

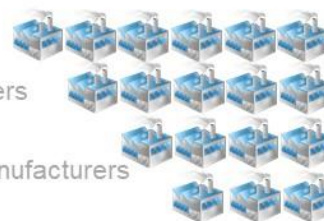
2019



100 years old
domestic
pharmaceutical
manufactures



34 Members



18 Manufacturers



Flagship
Of the Economy

Export-oriented, in
75 countries are
present



More than 14.000 employee

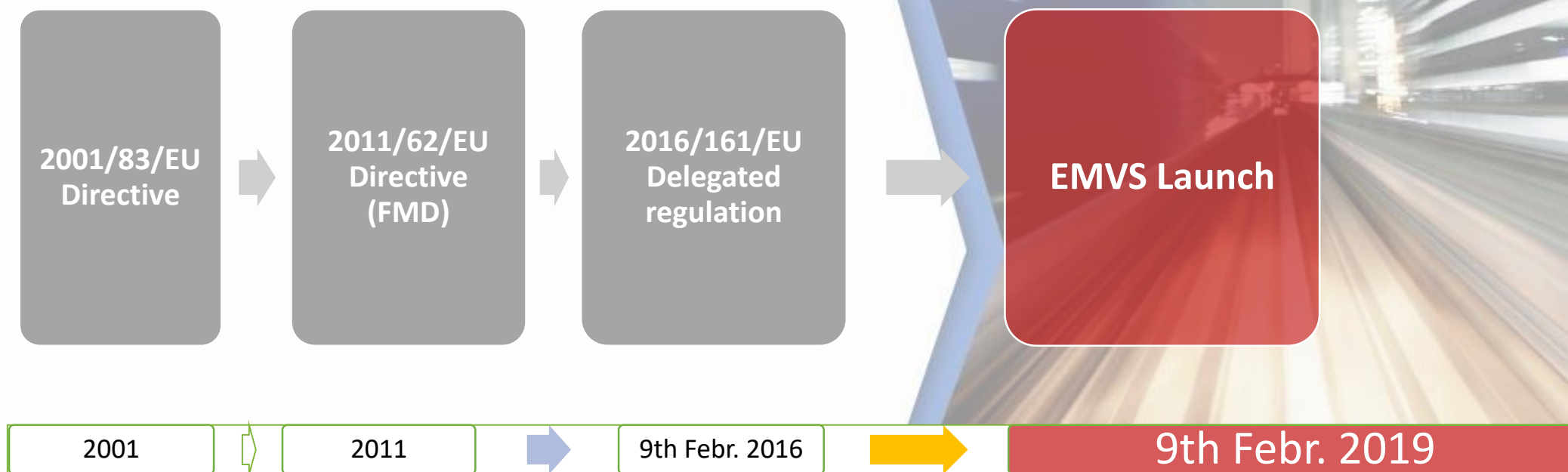
More than 2000 persons in R+D



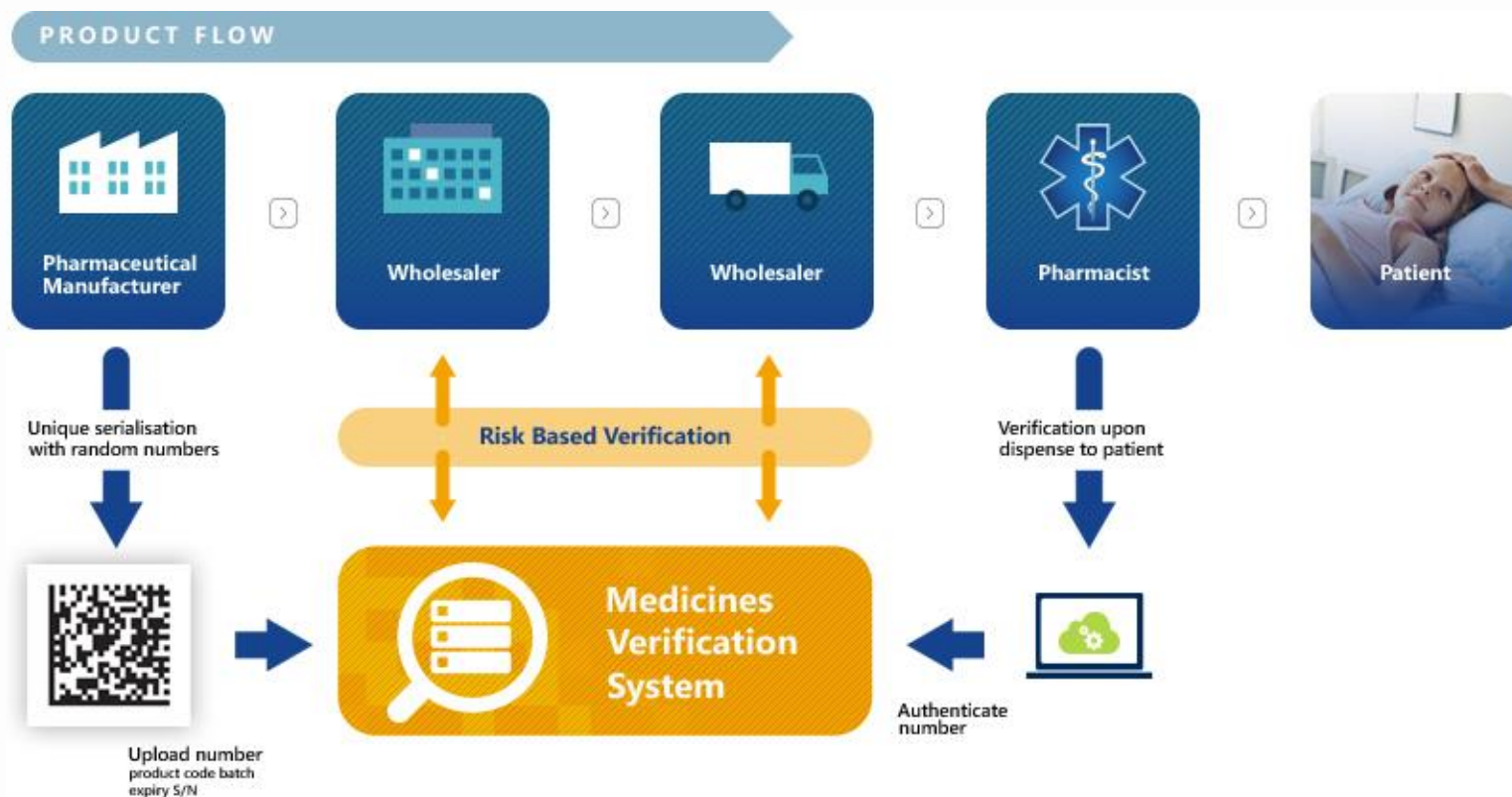
For nearly 30 years

Today in Hungary every
2nd patient is healing with
product of a MAGYOSZ Member

„European citizens deserve medicines that are safe, of high quality and effective. Falsified medicines may contain ingredients of low