EMVO MONITORING REPORT – CALENDAR WEEK 12 - 2020

European Medicines Verification Organisation

HOW TO NAVIGATE IN THE REPORT

Since the Monitoring Report is 268 slides long, links have been included in some slides in order to ease your navigation.

- In the agenda slides; click the bubble of the desired agenda item, you will be re-directed to the sections' start.

- In the slide displaying the map starting the country overview section; click on the desired country, you will be re-directed to the related country

- In the first slide of each country overview, displaying the name of the related country; click on the link at the bottom right of the slide, you will be re-directed to the country overview map

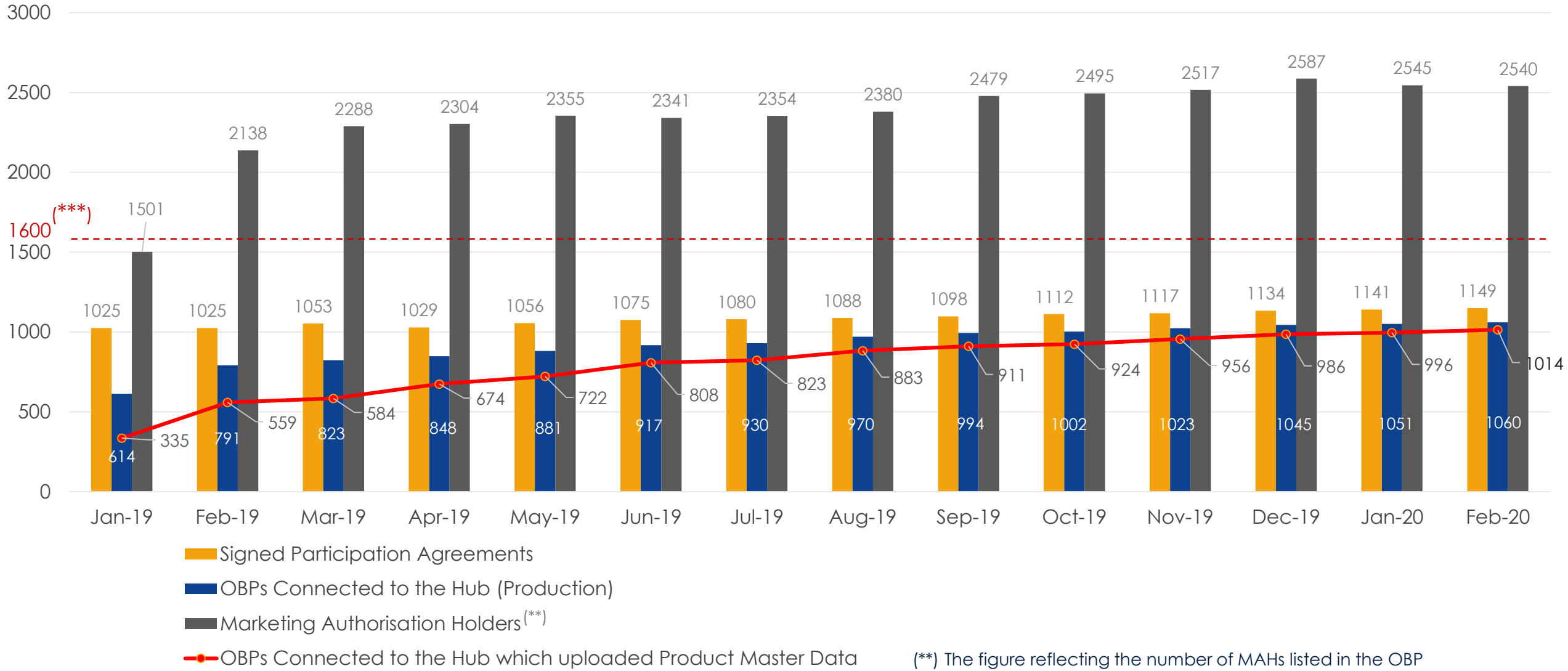
- In the country overview section, the highlights of the previous weeks may be consulted by clicking on the related links in the « history of highlights » slide, per country.

AGENDA

- Status OBP/MAH connection
- Status End-Users connection
- Development of alerts
- Country Overview
- Fines & Stabilisation Periods Overview

STATUS OBP/MAH ON-BOARDING(*)

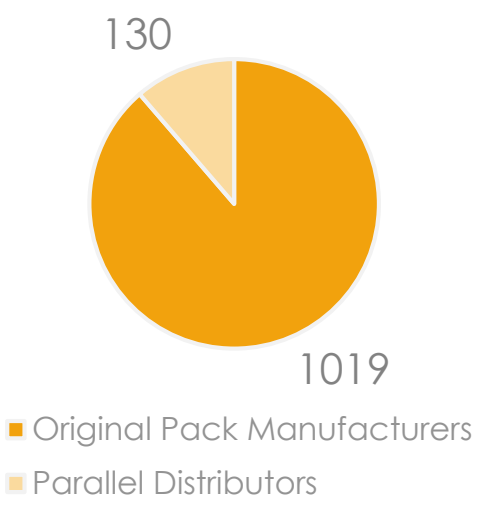
(*)The information figuring hereunder was collected in Calendar Week 11 2020 and will be updated on a monthly basis

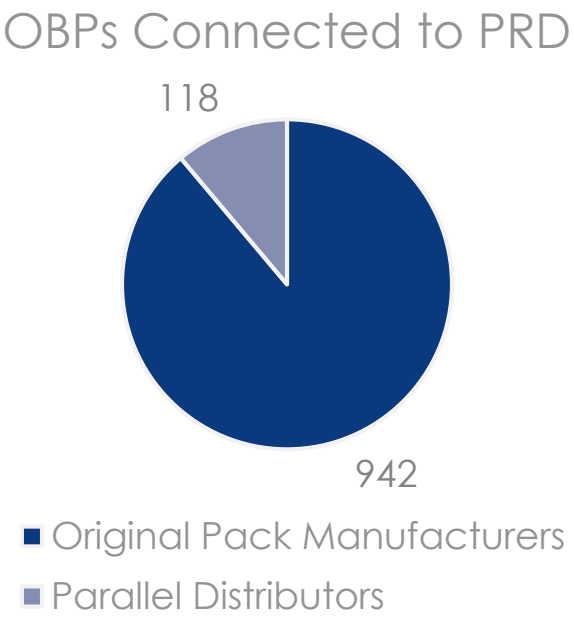


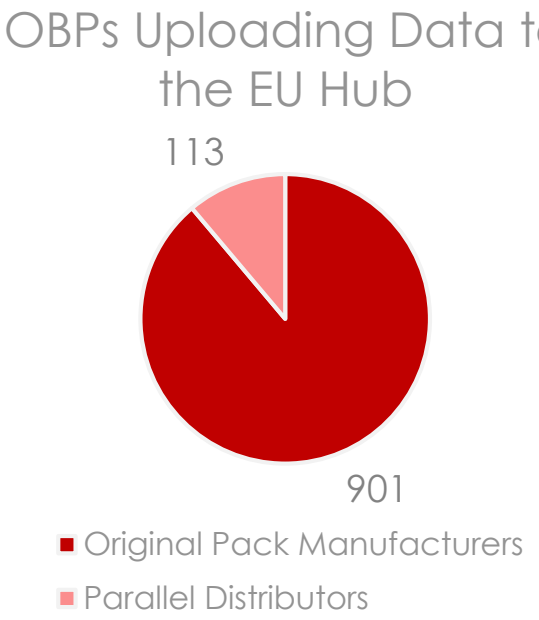
(**) The figure reflecting the number of MAHs listed in the OBP Portal may decrease from one month to the other, as quality check analyses are performed continuously to delete duplicate MAHs listed on the OBP Portal.

(***) Estimated number of OBPs

OBPs PER COMPANY TYPE (*)

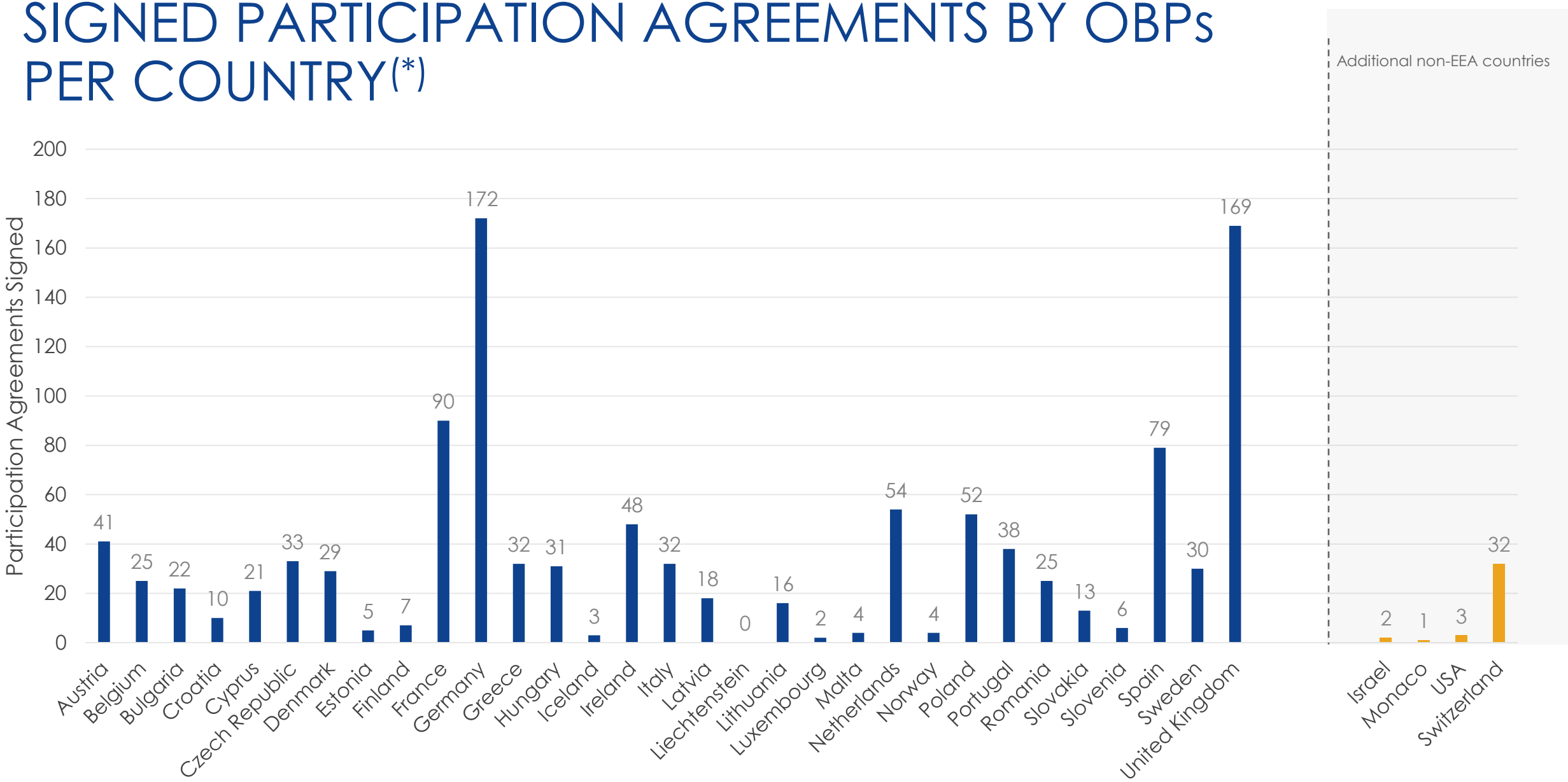






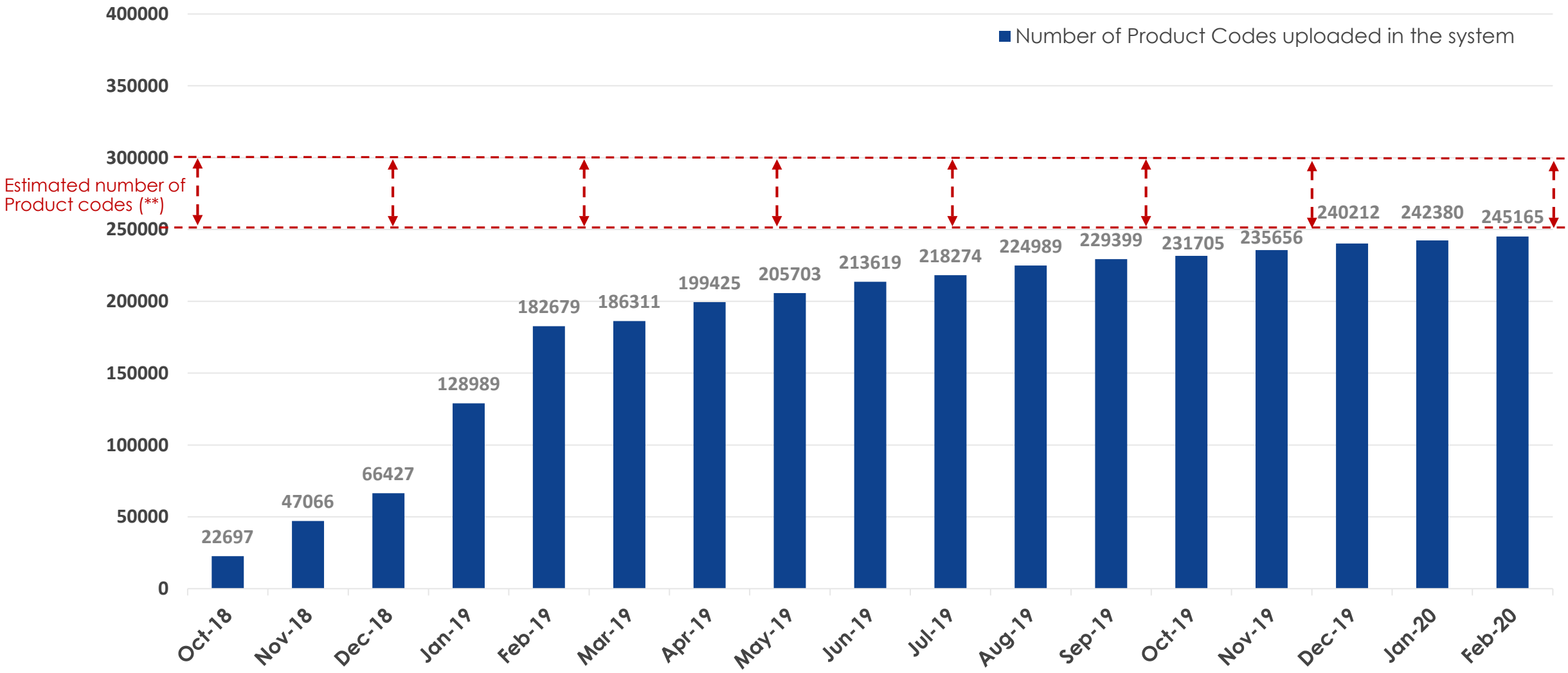
(*)The information figuring hereunder was collected in Calendar Week 11 2020 and will be updated on a monthly basis

SIGNED PARTICIPATION AGREEMENTS BY OBPs PER COUNTRY(*)



(*) The information figuring hereunder was collected in Calendar Week 11 2020 and will be updated on a monthly basis.
This graph shows where the OBP is located, not where the OBP and their affiliates are active in.

UPLOADED PRODUCT CODES(*)



(*) Product code is equal to Stock Keeping Units (SKUs)

(**) Please note that the reported base value is only a rough estimation and is subject to continuous change. EMVO does not warrant that this information is error-free, accurate, complete and up-to-date.

