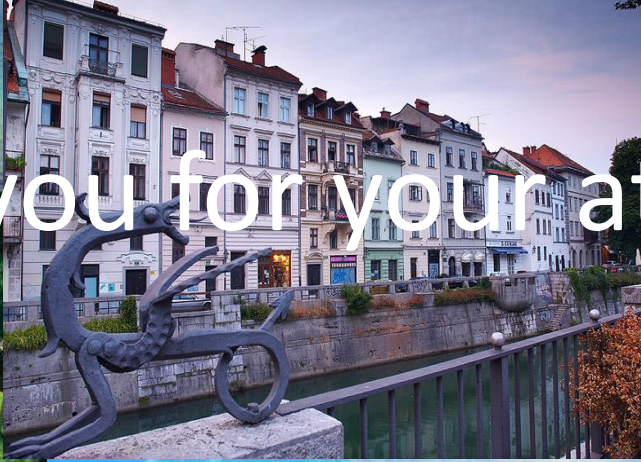


Precision Medicine



Stronger network





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Thank you for your attention!