quality or in the wrong dosage – and therefore pose a major health threat to EU citizens.”

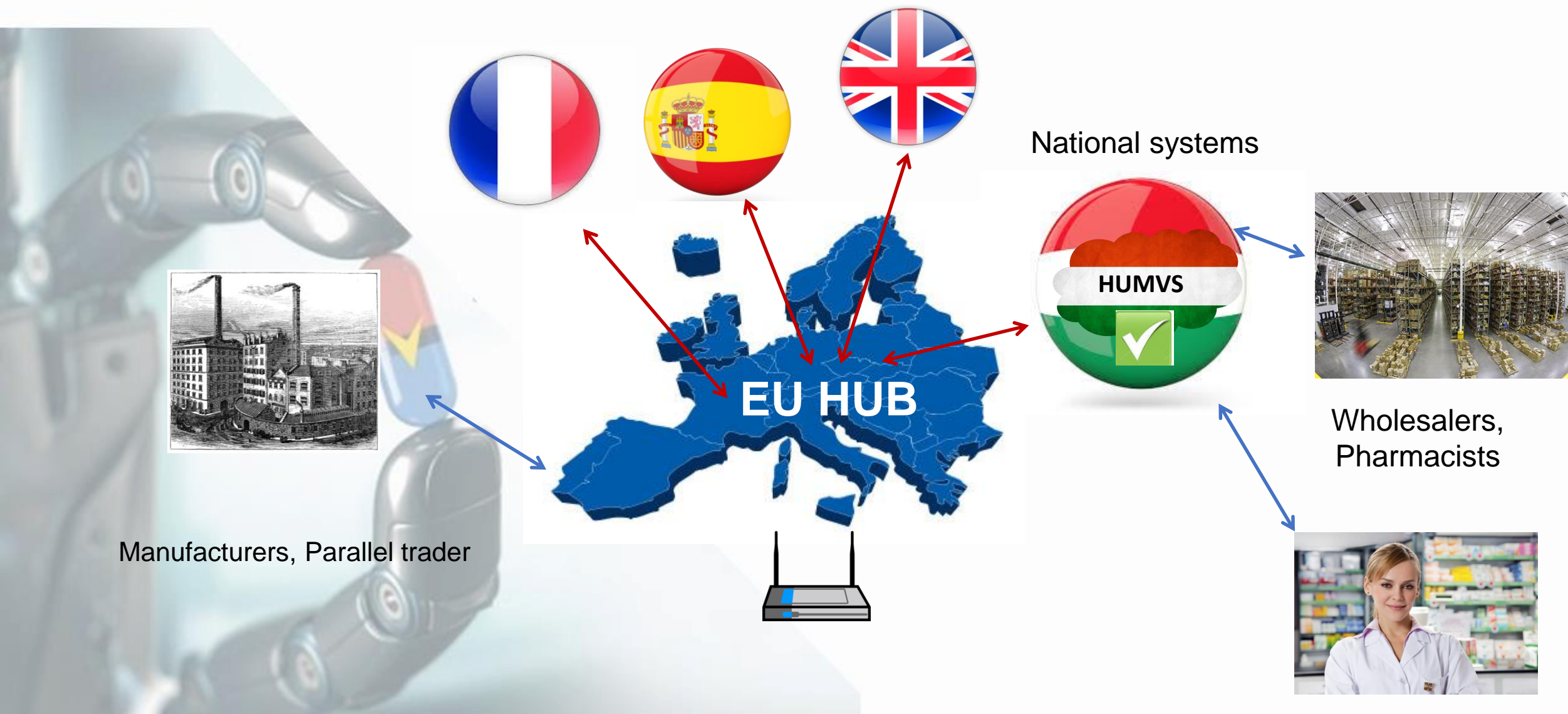


THE EUROPEAN MEDICINES VERIFICATION SYSTEM



28 EEA countries
2,000 manufacturers
6,000 wholesalers
5,000 hospitals
140,000 pharmacies

THE EUROPEAN MEDICINES VERIFICATION SYSTEM





EMVO

1. EFPIA- European Federation of Pharmaceutical Industries and Associations
2. Medicines For Europe
3. EAEPC – European Association of Euro-Pharmaceutical Companies
4. GIRP – European Healthcare Distribution Association
5. PGEU – Pharmaceutical Group of EU