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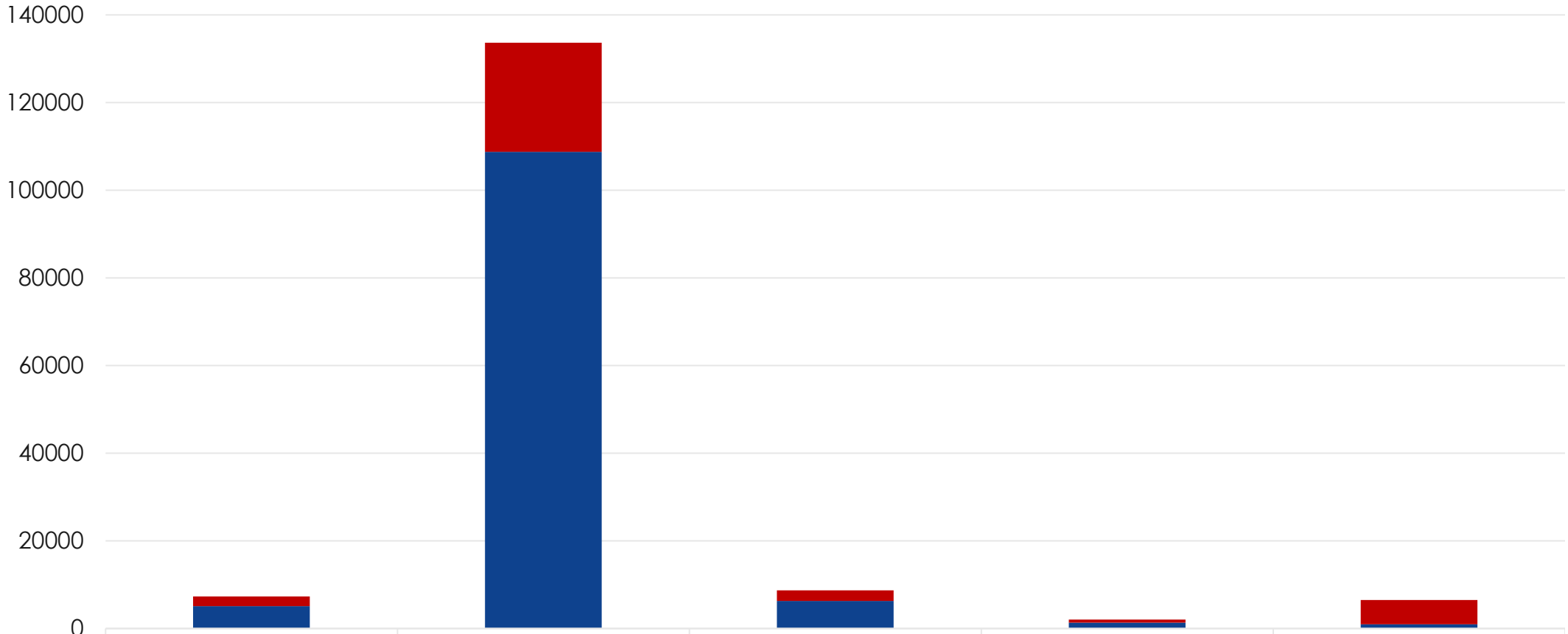
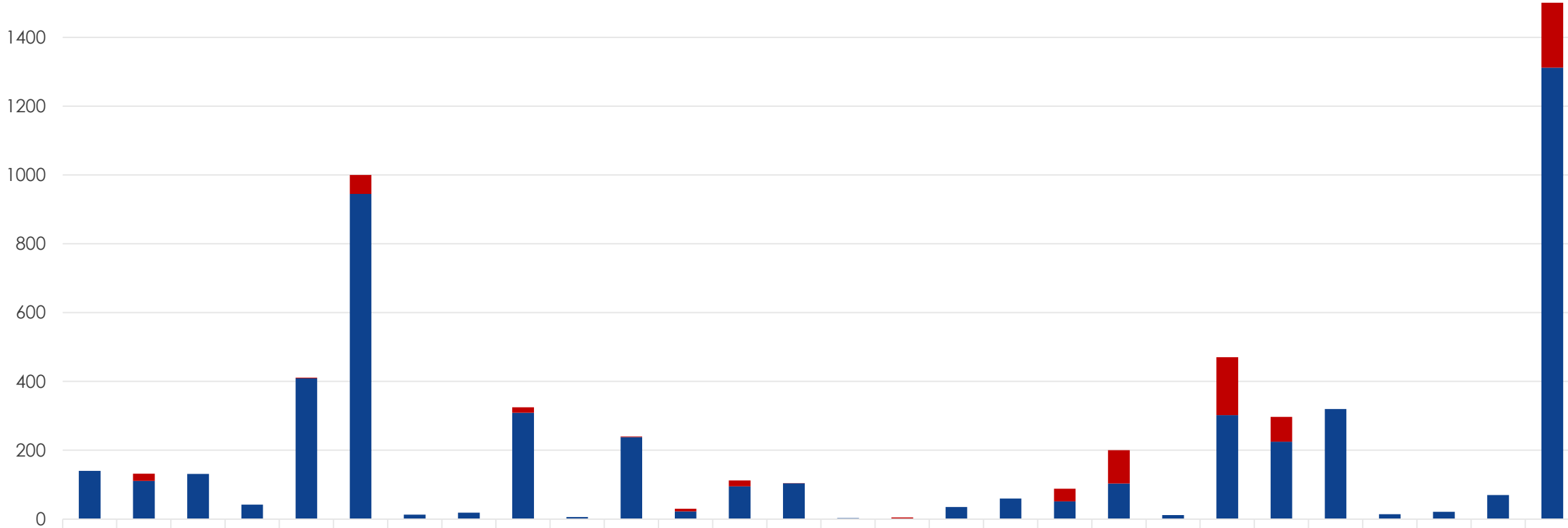
END-USERS CONNECTION OVERVIEW(*)



	Wholesalers	Pharmacies	Healthcare Institutions	Dispensing Doctors	Other Decommissioning Channels
Not connected	2189	24901	2401	728	5539
Connected	5111	108791	6324	1338	977
Percentage remaining	29.99%	18.63%	27.52%	35.24%	85.01%

(*)The information figuring hereunder was collected in Calendar Week 11 2020 and will be updated on a monthly basis

WHOLESALERS CONNECTION BY COUNTRY(*)

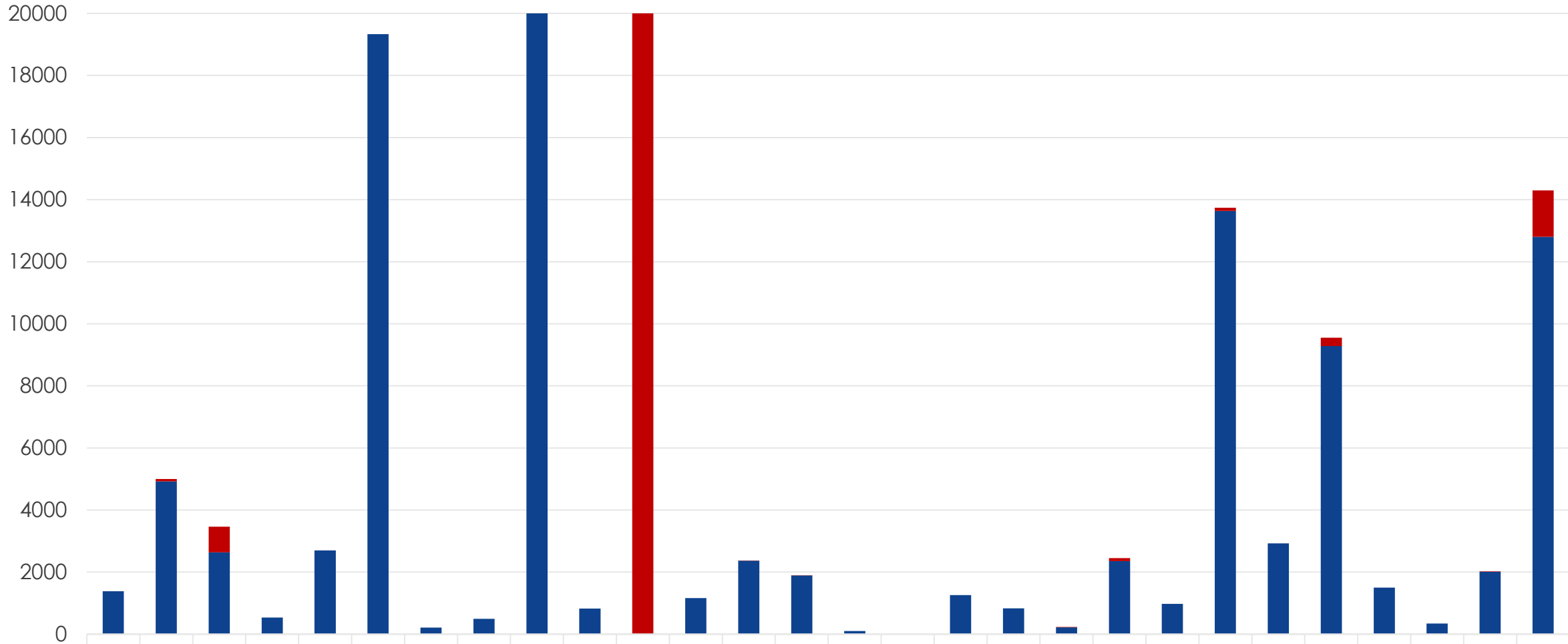


	AT	BE/LU	BG	CY	CZ	DE	DK	EE	ES	FI	FR	HR	HU	IE	IS	LI	LT	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK
Not connected	0	21	0	0	2	55	0	0	16	0	2	8	17	1	0	4	0	0	37	97	0	168	72	0	0	0	0	1689
Connected	140	111	131	42	409	945	13	19	309	6	238	22	95	104	3	0	35	60	51	103	12	302	225	320	14	21	70	1311
Percentage remaining	0%	16%	0%	0%	0%	6%	0%	0%	5%	0%	1%	27%	15%	1%	0%	100%	0%	0%	42%	49%	0%	36%	24%	0%	0%	0%	0%	56%

Country	AT	BE/LU	BG	CY	CZ	DE	DK	EE	ES	FI	FR	HR	HU	IE	IS		LT	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK
Number of Wholesale distribution authorisations (EudraGMDP)	392	312	230	105	736	1944	206	62	705	95	708	102	150	405	16		113	84	108	410	180	534	411	222	259	85	160	2126

(*)The information figuring hereunder was collected in Calendar Week 11 2020 and will be updated on a monthly basis

PHARMACIES CONNECTION BY COUNTRY CAP 20.000(*)



	AT	BE/LU	BG	CY	CZ	DE	DK	EE	ES	FI	FR	HR	HU	IE	IS	LI	LT	LV	MT	NL	NO	PL	PT	RO	SE	SI	SK	UK
Not connected	0	75	825	0	0	0	0	0	0	0	21991	0	12	10	0	0	0	0	13	98	0	103	0	267	0	0	12	1495
Connected	1380	4921	2635	538	2697	19330	210	495	22100	824	9	1165	2364	1891	98	5	1259	830	217	2352	974	13633	2922	9284	1500	341	2012	12805
Percentage remaining	0%	2%	24%	0%	0%	0%	0%	0%	0%	0%	99,9%	0%	1%	0,53%	0%	0%	0%	0%	6%	4%	0%	1%	0%	3%	0%	0%	1%	10%

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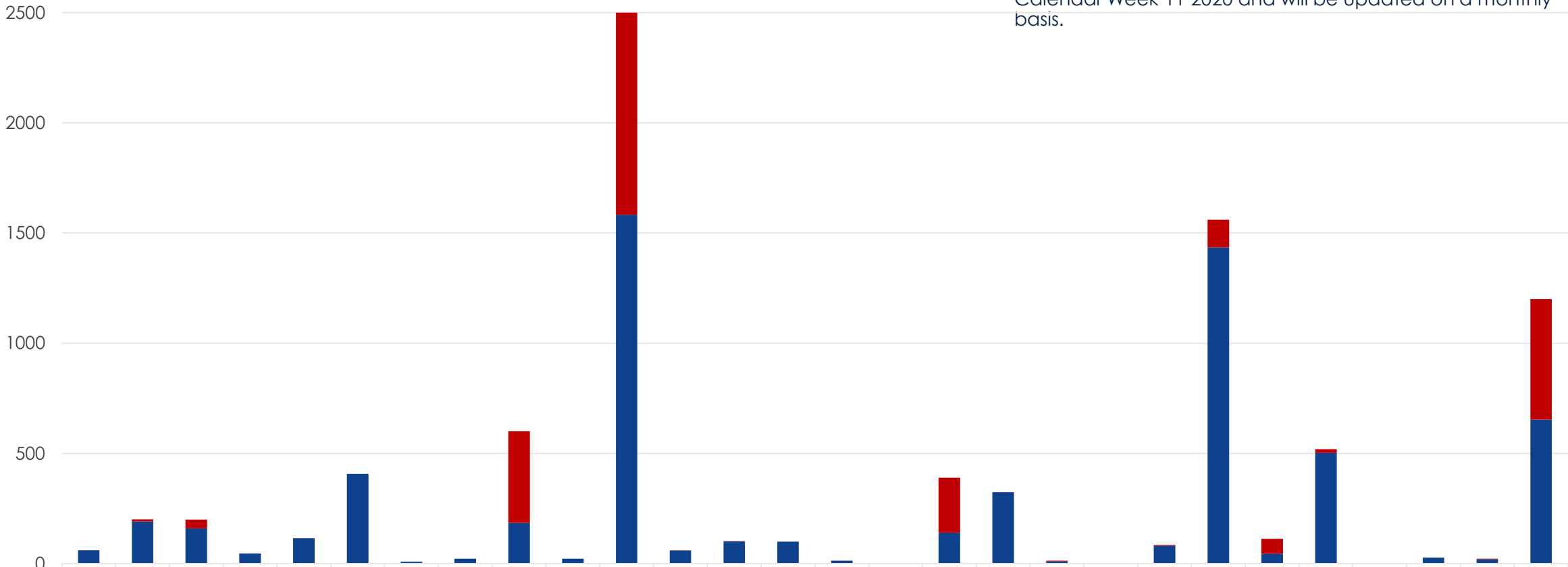
(*)The information figuring hereunder was collected in Calendar Week 11 2020 and will be updated on a monthly basis.

HEALTHCARE INSTITUTIONS CONNECTION BY COUNTRY(*)

(*)The information figuring hereunder was collected in Calendar Week 11 2020 and will be updated on a monthly basis.



	AT	BE/LU	BG	CY	CZ	DE	DK	EE	ES	FI	FR	HR	HU	IE	IS	LI	LT	LV(1)	MT	NL(2)	NO(3)	PL	PT	RO	SE	SI	SK	UK
Not connected	0	10	40	0	0	0	0	0	415	0	918	1	1	0	0	0	250	0	3	0	4	125	67	17	0	0	3	547
Connected	61	191	160	46	116	408	9	23	185	23	1582	60	101	100	14	1	140	325	11	0	81	1435	45	503	3	28	20	653
Percentage remaining	0%	5%	20%	0%	0%	0%	0%	0%	69%	0%	37%	2%	1%	0%	0%	0%	64%	0%	21%	N/A	5%	8%	60%	3%	0%	0%	13%	46%

(1) As of November, dispensing doctors in Latvia have been added to the healthcare institutions report as legally they all are healthcare institutions.

(2) In The Netherlands (NL) healthcare institutions are connected as pharmacies. Therefore, the On-boarding of healthcare institutions in NL is reflected in the overview on pharmacies connection.

(3) In Norway (NO), hospital pharmacies are connected as pharmacies. The overview on healthcare institutions reflect only the number of hospitals that are connected.

DISPENSING DOCTORS(*)

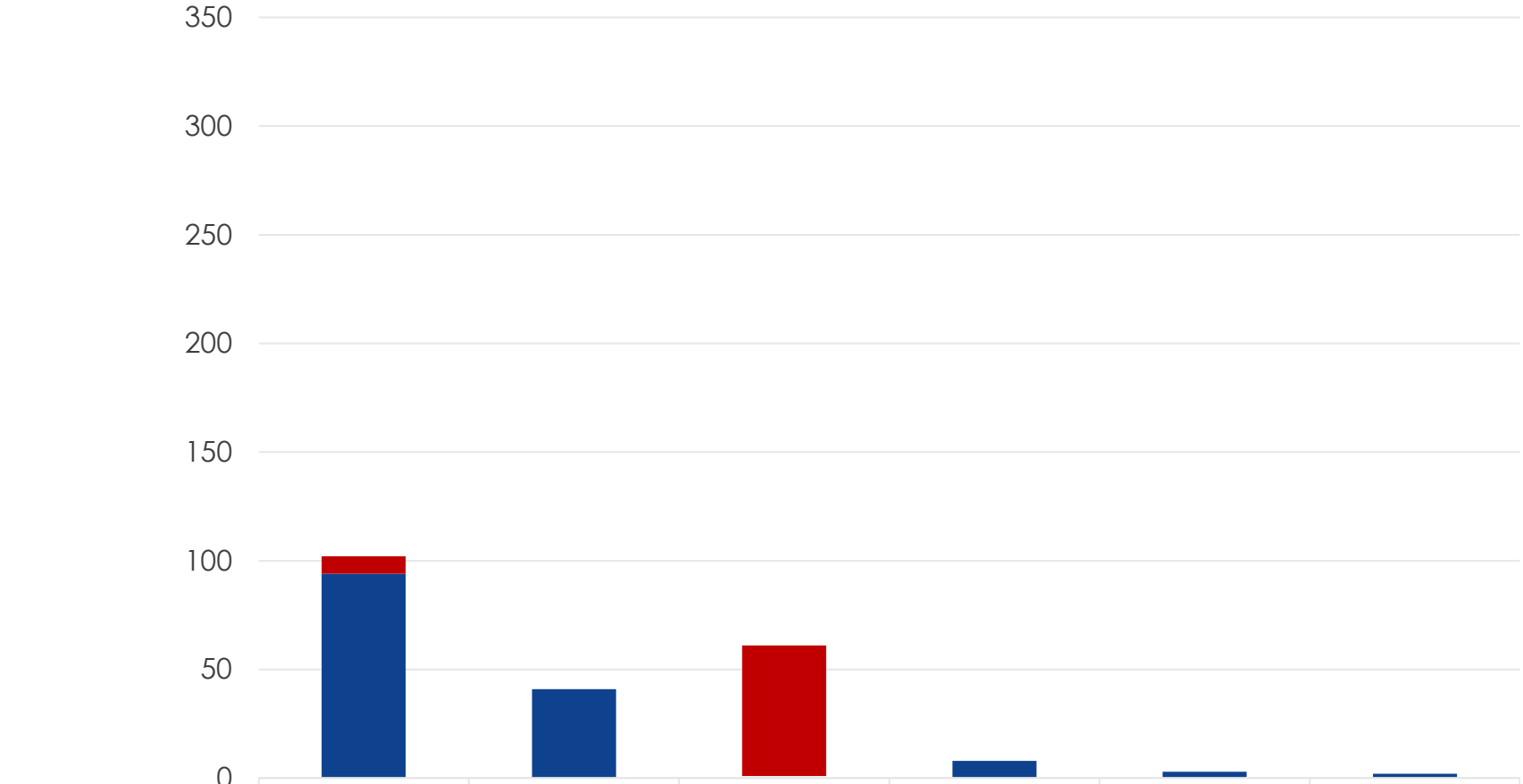
(*)The information figuring hereunder was collected in Calendar Week 11 2020 and will be updated on a monthly basis

	AT	HU	LI	UK
Not connected	0	1	48	679
Connected	807	4	6	521
Percentage remaining	0%	20%	89%	57%

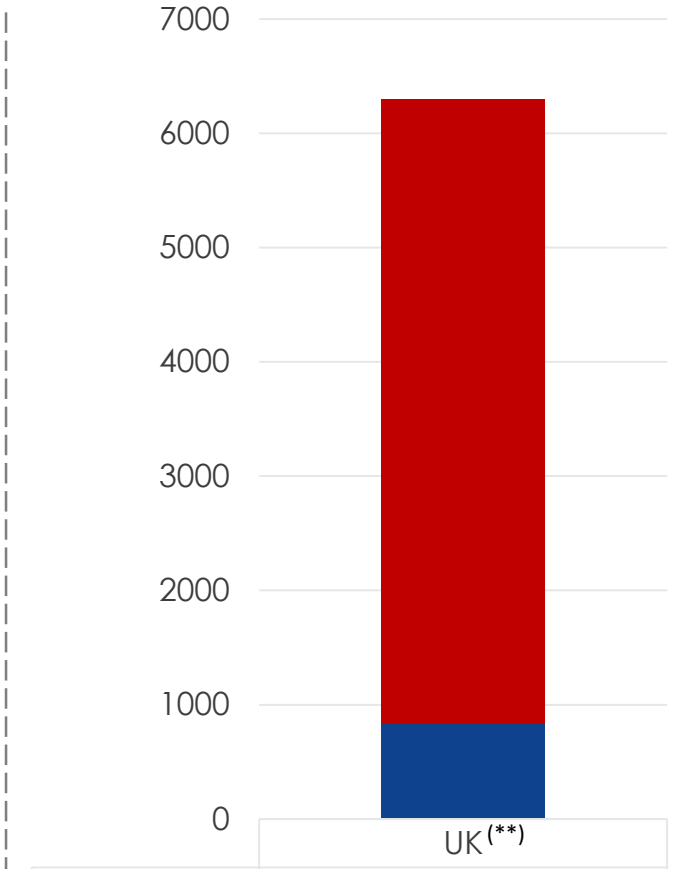
Note: As of November, dispensing doctors in Latvia have been added to the healthcare institutions report as legally they all are healthcare institutions.