Main tasks

- Establishing, managing, and operating the EU Hub,
- Creating interoperability between affiliated systems,
- Concluding contracts with national organizations
- Setting up EMVS standards
- Supporting establishment of standard interfaces
- Providing cost savings for connecting manufacturers

Blueprint Modell

- Allows national stakeholders to build national system without starting from scratch
- Based on a “standard” national verification system providing all necessary functionality
- Strong support by EMVO during deployment & operation (system management)
- Cost reduction for payers through economy of scale
- EMVO offers implementation package

Hungarian stakeholders have committed themselves to the Blueprint model, so the Hungarian industry associations were bound by a two-level system of the rules: EU legislation and the EMVO's Blueprint rules.

With the use of Blueprint systems, national organizations have achieved significant cost savings, and the implementation time was significantly shorter.

However, building systems was a long and expensive process.



AIPM

Új gyógyszer

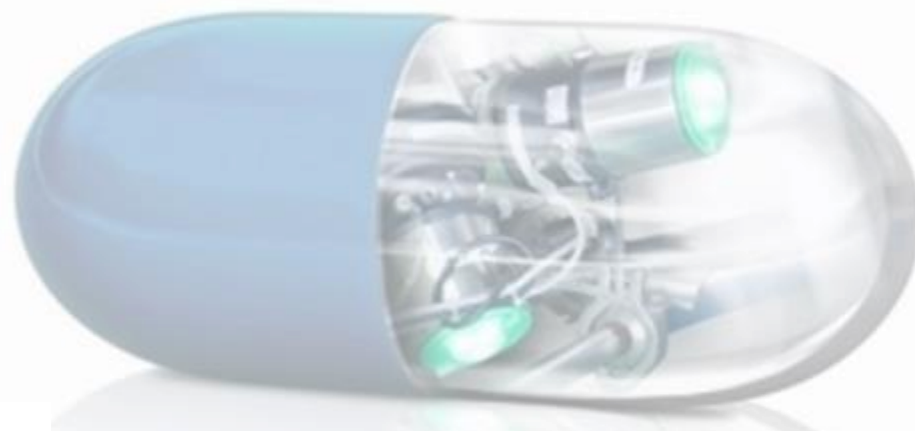
Új esély

Innovatív Gyógyszergyártók Egyesülete
Association of Innovative Pharmaceutical Manufacturers