OTHER DECOMMISSIONING CHANNELS (*)

(*)The information figuring hereunder was collected in Calendar Week 11 2020 and will be updated on a monthly basis.



	DE	FI	FR	HU	IE	SI
Not connected	8	0	60	0	0	0
Connected	94	41	0	8	3	2
Percentage remaining	8%	0%	100%	0%	0%	0%



	UK (**)
Not connected	5471
Connected	829
Percentage remaining	86.84%

(**) For the United Kingdom (UK) the figures on dispensing doctors and other decommissioning channels are all reflected in the present slide as dispensing doctors are part of the same GP/Health Centers community as the other decommissioning channels.

OTHER DECOMMISSIONING CHANNELS

Depending on the country, other decommissioning channels may include :

- Industrial Blister Centers
- Compounder
- Central Purchasing Agencies
- Health Centers
- Private renal dialysis clinics

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- **Development of alerts**
- Country Overview
- Fines & Stabilisation Periods Overview

IMPORTANT NOTE

- EMVO © 2019. All rights reserved.

- This version of the EMVO monitoring report represents EMVO's effort to provide the audience with the latest information regarding the development of alerts and to keep, to the best of its knowledge, the information complete, accurate and up-to-date. **EMVO is using its best efforts to collect and compile the necessary data for the above purposes and will continue to constantly working on improving the quality of the information contained herein.**

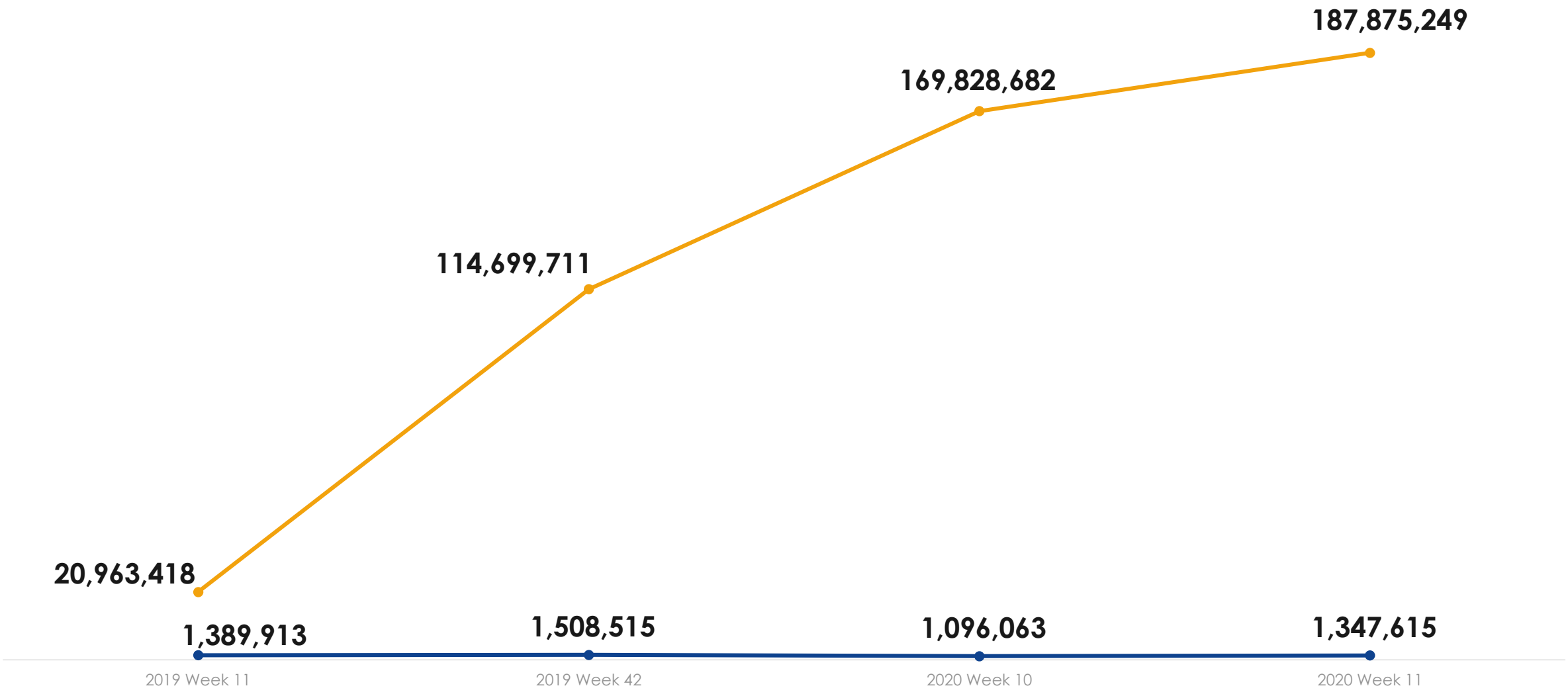
- Please note that the information included therein may be subject to continuous changes and that nothing therein constitutes any representation, guarantee or warranty of any kind, whether expressed or implied or against the occurrence or prevention of alerts on the part of EMVO. EMVO shall not be responsible for any direct or indirect damage, loss or claims of any kind in connection with or arising out of the use of any information disclosed hereunder.

- This report will be further developed in the upcoming weeks and EMVO and the NMVOs will work together with all involved parties on preventive actions.

- This report displays alert data related to all countries forming the EMVS.

- Glossary:
  - Absolute = Total number of Alerts
  - Rate = Total number of alerts in relation to the total number of scans by End-Users or in relation to the market size (divided by 52 to be reflected per week).

OVERVIEW OF ALERTS AND SCANS IN ALL COUNTRIES



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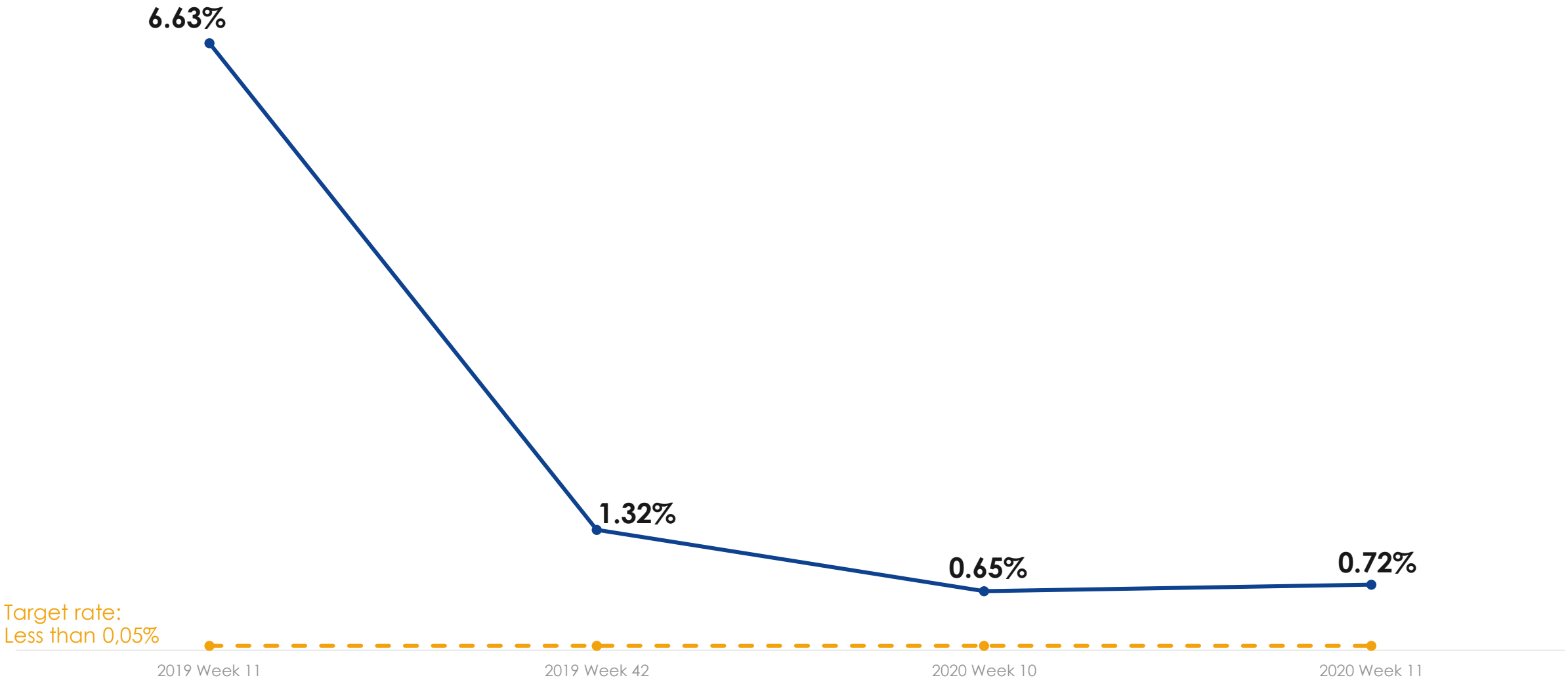
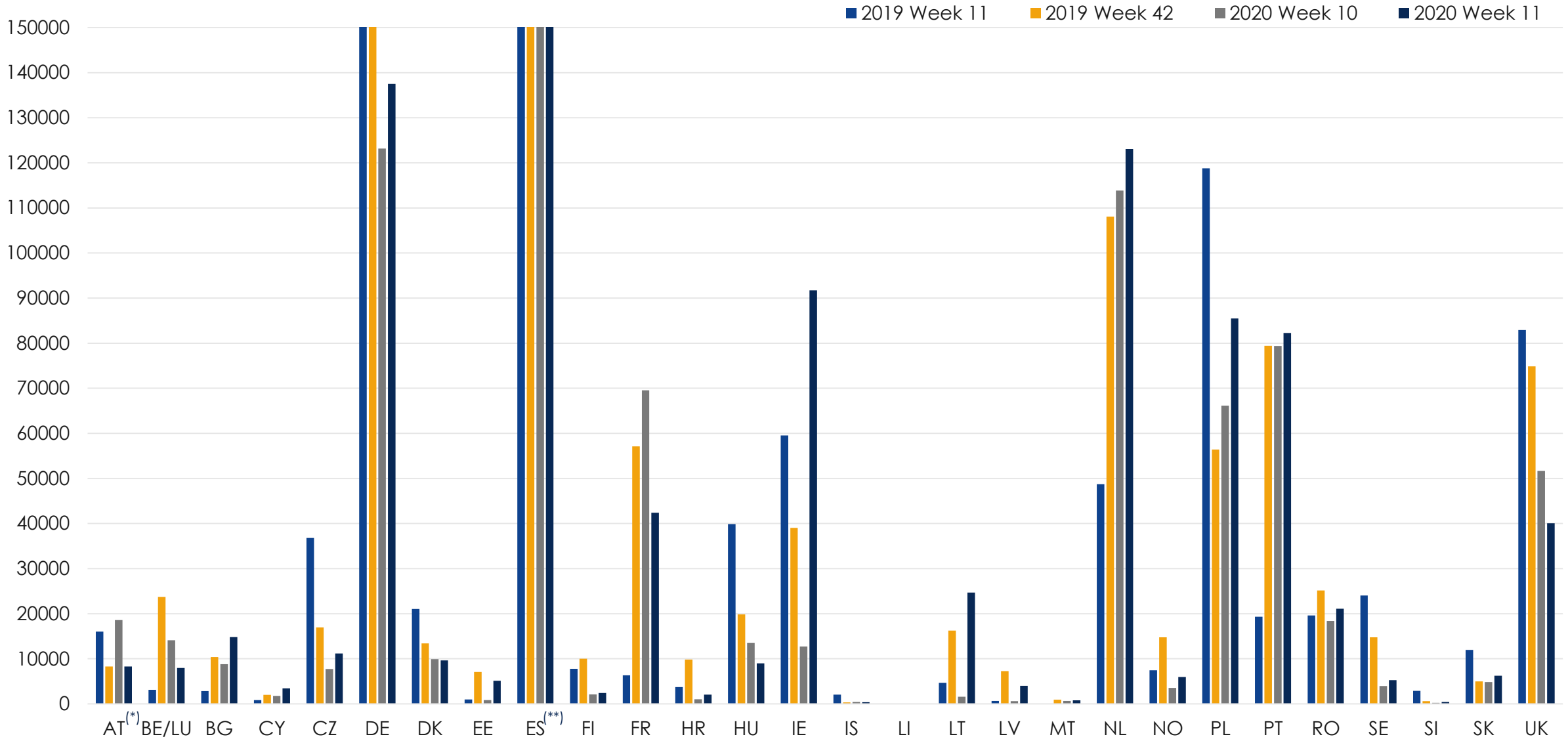
Note: The data provided for Austria Week 10 2020 is currently under investigation of AMVO.

TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS IN ALL COUNTRIES



Note: The data provided for Austria Week 10 2020 is currently under investigation.

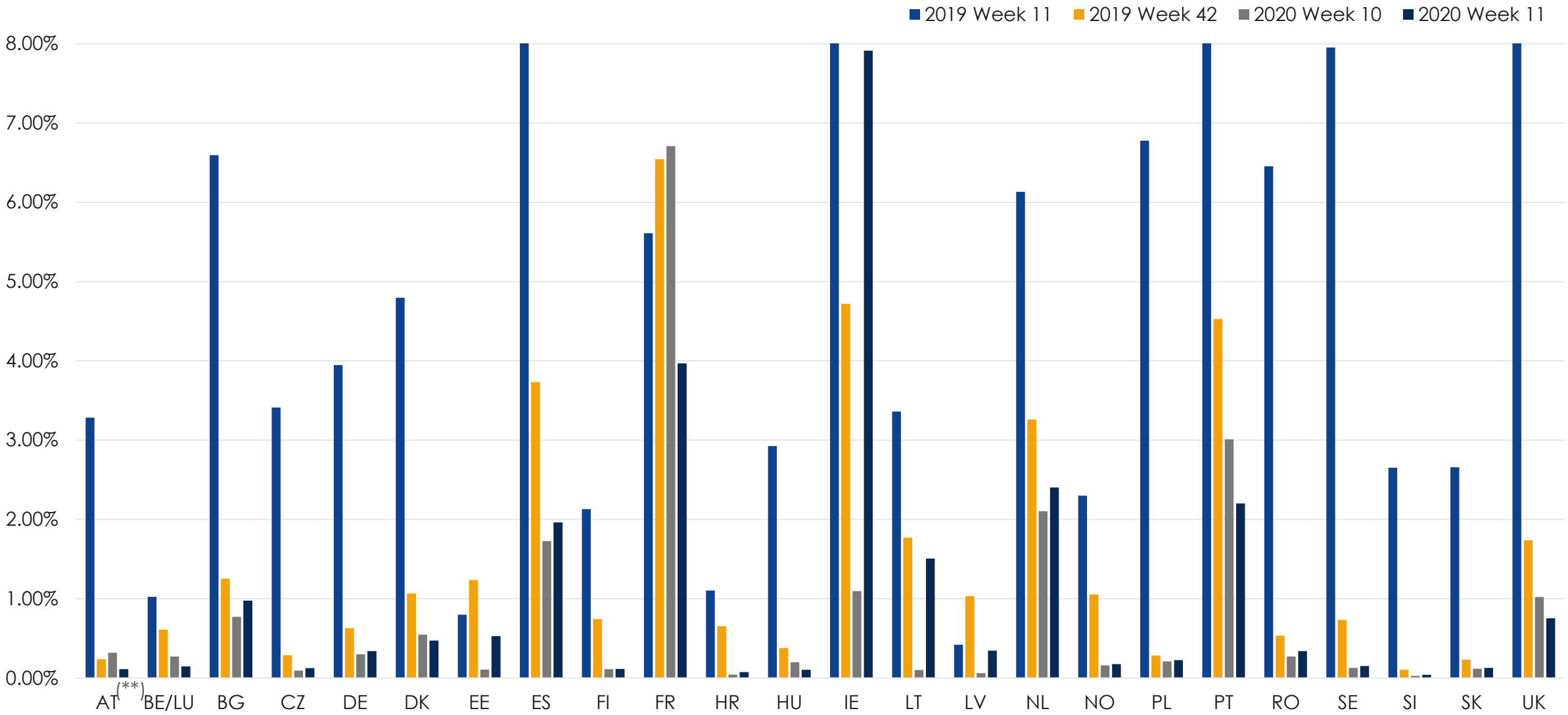
ABSOLUTE : ALL CATEGORIES OF ALERTS PER COUNTRY - CAP 150 000



(*)The data provided for Austria Week 10 2020 is currently under investigation of AMVO.