MAGYOSZ.org
Magyarországi Gyógyszergyártók
Országos Szövetsége



GENERIKUS GYÓGYSZERGYÁRTÓK ÉS
FORGALMAZÓK MAGYARORSZÁGI
ÉRDEKVÉDELMI EGYESÜLETE



GYNSZ

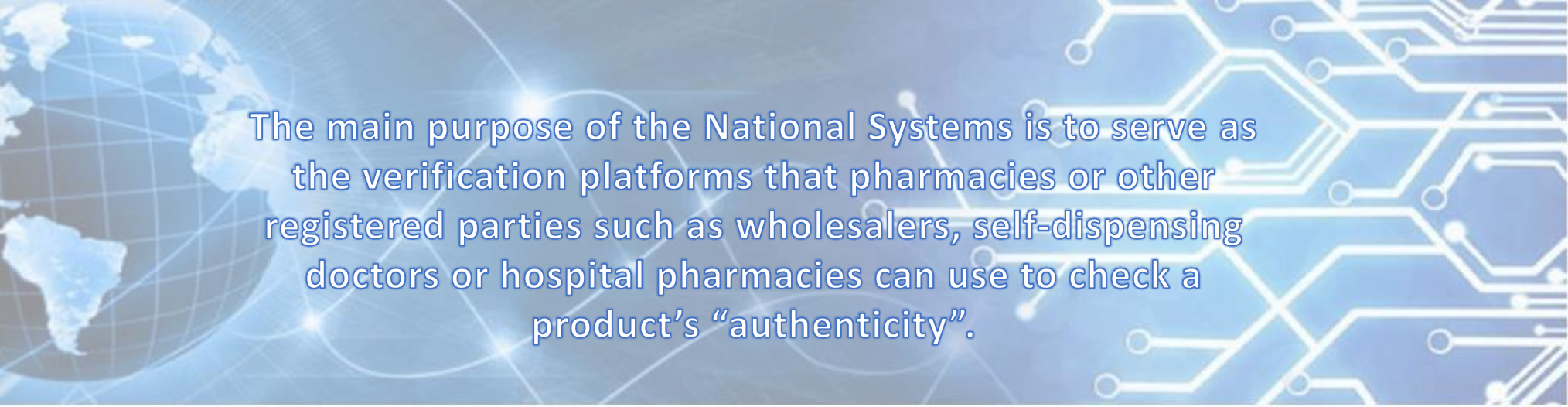
GYÓGYSZER-
NAGYKERESKEDŐK
SZÖVETSÉGE



OGYÉI

Országos Gyógyszerészeti és
Élmezés-egészségügyi Intézet

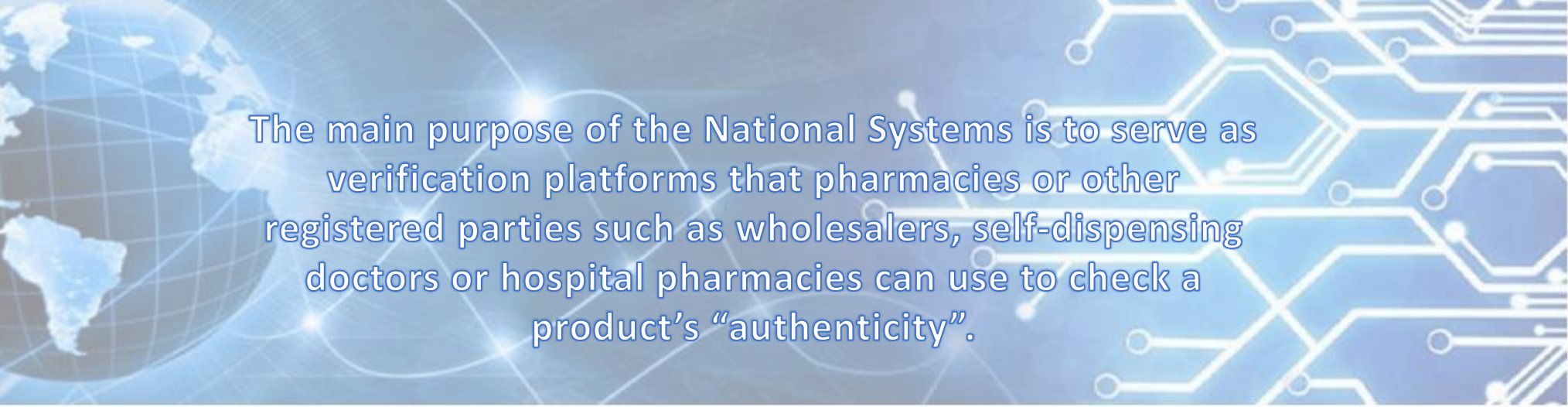


The background of the top section features a blue-toned graphic. On the left, a portion of a globe is visible, showing the Americas. To the right of the globe, there is a complex network of white lines and circles, resembling a circuit board or a digital data network. The overall aesthetic is technological and global.

The main purpose of the National Systems is to serve as the verification platforms that pharmacies or other registered parties such as wholesalers, self-dispensing doctors or hospital pharmacies can use to check a product's "authenticity".

A solid light-blue circle is positioned to the left of the section header text.

Establishment of HUMVS



The main purpose of the National Systems is to serve as verification platforms that pharmacies or other registered parties such as wholesalers, self-dispensing doctors or hospital pharmacies can use to check a product's "authenticity".

Apply legislation and EMVO requirements and ensure quality at all times

It manages IT tasks, creating a link between NMVO and EMVO

Concluding user contracts, settling fees and payments

Providing access to the system, determining its objective and transparent conditions