(**)Value for ES W11: 602.267

RATE : TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS – PER COUNTRY (*) – CAP 8%

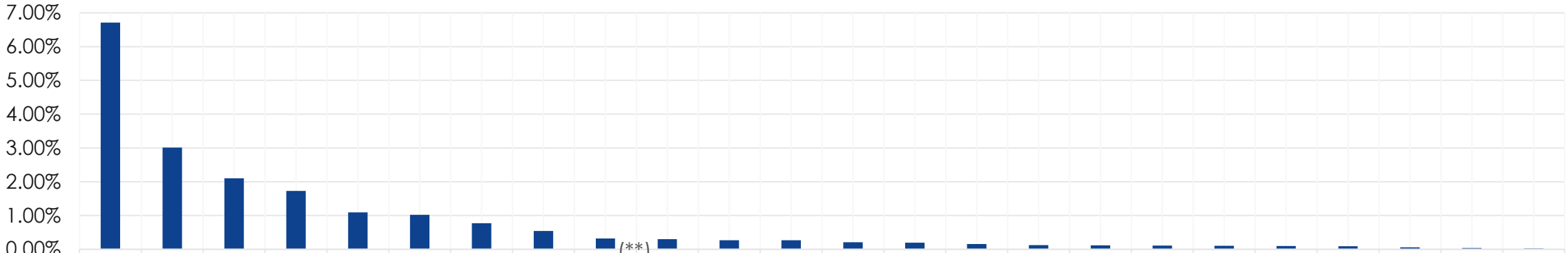


(**)The data provided for Austria Week 10 2020 is currently under investigation of AMVO.

(*)The information figuring hereunder does not display the total of alerts in relation to the number of scans for Cyprus, Iceland, Liechtenstein and Malta as, due to IMT, the figures are not meaningful.

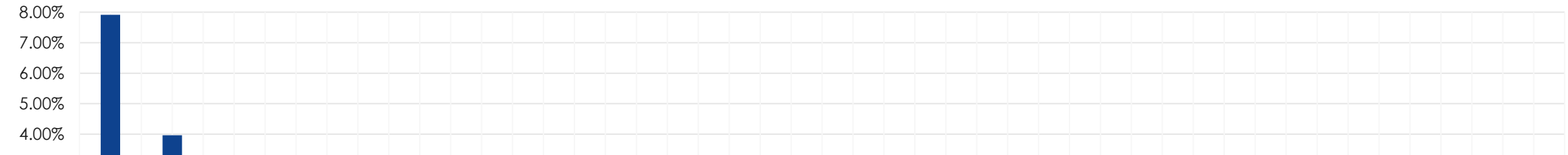
RATE : TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS – PER COUNTRY(*) – IN DECLINING ORDER

2020 Week 10



	FR	PT	NL	ES	IE	UK	BG	DK	AT(**)	DE	RO	BE/LU	PL	HU	NO	SE	SK	FI	EE	LT	CZ	LV	HR	SI
2020 Week 10	6.71%	3.01%	2.10%	1.73%	1.10%	1.02%	0.77%	0.55%	0.32%	0.30%	0.27%	0.27%	0.21%	0.20%	0.16%	0.13%	0.12%	0.11%	0.11%	0.10%	0.09%	0.06%	0.04%	0.03%

2020 Week 11



	IE	FR	NL	PT	ES	LT	BG	UK	EE	DK	LV	RO	DE	PL	NO	SE	BE/LU	SK	CZ	FI	AT	HU	HR	SI
2020 Week 11	7.91%	3.97%	2.40%	2.20%	1.96%	1.51%	0.98%	0.75%	0.53%	0.47%	0.34%	0.34%	0.34%	0.23%	0.18%	0.15%	0.15%	0.13%	0.13%	0.11%	0.11%	0.10%	0.07%	0.04%

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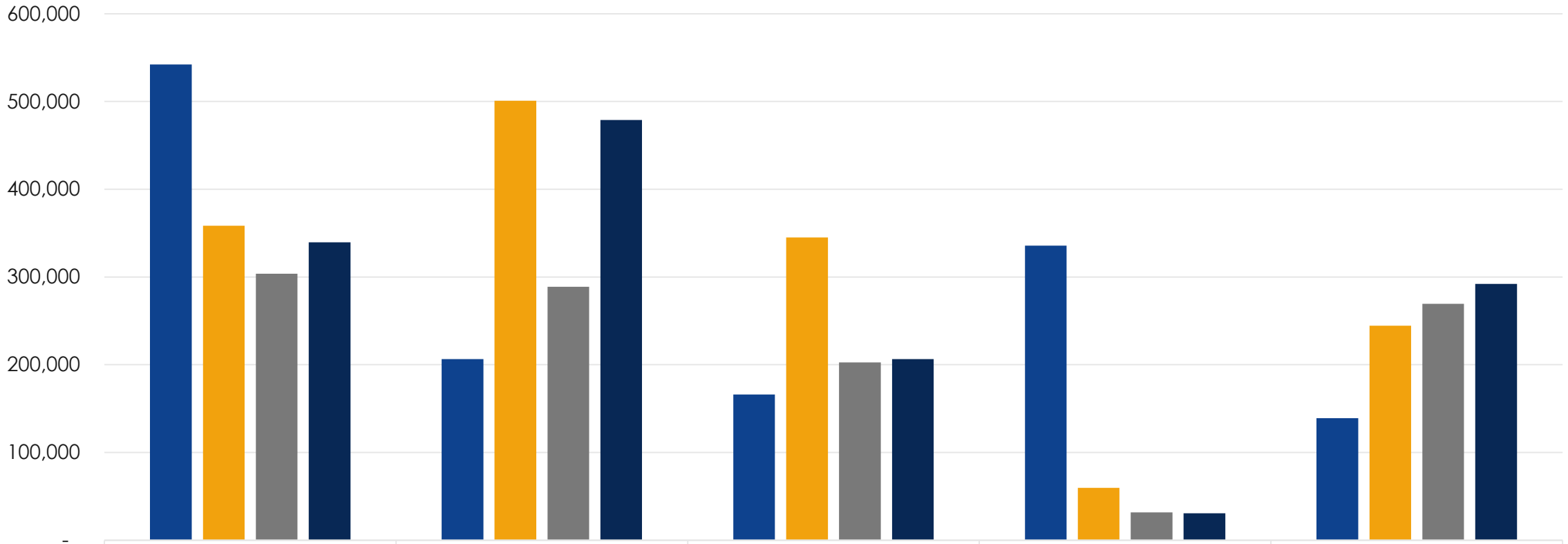
ABSOLUTE: ALERTS PER CATEGORY PER WEEK



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	542,285	206,479	166,158	335,799	139,192
2019 Week 42	358,457	500,772	345,128	59,655	244,503
2020 Week 10	303,564	288,737	202,545	31,791	269,426
2020 Week 11	339,384	478,942	206,489	30,735	292,065

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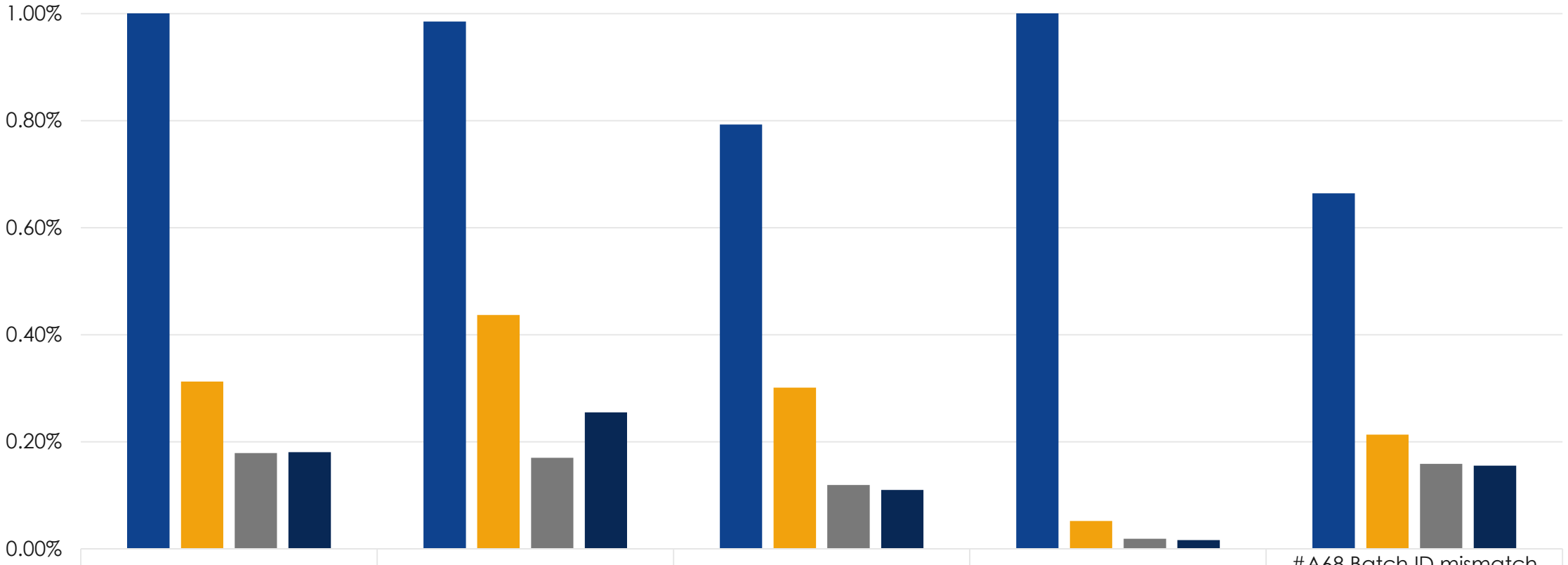
Note: The data provided for Austria Week 10 2020 is currently under investigation of AMVO.

RATE: ALERTS PER CATEGORY PER WEEK IN RELATION TO TOTAL SCANS – CAP 1%



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	2.59%	0.98%	0.79%	1.60%	0.66%
2019 Week 42	0.31%	0.44%	0.30%	0.05%	0.21%
2020 Week 10	0.18%	0.17%	0.12%	0.02%	0.16%
2020 Week 11	0.18%	0.25%	0.11%	0.02%	0.16%

Note: The data provided for Austria Week 10 2020 is currently under investigation of AMVO.

ABSOLUTE: ALERTS PER CATEGORY PER WEEK

Alert Category	Week 11 - 2019		Week 42 - 2019		Week 10 - 2020		Week 11 - 2020	
	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans
#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	542.285	20.963.418	358.457	114.699.711	303.564	169.828.682	339.384	187.875.249
#A24 & #A7 Attempt to decommission an already decommissioned pack	206.479	20.963.418	500.772	114.699.711	288.737	169.828.682	478.942	187.875.249
#A3 Unknown serial number	166.158	20.963.418	345.128	114.699.711	202.545	169.828.682	206.489	187.875.249
#A52 Expiry date mismatch	335.799	20.963.418	59.655	114.699.711	31.791	169.828.682	30.735	187.875.249
#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)	139.192	20.963.418	244.503	114.699.711	269.426	169.828.682	292.065	187.875.249

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Note: The data provided for Austria Week 10 2020 is currently under investigation of AMVO.

PREVENTATIVE ACTIONS - EMVO

- End-User scanner misconfiguration and End-User software are a root cause of a huge number of alerts. To address these, EMVO has reached out to provide guidance to End-User software providers. This is being spread via the Blueprint provider and the NMVOs;

- EMVO intends to facilitate the communication between OBPs and NMVOs and accelerate the identification of alert patterns. In that respect, EMVO has:
  - shared OBP SPOC and SPOC Assistant details with NMVOs
  - reached out to all OBPs with a Letter of Announcement which includes all alert specific NMVO email addresses.
  - will regularly share OBPs' Org. ID in the system to allow for enhanced investigations on the root cause of an alert

- EMVO has hosted workshops in Brussels which have allowed the sharing of experiences/learnings with NMVOs & OBPs and this will continue on an ongoing basis;

- EMVO is continuously assessing the means of improving the system design so to ease the process and the investigation of alerts, notably in terms of IMTs. EMVO also maintains close collaboration with the NMVOs in order to improve the system interoperability.

- EMVO will share further guidance to OBPs to mitigate #A7 and #A24 Alerts – *attempt to decommission an already decommissioned pack;*

- EMVO will be reaching out to OBPs on a regular basis via Letters of Announcement to provide further guidance and updates on the development of alerts in the EMVS;

- EMVO will reflect with the NMVOs regarding provision of test data (codes) to End-Users for the purpose of validating that each of their terminals passes the test set by these codes – this has been already successfully achieved in Slovenia.

PREVENTATIVE ACTIONS - NMVOs

- NMVOs have created dedicated task forces, which include stakeholder representatives to analyse alert data and identify ways to diminish the number of false alerts at national level;
- The NMVOs, where applicable, are continuously educating End-Users to only scan products which fall within the FMD scope. They are also in close contact with the manufacturers to remedy the missing or incorrect data upload, and with the IT providers to address the scanners incorrect configuration;
- The NMVOs are evaluating their systems and End-User behaviour patterns;
- The NMVOs are implementing ad hoc solutions designed to test and validate the End-Users' scanner configuration (caps lock, GS1 Data terminator reading, inverse barcodes, special characters, etc.);
- The NMVOs are working jointly with the end-user software providers, including circulating EMVO guidance;
- The NMVOs are organizing meetings and webinars to receive general feedback on alert profile & root causes to MAHs;
- The NMVOs are in contact with industry associations to flag the problems and the need for action;
- The NMVOs are requesting analyses of alerts per product/batch, as well as monthly report on alerts per MAH to be sent to the NCAs;
- The NMVOs are in continuous communication and alignment with the relevant NCAs;
- The NMVOs maintain a close collaboration with EMVO in order to improve the system interoperability (timestamps, for example).

These preventative actions will be regularly updated in future reports, per alert category, also identifying the responsible party and respective timeline.

DEVELOPMENT OF ALERTS

#A2	Batch ID unknown
#A24 & #A7	Attempt to decommission an already decommissioned pack
#A3	Unknown serial number
#A52	Expiry date mismatch
#A68	Batch ID mismatch

STRUCTURE OF THE SLIDES ON ALERT DATA

- In order to reflect the data on alerts, the following structure applies to each of the alert categories :
  - The rate of this alert: total number of alerts in relation to the total number of scans by End-Users
  - The absolute values : total number of alerts
  - The root causes which have been identified
  - The preventive actions which are being undertaken
- Every new input related to the root causes and preventive actions will be indicated in **bold**
- The list of root causes per alert is non-exhaustive
- In order to circulate a meaningful and readable report – showing the trend in the alerts generated and the follow-up accordingly – the data is not being reflected for all weeks. However, the data is being collected for all weeks starting from week 11 2019.

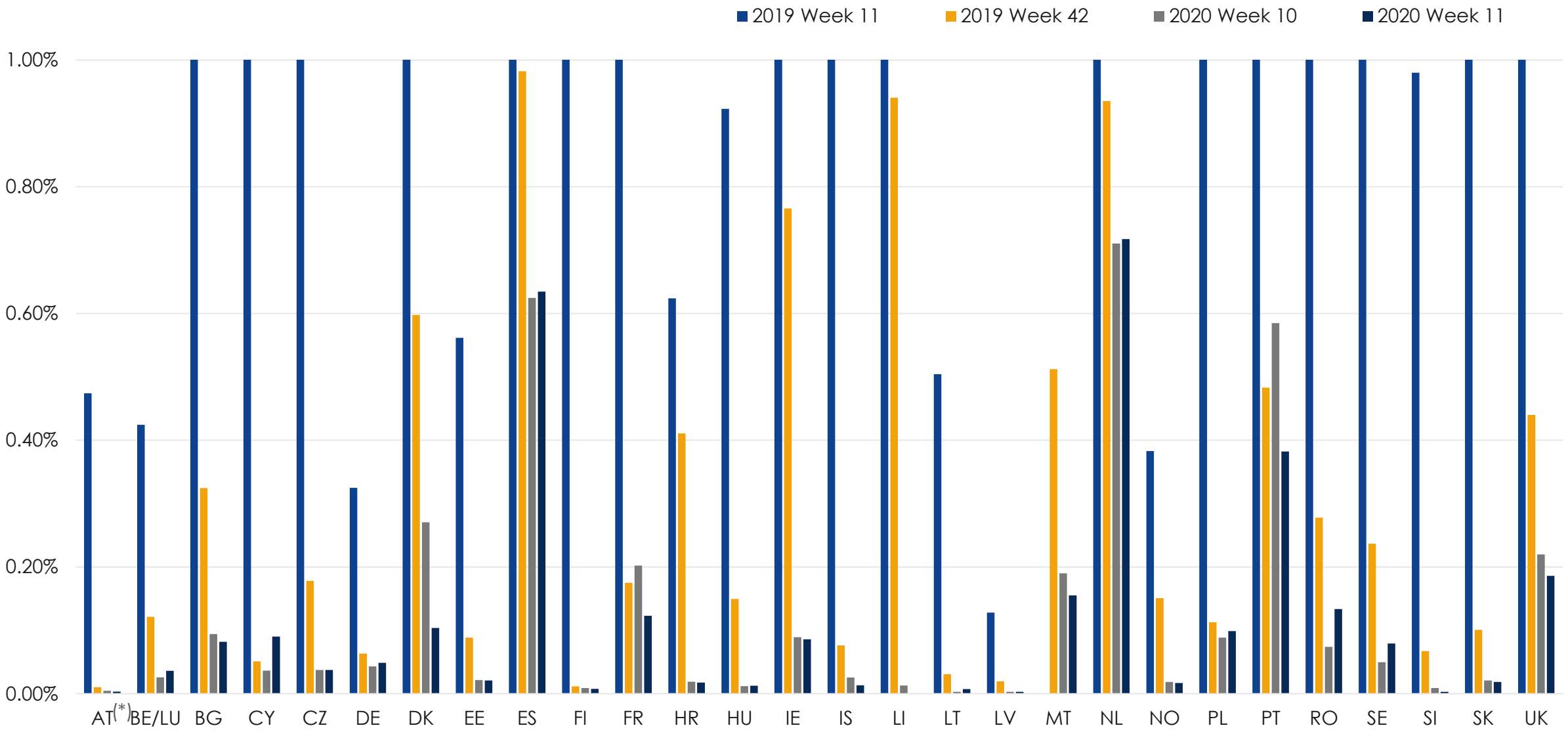
e.g. for the present report we have reflected the data for weeks 11 & 42 in 2019 and 10 & 11 in 2020.