MAH



Wholesalers

2305

Pharmacists

106

Hospitals



$$4 + 1 + 6$$

Basic element of the system

Loan of the founders

Hub
a HUF

NMVO operational costs
b HUF

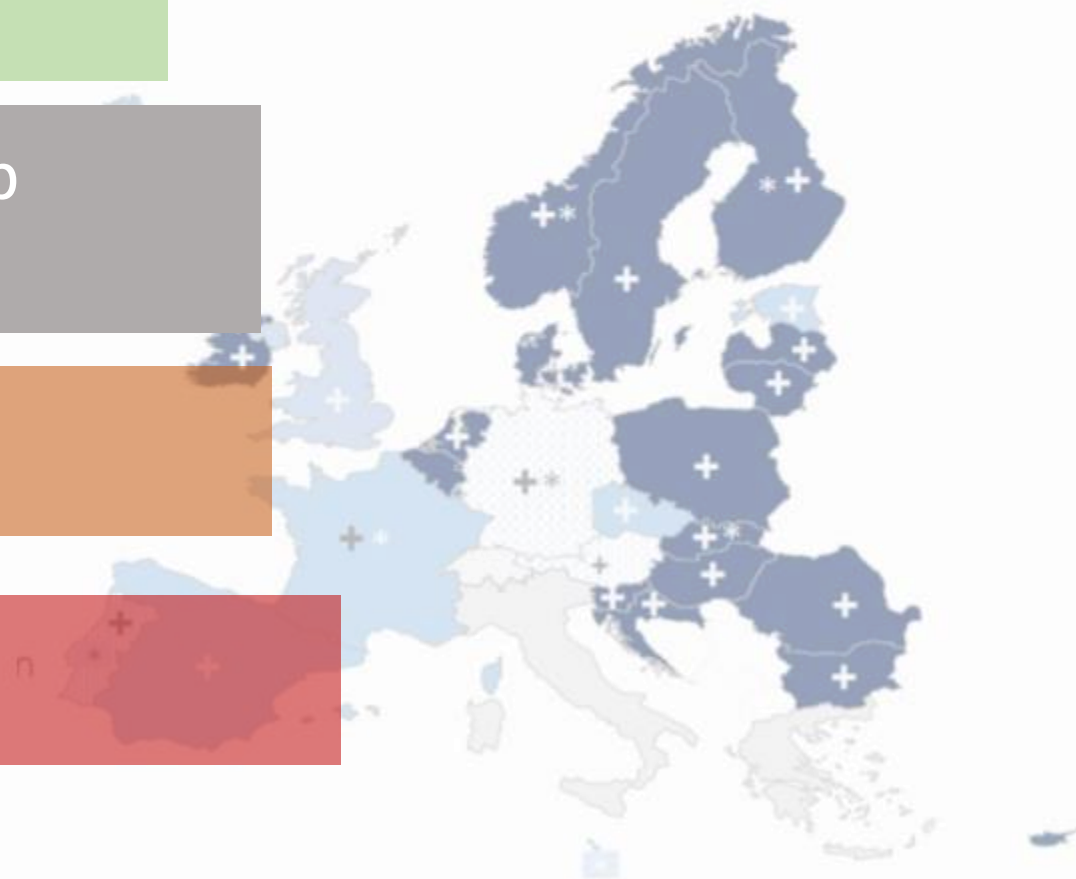
System – set up, and ramp up
c HUF

Total: x HUF

2019

Flat fee: **3.332.178 Ft + Áfa**

Entrance fee: **407.225 Ft + Áfa**





Burden of the manufacturers



MILESTONES

2018.

02



Arvato Systems GmbH was chosen by HUMVO, Contract with EMVO

04



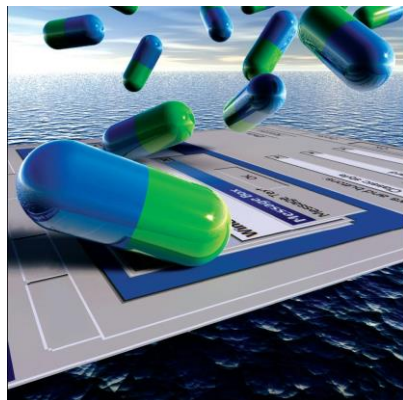
HUMVO open day
IT development tool is
available