NB: Alert rates for Malta are strictly number of alerts caused by scans by local End-Users, expressed as a percentage of total number of local scans.

DEVELOPMENT OF ALERTS

#A2	Batch ID unknown
#A24 & #A7	Attempt to decommission an already decommissioned pack
#A3	Unknown serial number
#A52	Expiry date mismatch
#A68	Batch ID mismatch

RATE: #A2 ALERTS PER WEEK - CAP 1%



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(*)The data provided for Austria Week 10 2020 is currently under investigation of AMVO.

ABSOLUTE: #A2 ALERTS PER WEEK

#A2	Week 11 - 2019		Week 42 - 2019		Week 10 - 2020		Week 11 - 2020	
Country	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans
AT(*)	2.314	488.000	357	3.508.409	269	5.843.622	231	7.397.404
BE/LU	1.302	306.933	4.708	3.879.530	1.358	5.226.749	1.964	5.427.054
BG	675	43.455	2.695	830.137	1.075	1.141.831	1.242	1.517.146
CY	196	12.355	96	187.752	90	247.569	281	311.810
CZ	15.091	1.079.056	10.570	5.942.180	3.117	8.338.840	3.344	8.930.088
DE	18.791	5.784.305	17.428	27.529.201	17.807	41.237.358	19.759	40.509.777
DK	5.848	438.970	7.528	1.259.541	4.918	1.818.933	2.130	2.050.525
EE	689	122.658	508	573.865	173	807.289	203	976.575
ES	269.550	5.052.352	187.939	19.133.506	168.866	27.032.673	194.714	30.681.024
FI	5.774	365.835	158	1.350.946	166	1.892.799	161	2.162.162
FR	1.841	112.755	1.528	873.119	2.096	1.036.650	1.315	1.068.035
HR	2.121	339.885	6.188	1.505.980	460	2.456.137	477	2.716.630
HU	12.580	1.363.086	7.889	5.276.443	807	6.769.007	1.083	8.652.902
IE	29.446	225.731	6.337	827.316	1.035	1.161.759	994	1.159.176
IS	67	6.408	43	56.452	29	113.736	16	119.969
LI	3	3	3	319	2	15.610	-	15.052
LT	702	139.253	282	918.733	49	1.580.475	118	1.638.260
LV	205	160.334	137	707.223	31	1.027.629	35	1.157.946
MT			520	101.552	283	148.869	327	210.578
NL	21.669	794.929	31.021	3.317.210	38.432	5.409.886	36.723	5.118.612
NO	1.239	323.617	2.113	1.400.808	417	2.233.024	571	3.383.758
PL	50.342	1.753.248	22.500	19.981.850	28.050	31.647.975	37.478	37.915.500
PT	1.291	120.806	8.479	1.754.792	15.414	2.636.011	14.299	3.739.875
RO	7.025	304.143	13.123	4.722.460	5.017	6.785.150	8.296	6.216.105
SE	15.673	302.251	4.784	2.021.736	1.555	3.129.794	2.791	3.517.025
SI	1.062	108.356	394	584.284	77	857.985	30	1.046.139
SK	6.474	451.174	2.163	2.143.890	866	4.176.016	912	4.917.489
UK	70.315	763.520	18.966	4.310.477	11.105	5.055.306	9.890	5.318.633

(*)The data provided for Austria Week 10 2020 is currently under investigation.

#A2 - BATCH ID UNKNOWN

ROOT CAUSES

➢ **CAUSED BY OBPs:**

- (Correct) batch not uploaded (legacy packs, pack distributed under Art. 126a of Directive 2001/83/EC)
- One element of the Data Matrix Code appears in the batch field, because group separators have not been set properly
- An OBP with 'Indian packs' uses a GTIN which they will later use for serialised packs causes this alert when master data is uploaded using the same GTIN
- Retrospective upload capability not implemented in the OBP software
- Transactions misuse for training/test purposes in PRD

➢ **CAUSED BY END-USERS:**

- End-Users scan products which are not in scope of FMD
- End-User software sends the wrong Batch ID, with a mismatch to the data which is encoded in the Data Matrix Code
- The decoding software of the End-User was unable to correctly interpret the group separator characters and/or the scanner was incorrectly configured
- Incorrect reading of uppercase/lowercase characters due to End-User software/scanner misconfiguration
- Manual entry error by the End-User
- Failed scanning procedure : batch number incomplete (missing characters) or linear barcode (EAN code) attached to batch number
- Scanner misconfiguration : concatenation of two codes in one during a fast scanning sequence
- Transactions misuse for training/test purposes in PRD

#A2 - BATCH ID UNKNOWN

PREVENTIVE ACTIONS

UNDERTAKEN BY NMVOs:

- **Towards OBPs**
  - Reaching out to OBPs to advise them on the missing data and/or confirm the date of the release of the batch
  - Highlighting the necessity for OBPs to retrospectively upload the data for EU-serialized products, released before the 9th February 2019 (referring to COM Q&A 1.12, version 13)
  - Collaboration with MAH and IT suppliers
- **Towards End-Users**
  - Reaching out to End-Users and End-Users' systems IT suppliers to urge the solving of scanners configuration
  - Implementation of ad hoc solutions for End-Users' scanners testing and validation (caps lock, GS1 Data terminator reading, inverse barcodes, special characters, etc.)
  - Educating End-Users regarding FMD scope and scanning best practices

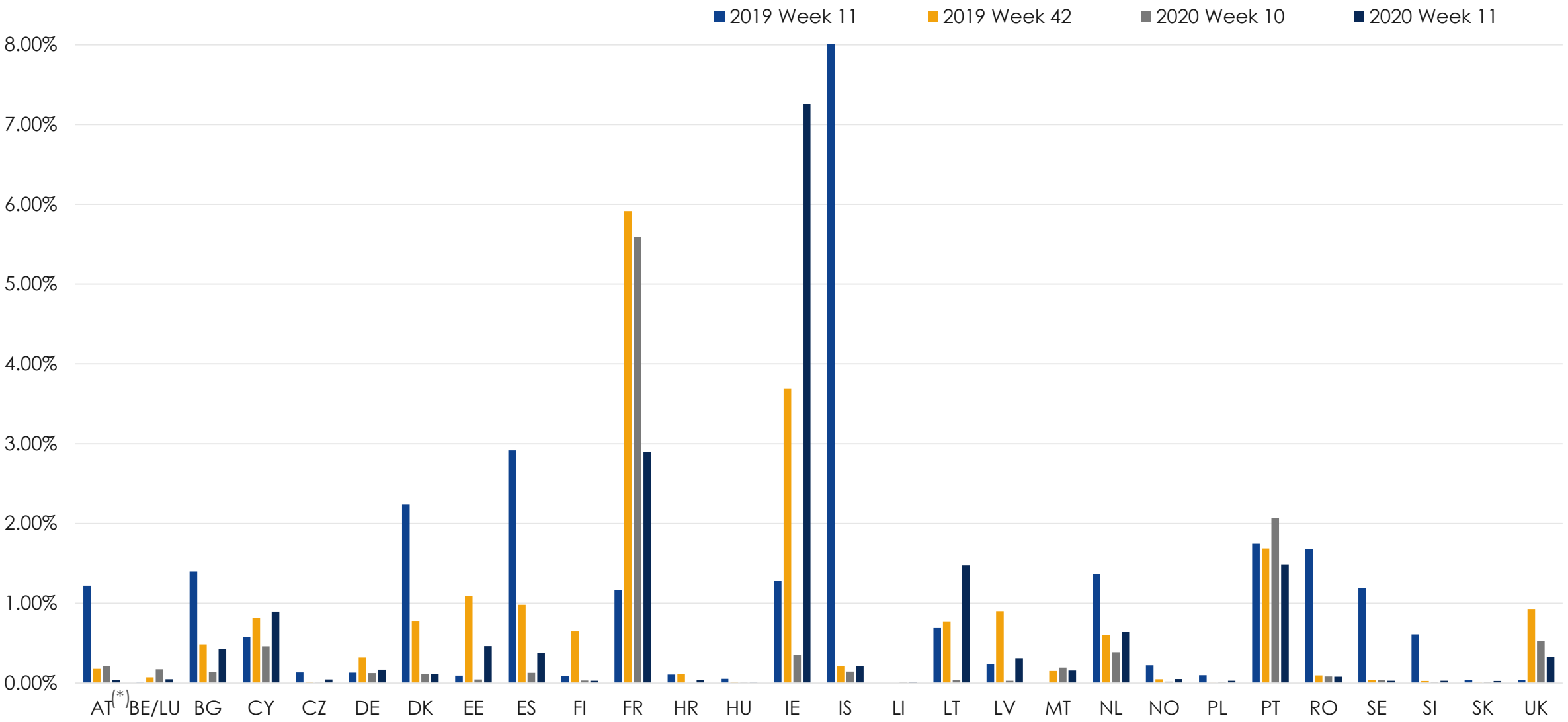
UNDERTAKEN BY EMVO:

- EMVO has circulated guidance to the intention of the End-Users, through the IT suppliers and NMVOs, related to scanners configuration and European pack coding guidelines
- Relayed the information about scanners testing and validation solutions implemented by ZAPAZ and private suppliers

DEVELOPMENT OF ALERTS

#A2	Batch ID unknown
#A24 & #A7	Attempt to decommission an already decommissioned pack
#A3	Unknown serial number
#A52	Expiry date mismatch
#A68	Batch ID mismatch

RATE: #A24 AND #A7 ALERTS PER WEEK - CAP 8%



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(*)The data provided for Austria Week 10 2020 is currently under investigation of AMVO.

ABSOLUTE: #A24 AND #A7 ALERTS PER WEEK

#A24 & #A7	Week 11 - 2019		Week 42 - 2019		Week 10 - 2020		Week 11 - 2020	
Country	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans
AT (*)	5944	488000	6227	3508409	12469	5843622	2593	7397404
BE/LU	10	306933	2745	3879530	9007	5226749	2560	5427054
BG	607	43455	4023	830137	1576	1141831	6428	1517146
CY	71	12355	1532	187752	1140	247569	2791	311810
CZ	1418	1079056	897	5942180	358	8338840	3962	8930088
DE	7447	5784305	88405	27529201	51411	41237358	67302	40509777
DK	9814	438970	229	1259541	1998	1818933	2198	2050525
EE	112	122658	6266	573865	346	807289	4532	976575
ES	147338	5052352	187722	19133506	34178	27032673	116060	30681024
FI	325	365835	8743	1350946	575	1892799	617	2162162
FR	1314	112755	51653	873119	57955	1036650	30898	1068035
HR	355	339885	1733	1505980	64	2456137	1089	2716630
HU	719	1363086	333	5276443	290	6769007	352	8652902
IE	2898	225731	30540	827316	4100	1161759	84097	1159176
IS	1581	6408	118	56452	162	113736	250	119969
LI	0	3	0	319	1	15610	2	15052
LT	957	139253	7112	918733	562	1580475	24154	1638260
LV	383	160334	6376	707223	285	1027629	3607	1157946
MT			152	101552	287	148869	330	210578
NL	10874	794929	19856	3317210	20841	5409886	32710	5118612
NO	717	323617	661	1400808	418	2233024	1699	3383758
PL	1694	1753248	461	19981850	2378	31647975	10362	37915500
PT	2106	120806	29589	1754792	54556	2636011	55650	3739875
RO	5092	304143	4436	4722460	5546	6785150	4871	6216105
SE	3606	302251	752	2021736	1229	3129794	943	3517025
SI	660	108356	150	584284	68	857985	305	1046139
SK	185	451174	98	2143890	419	4176016	1227	4917489
UK	252	763520	39963	4310477	26518	5055306	17353	5318633

(*)The data provided for Austria Week 10 2020 is currently under investigation of AMVO.

#A24 & #A7: ATTEMPT TO DECOMMISSION AN ALREADY DECOMMISSIONED PACK

ROOT CAUSES

- **CAUSED BY OBPS:**
  - OBP attempts to decommission an already decommissioned pack (e.g. 'sample to checked out')
  - OBP performs batch update on already distributed packs
- **CAUSED BY END-USERS:**
  - End-User (software) attempts to decommission an already decommissioned pack (double dispense)
  - End-User fails to perform the undo operation
  - Both a system dispense and a manual dispense operation are performed for the same pack and same customer
  - Pack decommissioned both in central filing and local pharmacies
  - End-User performs a destroy operation for a pack already dispensed and inactive in the EMVS
  - End-User performs a destroy operation for an expired pack
  - Software bugs (creation of a loop)
  - Errors leading to the re-sending of request
- **CAUSED BY THE SYSTEM SETTING:**
  - Timestamps related issues in IMT in the EU Hub/NMVSs (UTC and local time inconsistency)

#A24 & #A7: ATTEMPT TO DECOMMISSION AN ALREADY DECOMMISSIONED PACK

PREVENTIVE ACTIONS

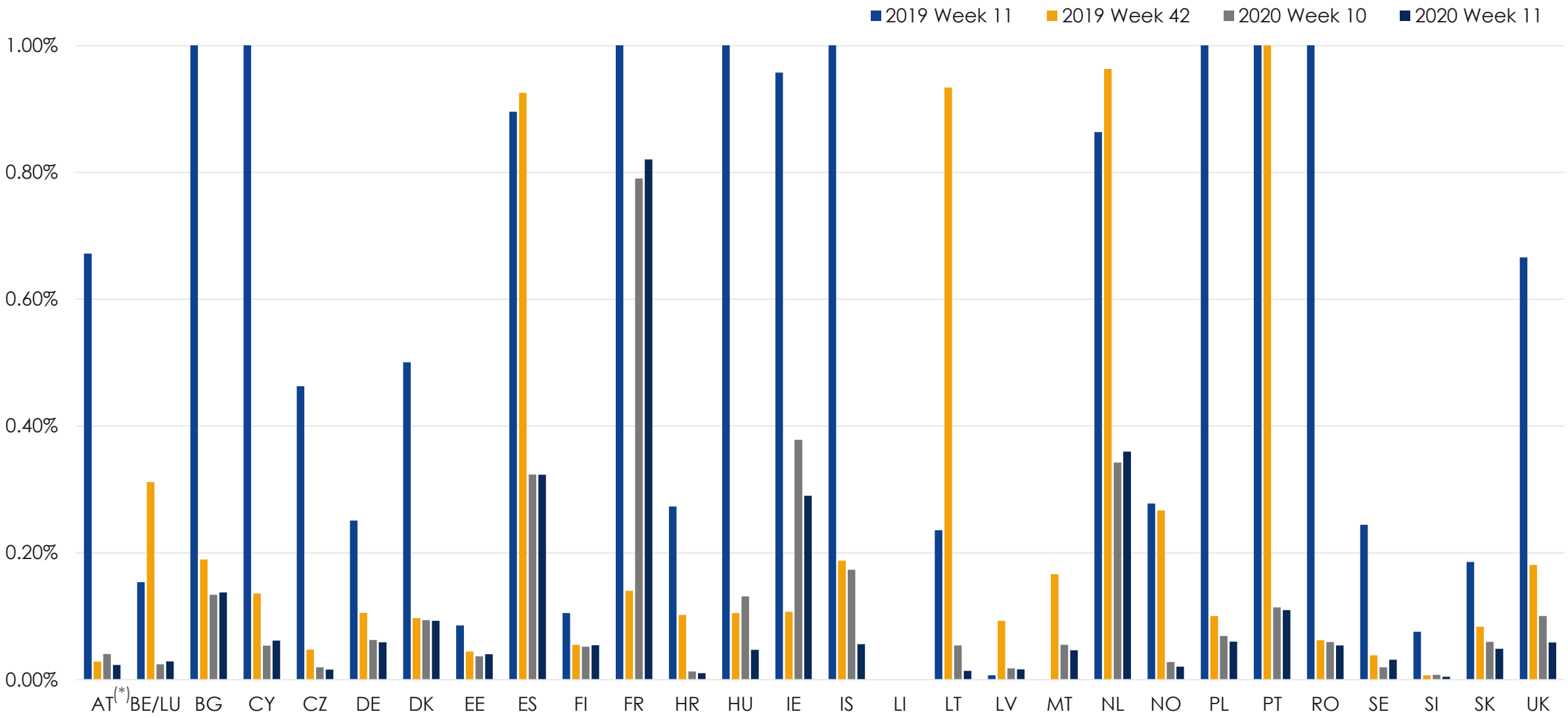
- **UNDERTAKEN BY NMVOs:**
  - **Towards OBPs**
    - Verifying with the MAH if not other root cause of the alert
    - Collaboration with Parallel traders and IT suppliers
  - **Towards End-Users**
    - Reaching out to End-Users to advise them on the incorrect process
    - Educating End-Users regarding scanning best practices
    - Testing software systems
    - Collaboration with end-users and IT suppliers