06



National System had been
linked to the test
environment of EU HUB,
MAH GTC

07



HUMVO joined the
EU Hub in a PRD
environment

General Terms and
Conditions for the
wholesalers



09

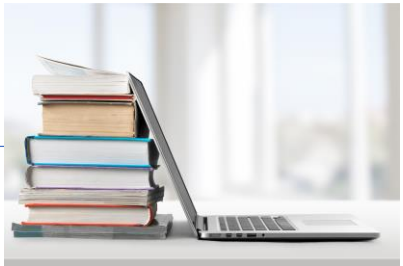
10

11

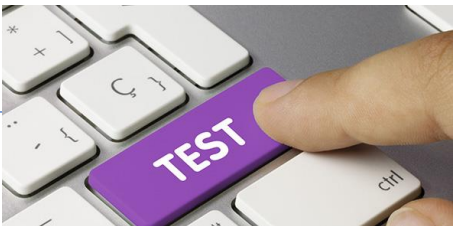
12

2019

01



General Terms and
Conditions for the
Pharmacists



First pack verified

MAH pilot tests



Contract received

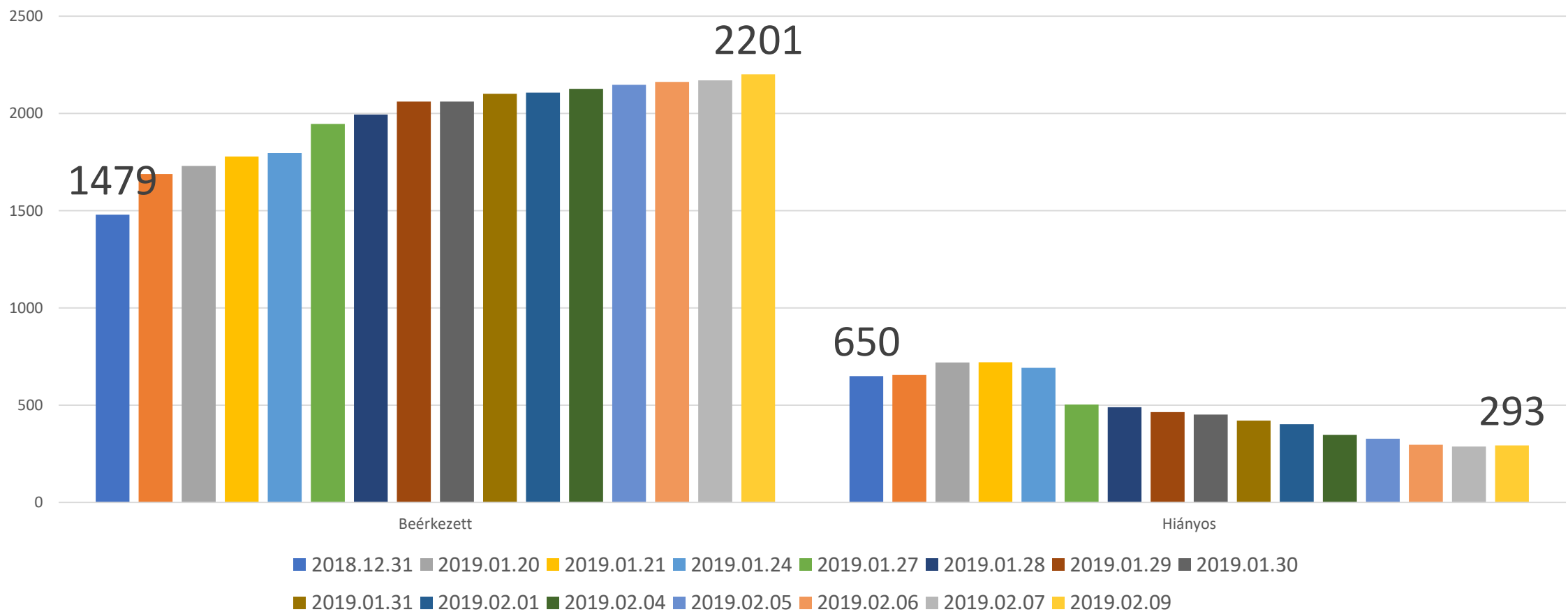




Statistics

2019.05.06	Total nr	Contract received	Incompetely	Total nr of password
Pharmacies	2295	2284	45	2853
Hospitals	80	80	0	80
Wholesales	113	93	10	98

Nr of contracts of pharmacists





Alert code	Description
NMVS_NC_PCK_22	Pack is already inactive
NMVS_NC_PCK_19	Property is already set on pack

medicine supply chain members should
comply with the Regulation,

upload the product data,

sign the contract with the HUMVO

connect to the HUMVS

verify and deactivate due to the Regulation

Common learning

The Hungarian medicines supply chain is closed, and safe.

A signal from the system does not automatically mean that the medicine is falsified

The goal is to separate the potential cases of counterfeiting in the system from system failures.

The system is a newly launched system

However, this is a period of common learning. It is important that everybody has the duty to use the system, because the stabilization period won't last forever. If we can't fix the bugs together now, we won't be able to despend all the boxes after the end of this session.

Alert

- An error describes a situation where the normal operation of the EMVS is interrupted;
- 5 levels of error

Process

- The System sends a message to the end user and the OBP about the alarms.
- In addition, HUMVO monitors alerts in HUMVS on a daily basis and analyzes it on a weekly basis, by the type of the alarm and the end user.
- In case of repeated large number of alarms generated by the same end-user, HUMVO contacts the concerned party to initiate an investigation.



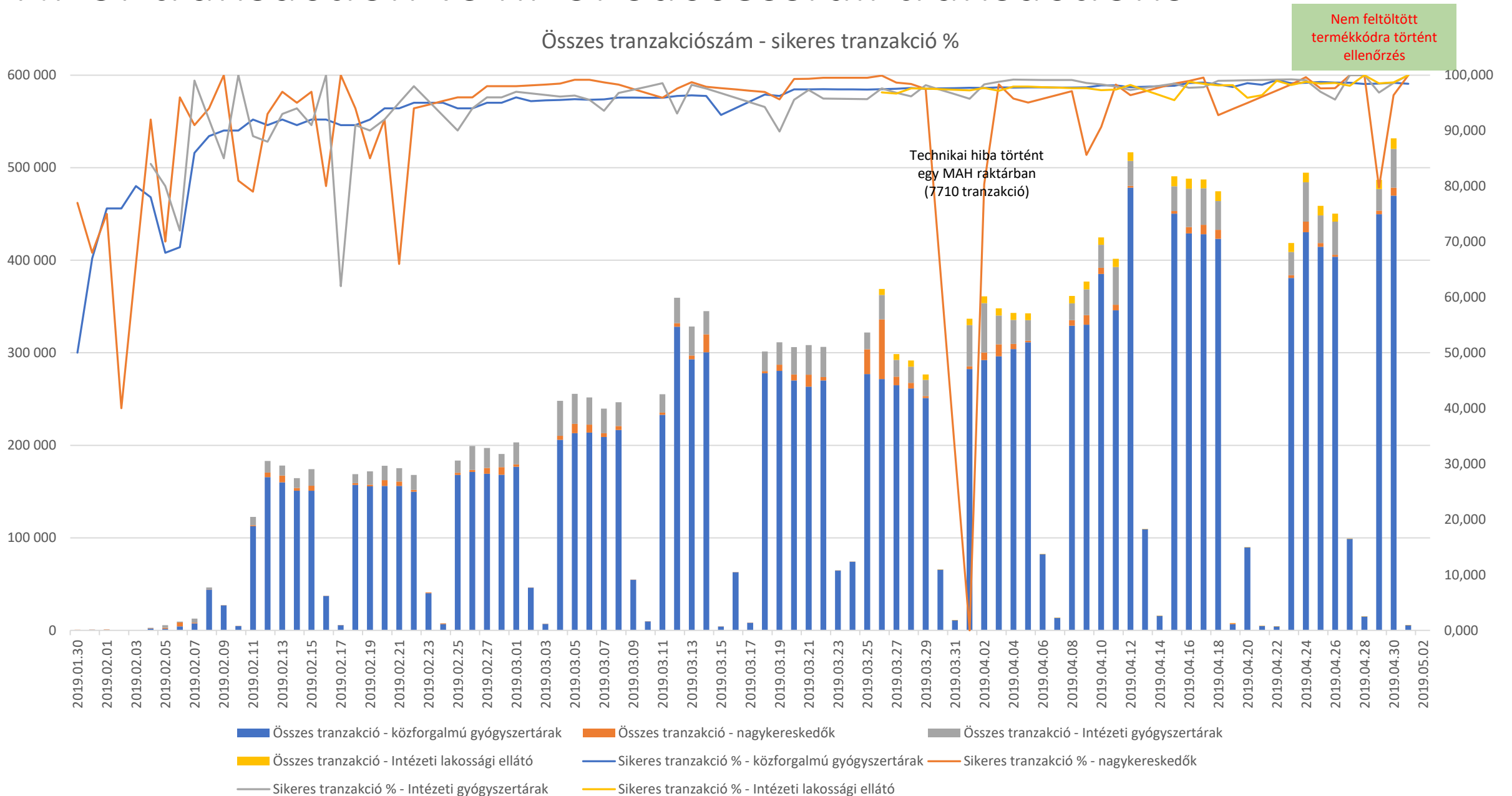
Alerts on End-user side:

- y/z characters replacement during the scanning process
- small and CAPITAL letters replacement during the scanning process
- wrong “-” character management during the scanning process (“-” à “/”, “ü”, nothing)

Alerts on MAH side:

- not uploaded batch (upload 2-3 days after the packs reach the WS)
- data upload to incorrect target market (instead of HUMVS to other NMVS)
- Sample dispensed by MAH (double scanning issue at the hospital)

Nr of transaction vs nr of successfull transactions

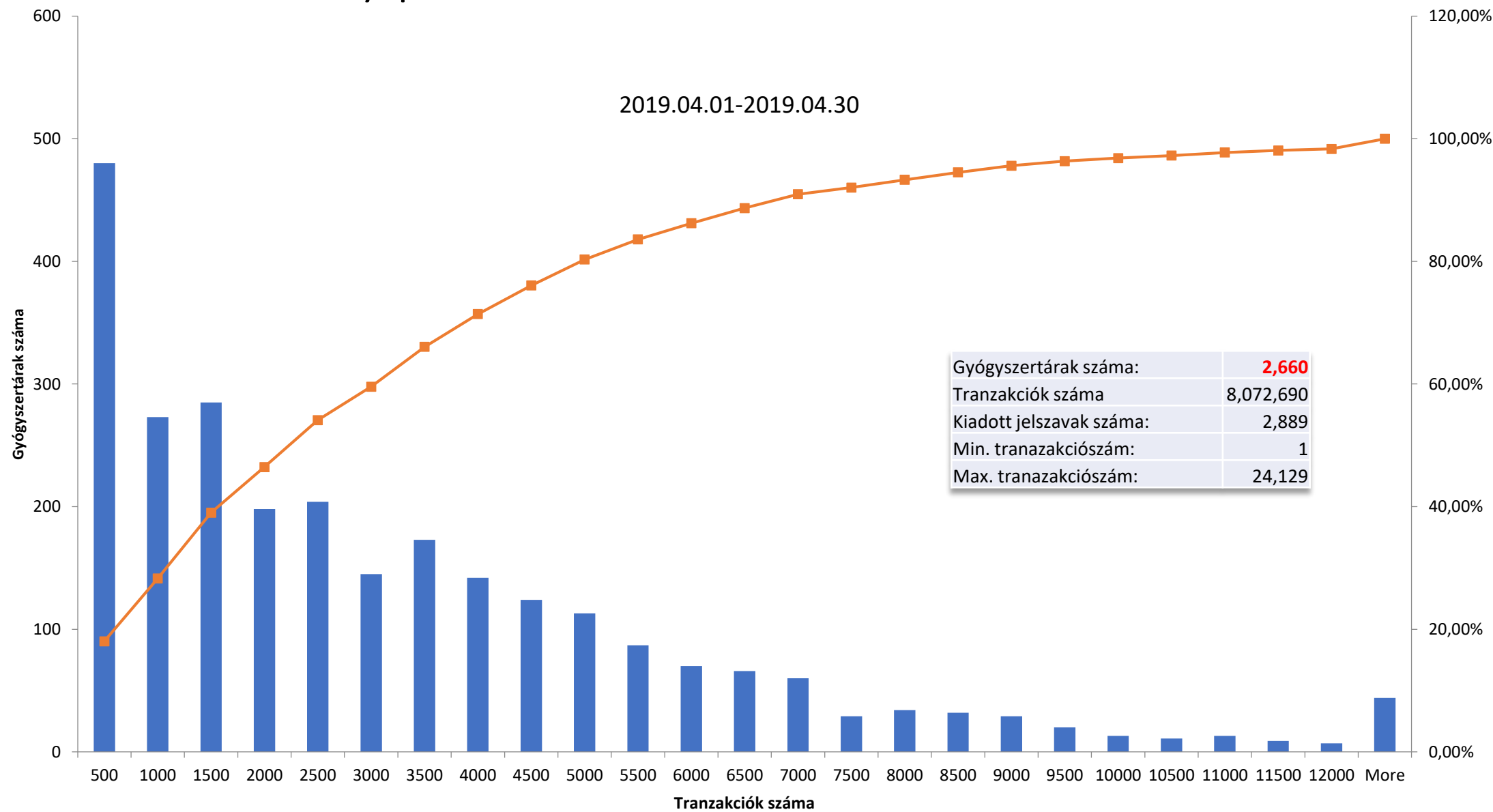


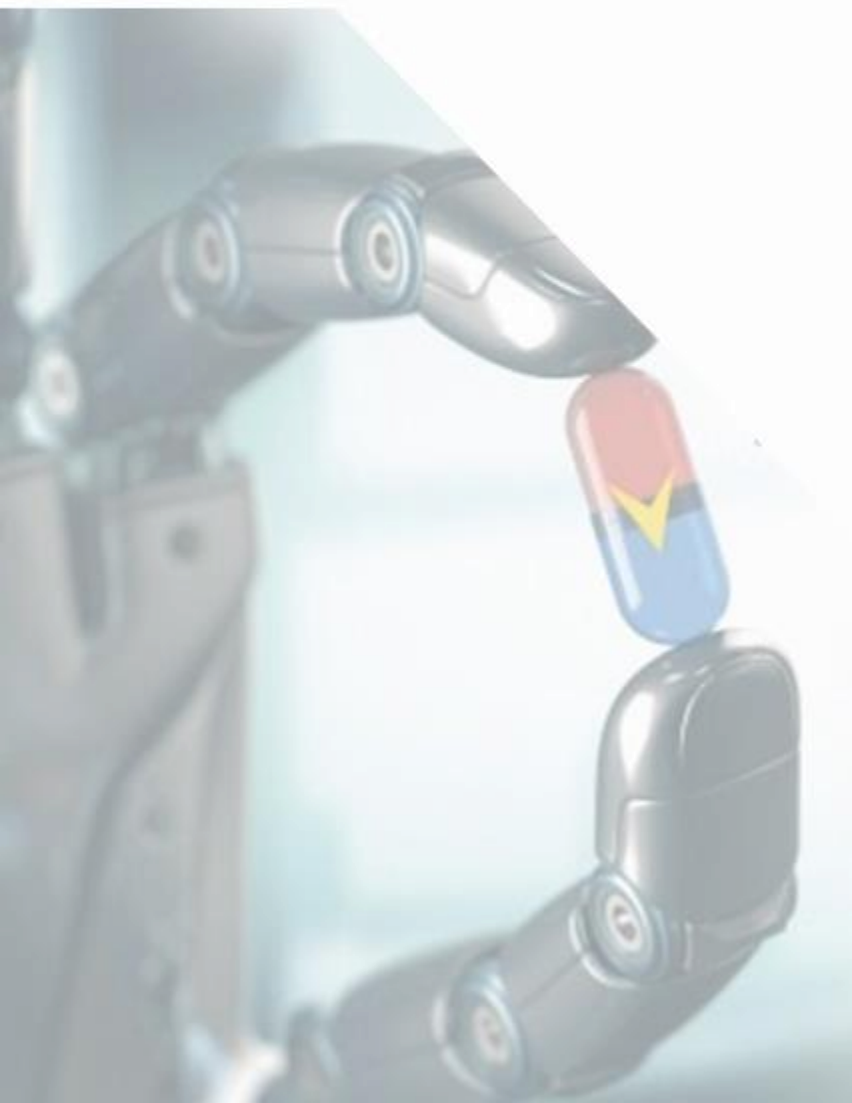
Number of transactions

- Hungary in comparison has the 4th largest transaction number each week, comparing the number of weekly operations in countries using the medicines verification system, ahead of countries larger both in size and market position.

Country	Sum of Total Scans Week 11	Sum of Total Scans Week 13	Sum of Total scans Week 15	Sum of Total scans Week 16
DE	5,784,305	6,959,692	9,399,742	8,054,656
ES	5,052,352	6,552,241	7,917,153	6,500,576
PL	1,753,248	2,424,596	3,818,732	4,213,287
HU	1,363,086	1,648,172	2,222,237	2,055,991
CZ	1,079,056	1,355,110	1,738,590	1,687,140
FR	112,755	160,364	337,628	1,390,661
BE/LU	306,933	339,433	607,000	1,023,598
UK	763,520	671,760	766,159	824,430