- **UNDERTAKEN BY EMVO:**
  - Relaying educational material and guidance to End-Users
  - Assessing the means to improve system interoperability (timestamp issue in IMT, for example)

DEVELOPMENT OF ALERTS

#A2	Batch ID unknown
#A24 & #A7	Attempt to decommission an already decommissioned pack
#A3	Unknown serial number
#A52	Expiry date mismatch
#A68	Batch ID mismatch

RATE: #A3 ALERTS PER WEEK – CAP 1%



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ABSOLUTE: #A3 ALERTS PER WEEK

#A3	Week 11 - 2019		Week 42 - 2019		Week 10 - 2020		Week 11 - 2020	
Country	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans
AT (*)	3.280	488.000	999	3.508.409	2.353	5.843.622	1.707	7.397.404
BE/LU	472	306.933	12.089	3.879.530	1.263	5.226.749	1.570	5.427.054
BG	435	43.455	1.573	830.137	1.528	1.141.831	2.088	1.517.146
CY	381	12.355	255	187.752	133	247.569	192	311.810
CZ	4.993	1.079.056	2.806	5.942.180	1.641	8.338.840	1.406	8.930.088
DE	14.510	5.784.305	29.033	27.529.201	25.838	41.237.358	23.831	40.509.777
DK	2.198	438.970	1.223	1.259.541	1.708	1.818.933	1.901	2.050.525
EE	105	122.658	254	573.865	298	807.289	393	976.575
ES	45.253	5.052.352	177.104	19.133.506	87.453	27.032.673	99.168	30.681.024
FI	384	365.835	745	1.350.946	985	1.892.799	1.177	2.162.162
FR	2.439	112.755	1.224	873.119	8.192	1.036.650	8.764	1.068.035
HR	929	339.885	1.537	1.505.980	313	2.456.137	276	2.716.630
HU	16.373	1.363.086	5.545	5.276.443	8.879	6.769.007	4.066	8.652.902
IE	2.161	225.731	885	827.316	4.394	1.161.759	3.362	1.159.176
IS	189	6.408	106	56.452	197	113.736	67	119.969
LI	-	3	-	319	-	15.610	-	15.052
LT	328	139.253	8.579	918.733	855	1.580.475	229	1.638.260
LV	11	160.334	656	707.223	184	1.027.629	189	1.157.946
MT			169	101.552	82	148.869	98	210.578
NL	6.866	794.929	31.947	3.317.210	18.527	5.409.886	18.408	5.118.612
NO	899	323.617	3.740	1.400.808	620	2.233.024	693	3.383.758
PL	50.661	1.753.248	20.047	19.981.850	21.823	31.647.975	22.769	37.915.500
PT	1.370	120.806	31.254	1.754.792	3.008	2.636.011	4.108	3.739.875
RO	5.178	304.143	2.949	4.722.460	4.024	6.785.150	3.349	6.216.105
SE	738	302.251	775	2.021.736	613	3.129.794	1.103	3.517.025
SI	82	108.356	41	584.284	65	857.985	50	1.046.139
SK	838	451.174	1.792	2.143.890	2.485	4.176.016	2.401	4.917.489
UK	5.085	763.520	7.801	4.310.477	5.084	5.055.306	3.124	5.318.633

(*)The data provided for Austria Week 10 2020 is currently under investigation of AMVO.

#A3 - UNKNOWN SERIAL NUMBER

ROOT CAUSES

- **CAUSED BY OBPs:**
  - Incomplete upload:
    - Serial number not uploaded
    - Correct serial numbers not uploaded
  - One element of the Data Matrix Code appears in the Serial Number field, because group separators have not been set properly
  - PSUM* request reaching NMVS before Pack state change, generating alerts
  - Misuse of (bulk) verification of packs by OBPs
- **CAUSED BY THE END-USERS:**
  - End-User software sends the wrong Serial Number, with a mismatch to the data encoded in the Data Matrix Code (e.g. incorrect reading of character cases, due to Y/Z transformation- UK/US vs DE keyboard)
  - The decoding software of the End-User was unable to correctly interpret the group separator characters and/or the scanner was incorrectly configured such that it failed to send the group separator characters
  - Manual entry error by the End-User
  - Failed scanning procedure : batch number incomplete (missing characters) or linear barcode (EAN code) attached to batch number

* Pack Status Update done by Manufacturer

#A3 – UNKNOWN SERIAL NUMBER

PREVENTIVE ACTIONS

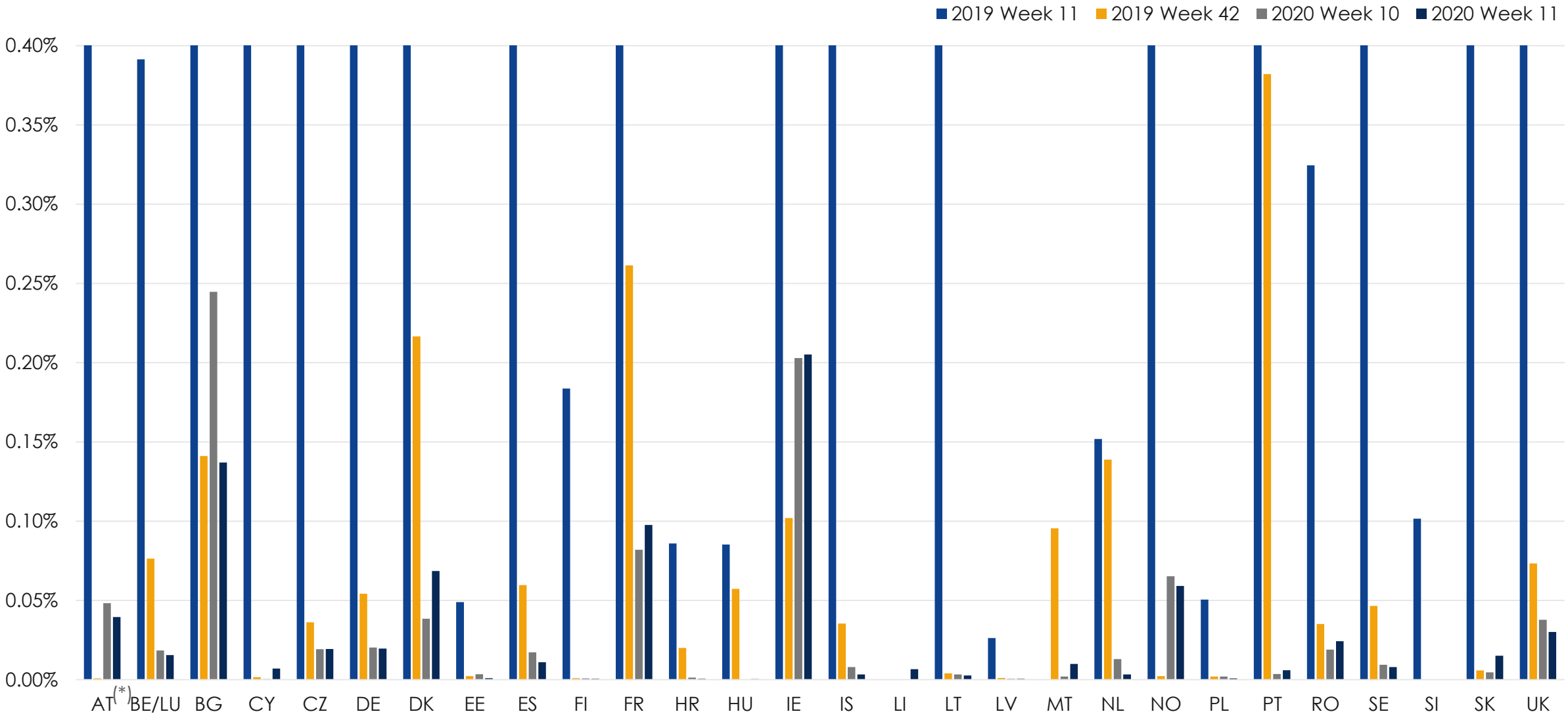
- **UNDERTAKEN BY NMVOs:**
  - **Towards OBPs**
    - Reaching out to OBPs to advise them on the missing data
    - Collaboration with MAH and IT suppliers
  - **Towards End-Users**
    - Reaching out to end-users and End-Users' systems IT suppliers to urge the solving of scanners configuration
    - Implementation of ad hoc solutions for End-Users' scanners testing and validation (caps lock, GS1 Data terminator reading, inverse barcodes, special characters, etc.)
    - Educating End-Users regarding scanning best practices

- **UNDERTAKEN BY EMVO:**
  - Relaying the information about scanners testing and validation solutions implemented by ZAPAZ and private suppliers

DEVELOPMENT OF ALERTS

#A2	Batch ID unknown
#A24 & #A7	Attempt to decommission an already decommissioned pack
#A3	Unknown serial number
#A52	Expiry date mismatch
#A68	Batch ID mismatch

RATE: #A52 ALERTS PER WEEK – CAP 0,04%



(*)The data provided for Austria Week 10 2020 is currently under investigation of AMVO.

ABSOLUTE: #A52 ALERTS PER WEEK

#A52	Week 11 - 2019		Week 42 - 2019		Week 10 - 2020		Week 11 - 2020	
Country	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans
AT(*)	3.423	488.000	27	3.508.409	2.823	5.843.622	2.919	7.397.404
BE/LU	1.201	306.933	2.961	3.879.530	963	5.226.749	844	5.427.054
BG	521	43.455	1.171	830.137	2.794	1.141.831	2.078	1.517.146
CY	95	12.355	3	187.752	1	247.569	22	311.810
CZ	15.020	1.079.056	2.149	5.942.180	1.604	8.338.840	1.726	8.930.088
DE	187.217	5.784.305	14.938	27.529.201	8.337	41.237.358	7.960	40.509.777
DK	2.769	438.970	2.728	1.259.541	700	1.818.933	1.407	2.050.525
EE	60	122.658	13	573.865	28	807.289	9	976.575
ES	62.101	5.052.352	11.419	19.133.506	4.644	27.032.673	3.392	30.681.024
FI	672	365.835	13	1.350.946	16	1.892.799	12	2.162.162
FR	615	112.755	2.282	873.119	849	1.036.650	1.042	1.068.035
HR	292	339.885	302	1.505.980	31	2.456.137	13	2.716.630
HU	1.163	1.363.086	3.024	5.276.443	19	6.769.007	28	8.652.902
IE	24.819	225.731	844	827.316	2.357	1.161.759	2.378	1.159.176
IS	183	6.408	20	56.452	9	113.736	4	119.969
LI	-	3	-	319	-	15.610	1	15.052
LT	2.315	139.253	36	918.733	52	1.580.475	44	1.638.260
LV	42	160.334	7	707.223	6	1.027.629	6	1.157.946
MT			97	101.552	3	148.869	21	210.578
NL	1.207	794.929	4.607	3.317.210	701	5.409.886	167	5.118.612
NO	2.941	323.617	32	1.400.808	1.457	2.233.024	2.003	3.383.758
PL	886	1.753.248	385	19.981.850	627	31.647.975	306	37.915.500
PT	13.764	120.806	6.705	1.754.792	93	2.636.011	221	3.739.875
RO	987	304.143	1.662	4.722.460	1.282	6.785.150	1.507	6.216.105
SE	3.436	302.251	942	2.021.736	294	3.129.794	280	3.517.025
SI	110	108.356	-	584.284	-	857.985	2	1.046.139
SK	4.170	451.174	126	2.143.890	191	4.176.016	743	4.917.489
UK	5.790	763.520	3.162	4.310.477	1.910	5.055.306	1.600	5.318.633

(*)The data provided for Austria Week 10 2020 is currently under investigation of AMVO.

#A52 - EXPIRY DATE MISMATCH

ROOT CAUSES

➢ **CAUSED BY OBPs:**

- Wrong expiry date uploaded, meaning that the data uploaded into the Hub is different from the data encoded in the Data Matrix Code (e.g. the date '00' printed in the DMC and then '31' uploaded in the in the EMVS)
- One element of the Data Matrix Code appears in the Product Code field, because group separators have not been set properly

➢ **CAUSED BY END-USERS:**

- End-User software sends wrong expiry date. For instance, some software and scanners being used by End-Users convert the expiry date 210600 wrongly into other dates e.g. 210531 or 210631 etc. instead of sending the data as encoded in the Data Matrix Code (210600) without adulteration or change)
- Incorrect manual entry of the expiry date or misinterpretation of MM/YYYY

➢ **CAUSED BY THE SYSTEM :**

- Inconsistent expiry date interpretation (interchangeability of YYMM00 and YYMM31) amongst national systems

#A52 - EXPIRY DATE MISMATCH

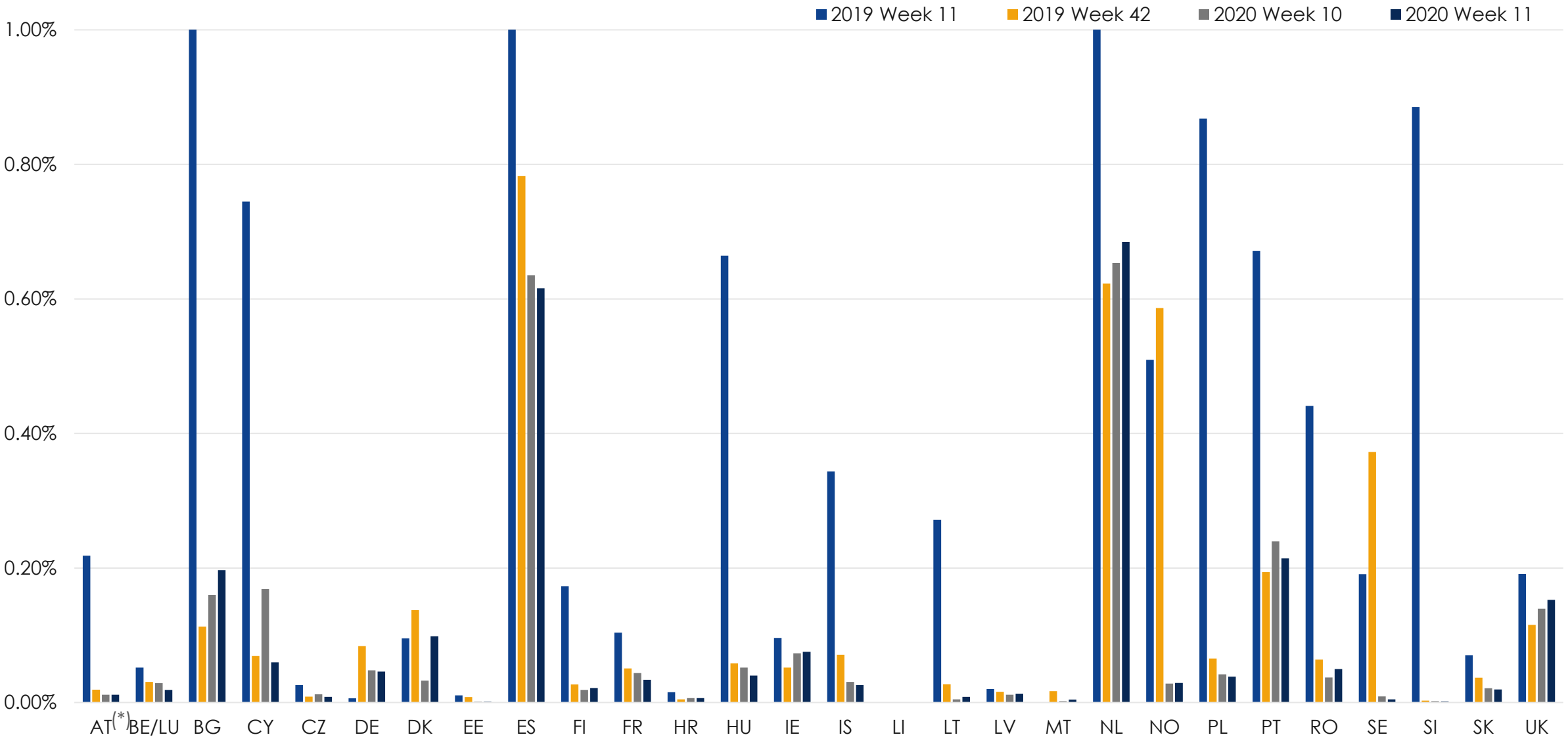
PREVENTIVE ACTIONS

- **UNDERTAKEN BY NMVOs:**
  - **Towards OBPs**
    - Reaching out to OBPs to advise them on the incorrect data
    - Collaboration with MAH and IT suppliers
  - **Towards End-Users**
    - Reaching out to End-Users' IT suppliers to provide guidance
    - Educating End-Users regarding scanning best practices
    - Analyse alert patterns for software or scanning issues and communicate the issue to the respective IT provider
- **UNDERTAKEN BY EMVO:**
  - "Expiry Date Mismatch" Letter of Announcement issued on the 8th April to OBPs
  - Advising OBPs on how to proceed with the correction of data (EMVO Gateway access)
  - Relaying educational material and guidance to End-Users

DEVELOPMENT OF ALERTS

#A2	Batch ID unknown
#A24 & #A7	Attempt to decommission an already decommissioned pack
#A3	Unknown serial number
#A52	Expiry date mismatch
#A68	Batch ID mismatch

RATE: #A68 ALERTS PER WEEK – CAP 1%



(*)The data provided for Austria Week 10 2020 is currently under investigation of AMVO.

ABSOLUTE: #A68 ALERTS PER WEEK

#A68	Week 11 - 2019		Week 42 - 2019		Week 10 - 2020		Week 11 - 2020	
Country	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans	Number of Alerts	Number of Total Scans
AT(*)	1.066	488.000	664	3.508.409	675	5.843.622	866	7.397.404
BE/LU	159	306.933	1.192	3.879.530	1.504	5.226.749	1.012	5.427.054
BG	627	43.455	938	830.137	1.826	1.141.831	2.985	1.517.146
CY	92	12.355	130	187.752	417	247.569	186	311.810
CZ	280	1.079.056	524	5.942.180	1.024	8.338.840	760	8.930.088
DE	366	5.784.305	23.113	27.529.201	19.772	41.237.358	18.673	40.509.777
DK	419	438.970	1.728	1.259.541	593	1.818.933	2.021	2.050.525
EE	13	122.658	47	573.865	11	807.289	12	976.575
ES	95.209	5.052.352	149.747	19.133.506	171.716	27.032.673	188.933	30.681.024
FI	633	365.835	365	1.350.946	356	1.892.799	468	2.162.162
FR	117	112.755	443	873.119	454	1.036.650	360	1.068.035
HR	52	339.885	73	1.505.980	160	2.456.137	177	2.716.630
HU	9.055	1.363.086	3.073	5.276.443	3.525	6.769.007	3.461	8.652.902
IE	217	225.731	429	827.316	852	1.161.759	875	1.159.176
IS	22	6.408	40	56.452	35	113.736	31	119.969
LI	-	3	-	319	-	15.610	-	15.052
LT	378	139.253	251	918.733	72	1.580.475	138	1.638.260
LV	32	160.334	112	707.223	120	1.027.629	151	1.157.946
MT			17	101.552	3	148.869	9	210.578
NL	8.126	794.929	20.653	3.317.210	35.343	5.409.886	35.045	5.118.612
NO	1.649	323.617	8.216	1.400.808	629	2.233.024	989	3.383.758
PL	15.215	1.753.248	13.036	19.981.850	13.257	31.647.975	14.572	37.915.500
PT	811	120.806	3.403	1.754.792	6.312	2.636.011	8.007	3.739.875
RO	1.341	304.143	3.007	4.722.460	2.536	6.785.150	3.088	6.216.105
SE	577	302.251	7.528	2.021.736	285	3.129.794	162	3.517.025
SI	959	108.356	17	584.284	17	857.985	16	1.046.139
SK	318	451.174	788	2.143.890	887	4.176.016	953	4.917.489
UK	1.459	763.520	4.969	4.310.477	7.045	5.055.306	8.115	5.318.633

emvo European Medicines Verification Organisation

(*)The data provided for Austria Week 10 2020 is currently under investigation of AMVO.

#A68 - BATCH ID MISMATCH

ROOT CAUSES

- **CAUSED BY OBPs:**
  - (Correct) batch not uploaded
  - Incorrect batch ID uploaded
  - One element of the Data Matrix Code appears in the batch field, because group separators have not been set properly
  - Misuse of verification action by OBPs to verify correct upload of MMP

- **CAUSED BY END USERS:**
  - End-User (software/scanner) sends the wrong Batch ID, with a mismatch to the data encoded in the Data Matrix Code
  - Incorrect reading of the characters in the batch, for example "/","_","-"
  - Manual entry error by the End-User
  - The decoding software of the End-User was unable to correctly interpret the group separator characters and/or the scanner was incorrectly configured so that it failed to send the group separator characters
  - End-User software sends the wrong Serial Number, with a mismatch to the data encoded in the Data Matrix Code (e.g. incorrect reading of character cases, due to Y/Z transformation- UK/US vs DE keyboard)
  - Failed scanning procedure : batch number incomplete (missing characters) or linear barcode (EAN code) attached to batch number

#A68 - BATCH ID MISMATCH

PREVENTIVE ACTIONS

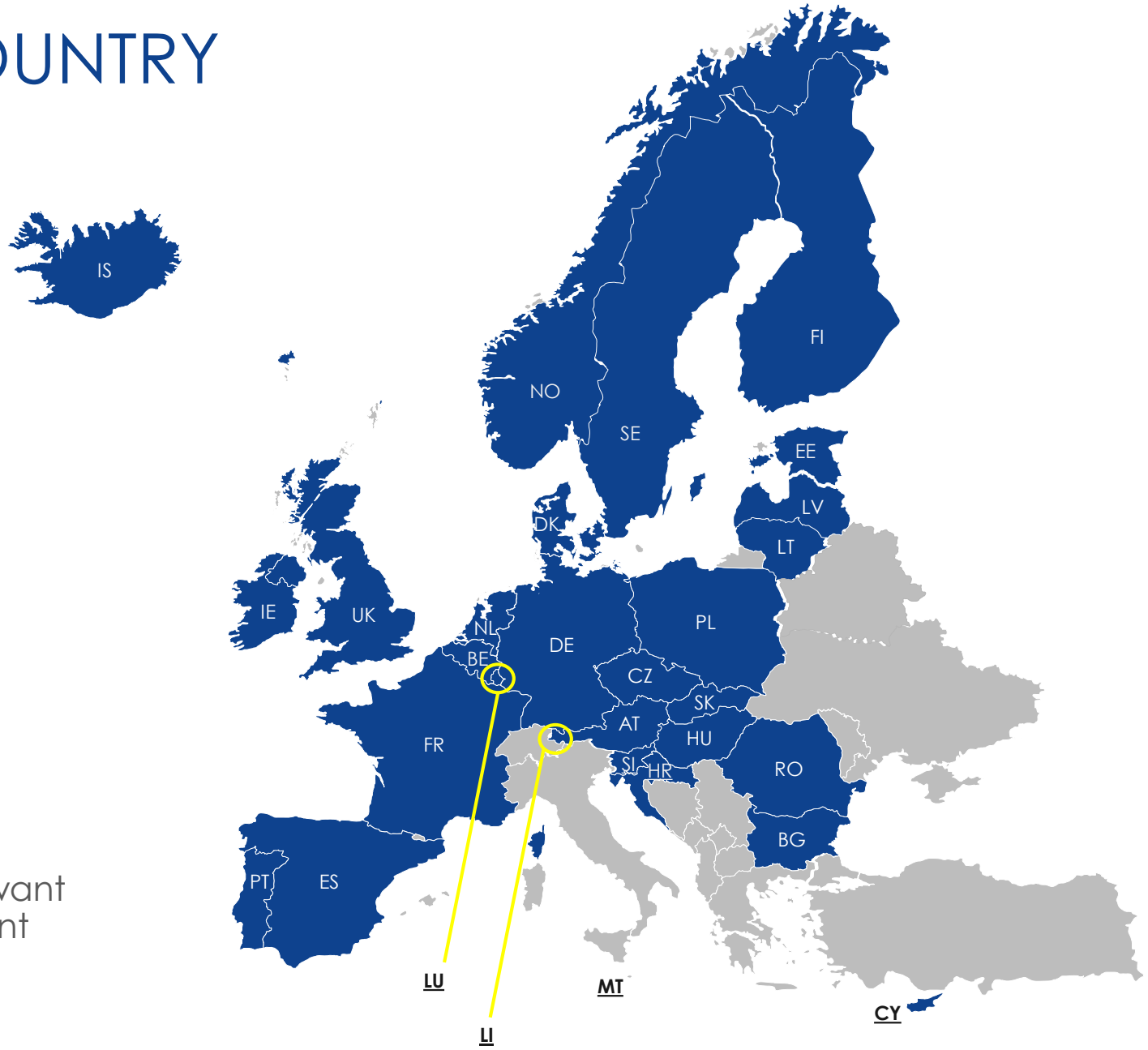
- **UNDERTAKEN BY NMVOs:**
  - **Towards OBPs**
    - Reaching out to OBPs to advise them on the missing data and/or confirm the date of the release of the batch
    - Collaboration with IT suppliers
  - **Towards End-Users**
    - Reaching out to End-Users and End-Users' systems IT suppliers to urge the solving of scanners configuration
    - Implementation of ad hoc solutions for End-Users' scanners testing and validation (caps lock, GS1 Data terminator reading, inverse barcodes, special characters, etc.)
    - Educating end-users regarding scanning best practices

- **UNDERTAKEN BY EMVO:**
  - EMVO has circulated guidance to the intention of the End-Users, through the IT suppliers and NMVOs, related to scanners configuration and European pack coding guidelines
  - Relayed the information about scanners testing and validation solutions implemented by ZAPAZ and private suppliers

AGENDA

- Status OBP/MAH connection
- Status End-Users connection
- Development of alerts
- Country Overview
- Fines & Stabilisation Periods Overview

OVERVIEW PER COUNTRY

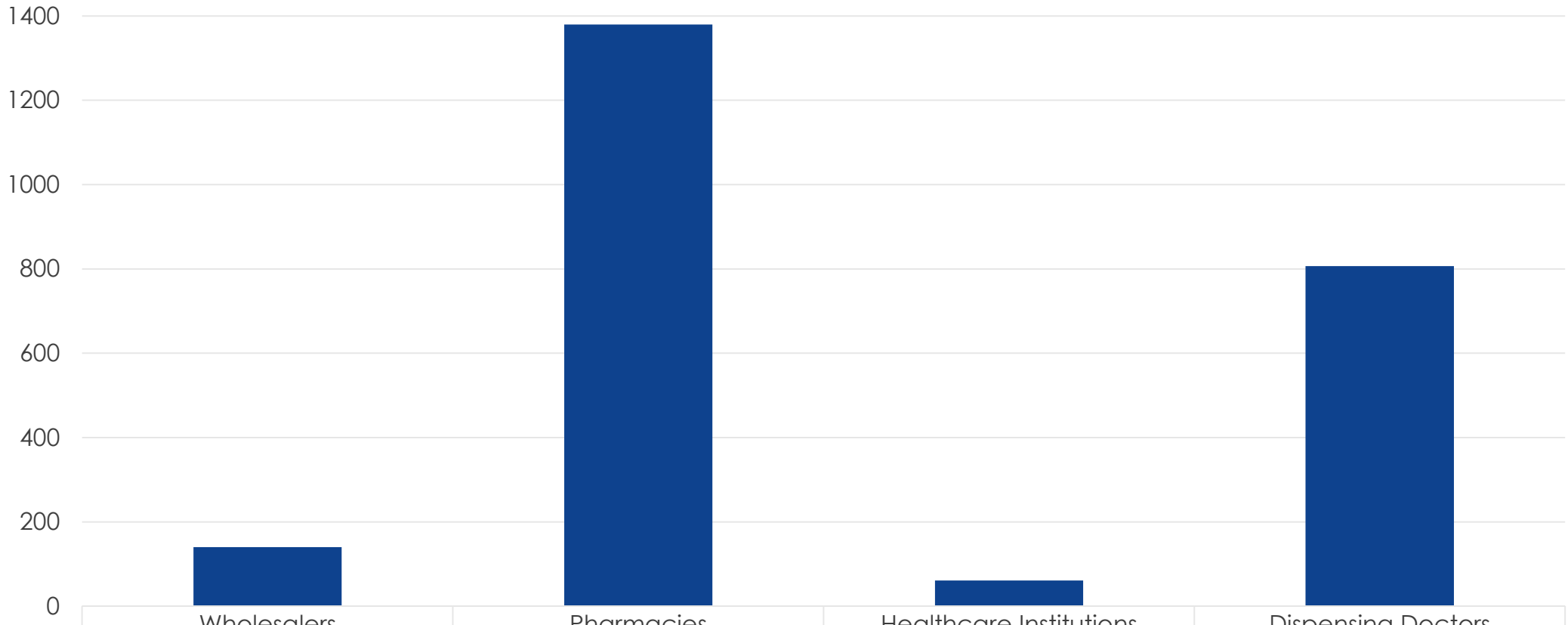


By clicking on ISO code of the country you want to consult, you will be directed to the relevant slide.

AUSTRIA

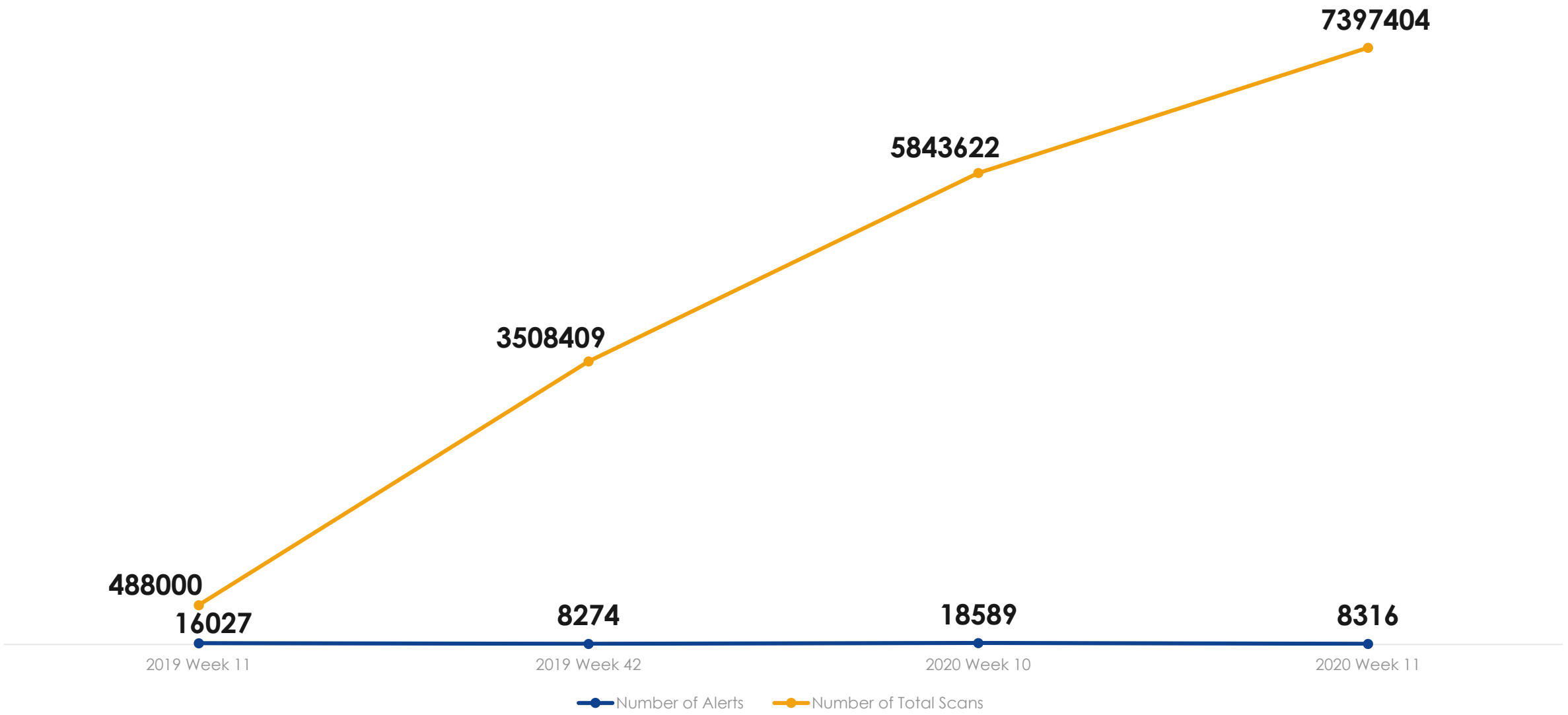
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION



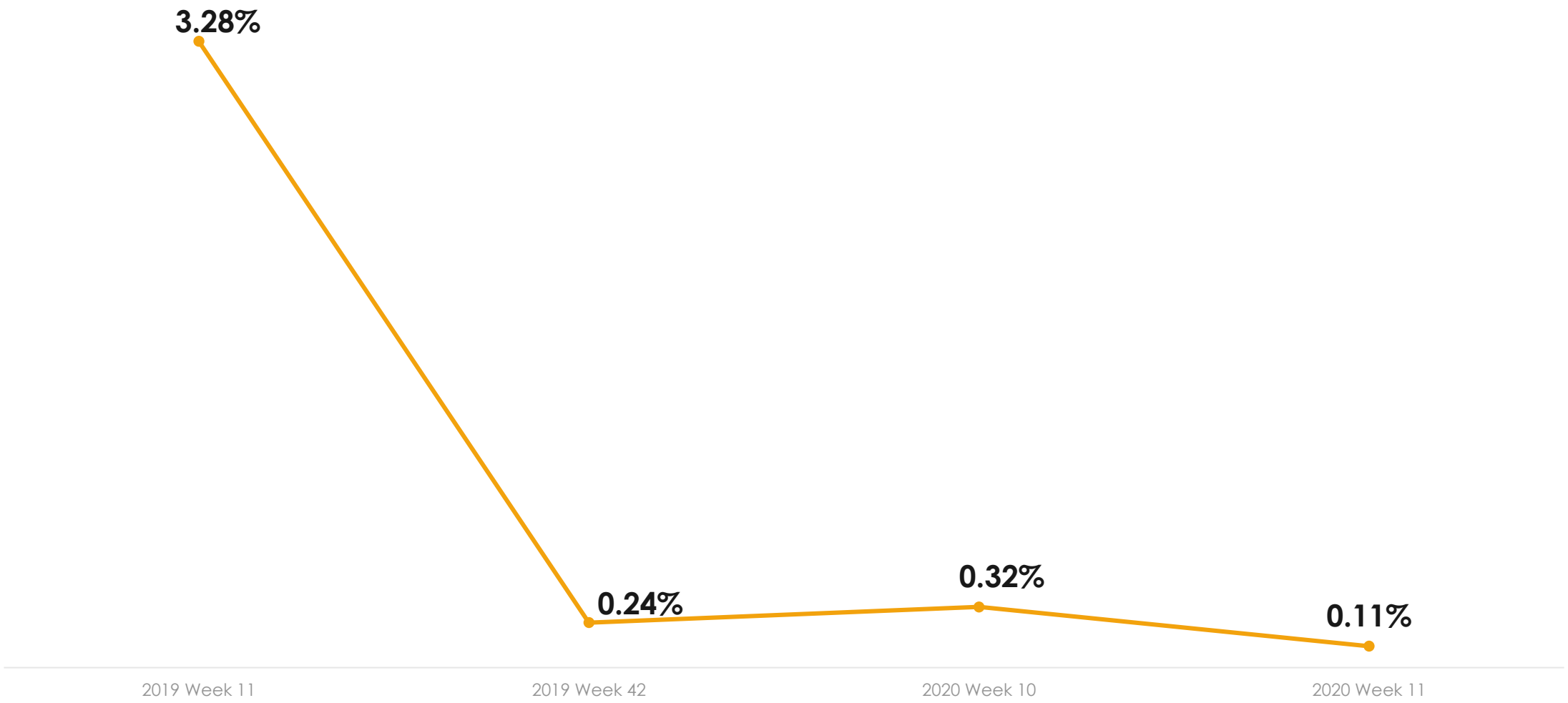
	Wholesalers	Pharmacies	Healthcare Institutions	Dispensing Doctors
Not connected	0	0	0	0
Connected	140	1380	61	807
Percentage remaining	0.00%	0.00%	0.00%	0.00%