AT	488,000	575,500	909,432	815,580
SK	451,174	565,163	737,991	710,979
SE	302,251	479,521	630,092	601,960
RO	304,143	317,955	451,074	567,313
FI	365,835	420,564	480,574	514,686
HR	339,885	373,123	458,210	464,365
NO	323,617	379,727	578,851	376,296
DK	334,287	371,283	482,506	345,295
IE	225,731	261,392	312,904	341,464
LT	139,253	194,347	223,013	278,496
LV	160,334	179,084	228,264	242,679
PT	120,806	197,017	226,772	210,009
SI	108,356	114,622	157,383	167,509
EE	122,658	119,912	182,773	159,320
BG	43,455	46,640	77,141	90,220
CY	12,355	15,948	21,851	26,598
MT	0	6,796	12,865	10,534
IS	6,408	7,780	11,418	7,590
LI/CH	3	1	64	2

Nr of transactions by pharmacies





HUMVO regularly informs the users of the types of false alarms either it is caused by end-user hardware or software.

HUMVO publishes experiences in direct communication, and in newsletters.

HUMVO prepares the reports referred to the Regulation, which shall be made available for the NCA on a weekly basis.

The next key point is to strengthen the full application of the Decree and the total use of the system to have best practice.

In Hun we have some specialties for example the self dispensing doctors, whom has to be connected to the system too.

We also have some pending cases on the national vaccination program