OVERVIEW OF TOTAL OF ALERTS AND SCANS



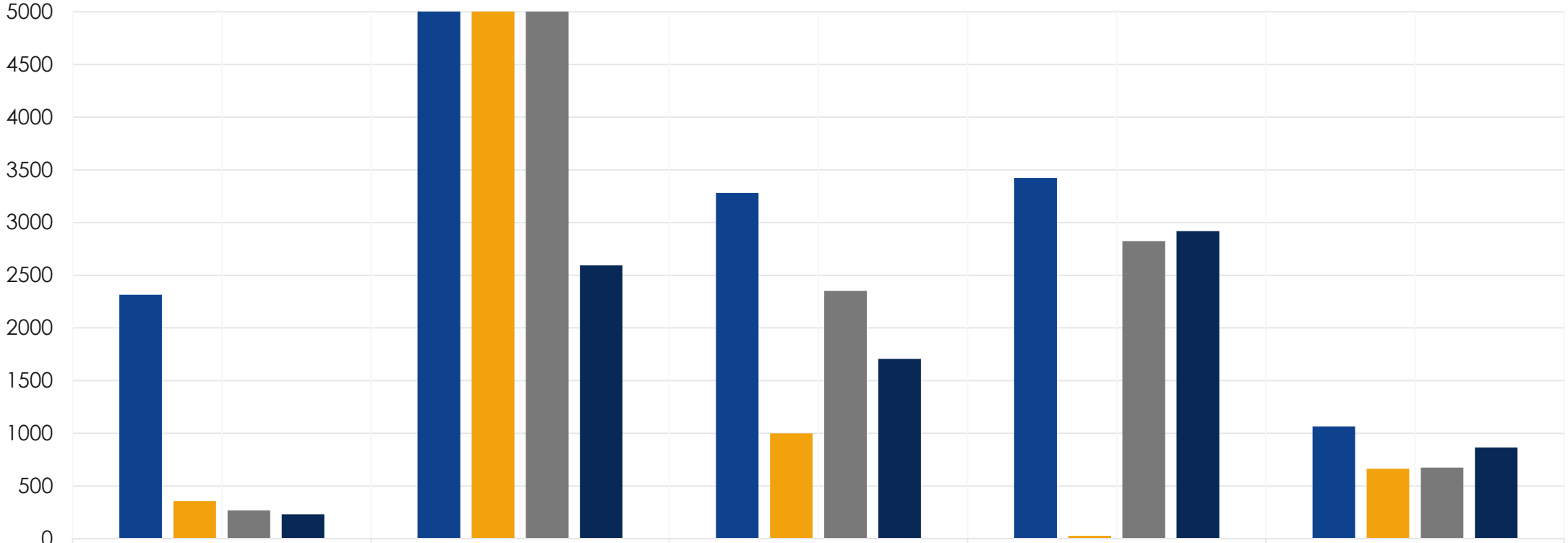
Note: The data provided for Austria Week 10 2020 is currently under investigation of AMVO

TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



Note: The data provided for Austria Week 10 2020 is currently under investigation of AMVO

ABSOLUTE: ALERTS PER CATEGORY PER WEEK



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	2314	5944	3280	3423	1066
2019 Week 42	357	6227	999	27	664
2020 Week 10	269	12469	2353	2823	675
2020 Week 11	231	2593	1707	2919	866

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Note: The data provided for Austria Week 10 2020 is currently under investigation of AMVO

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

The Austrian NMVO has provided no particular insight for the past 4 weeks.

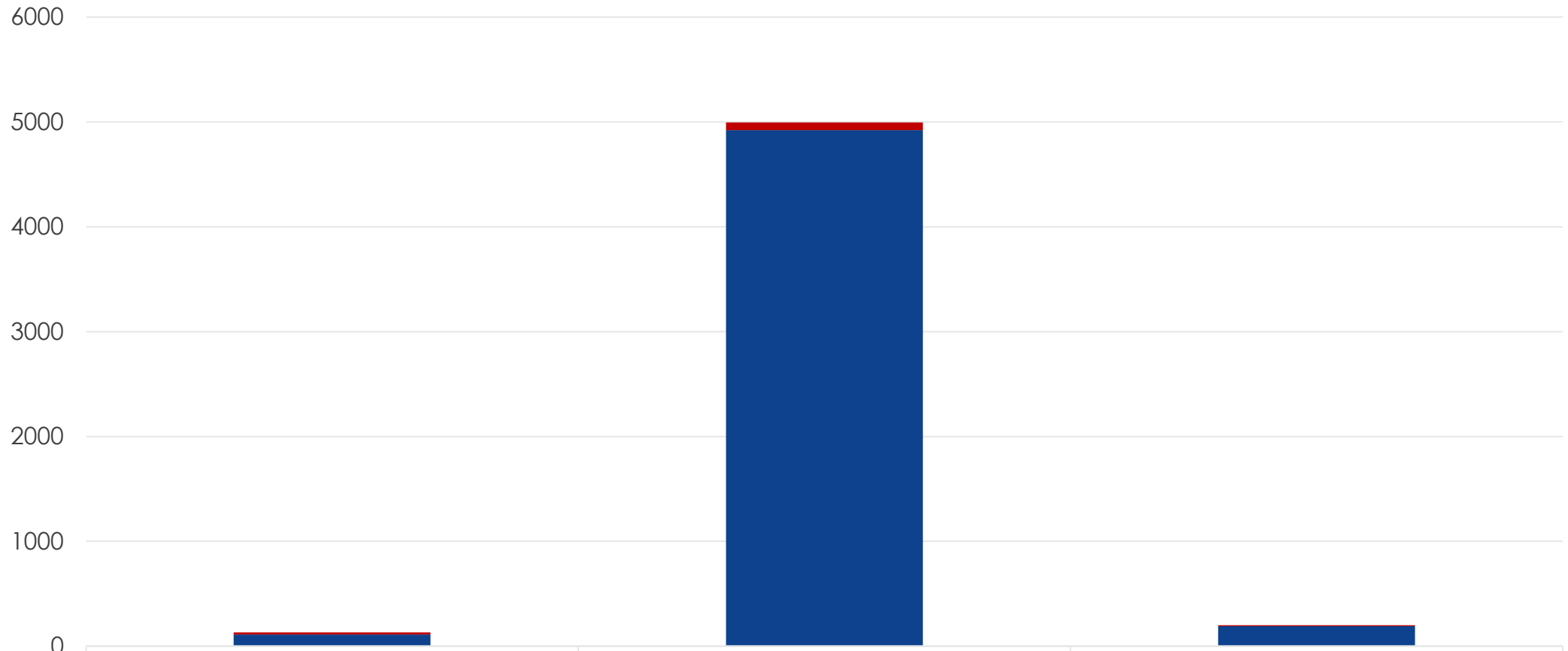
HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

BELGIUM

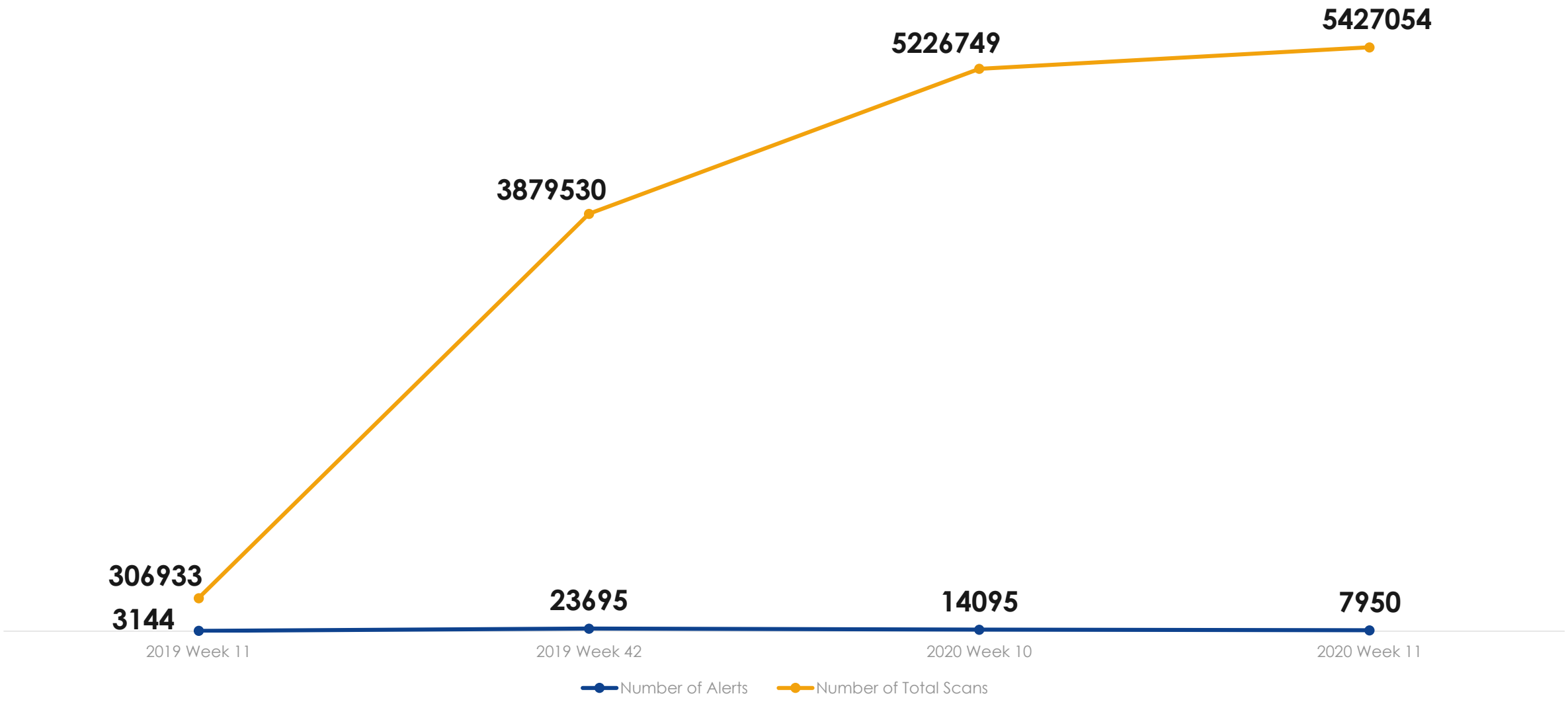
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

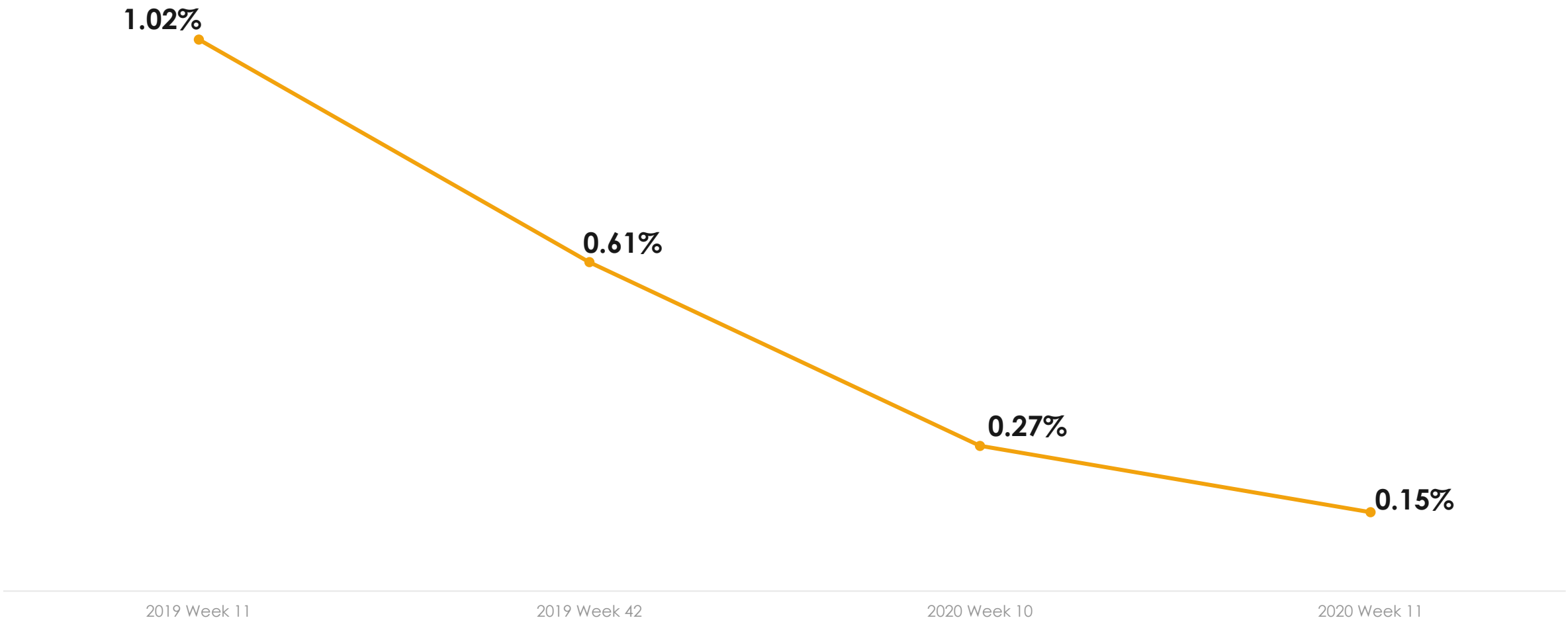


	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	21	75	10
Connected	111	4921	191
Percentage remaining	15.91%	1.50%	4.98%

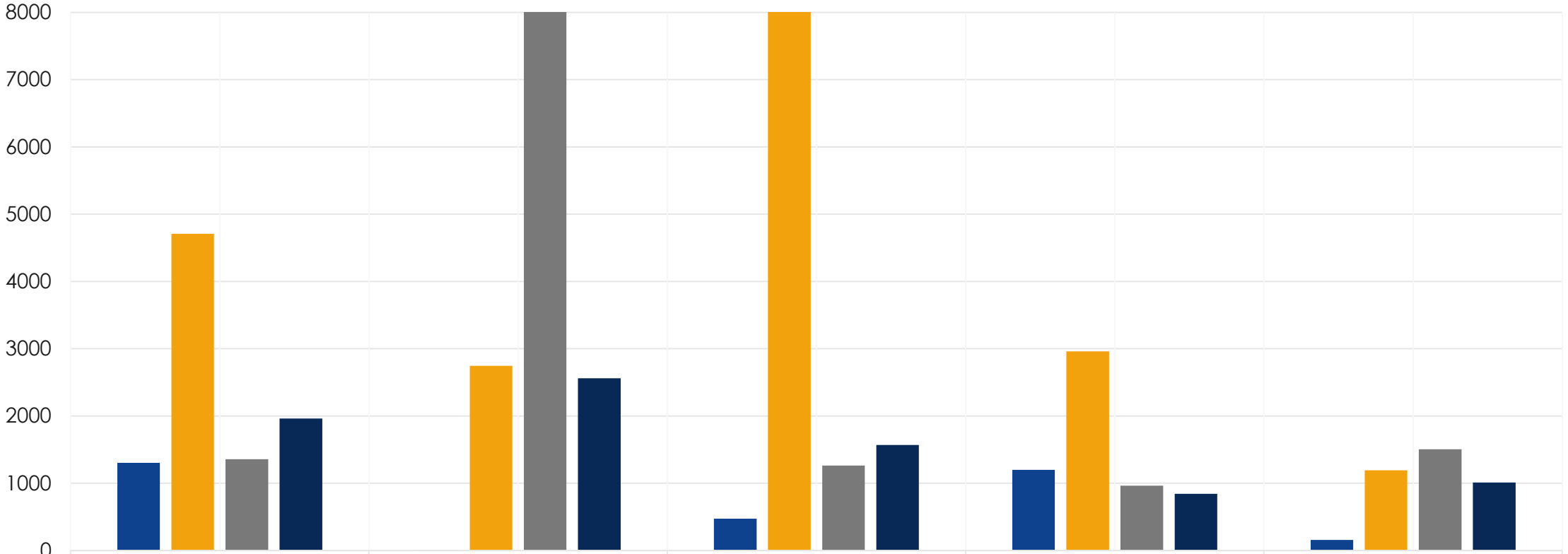
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 10.000



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	1302	10	472	1201	159
2019 Week 42	4708	2745	12089	2961	1192
2020 Week 10	1358	9007	1263	963	1504
2020 Week 11	1964	2560	1570	844	1012

emvo European Medicines Verification Organisation

Note: This overview reflects the data for alerts in Luxembourg and in Belgium

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

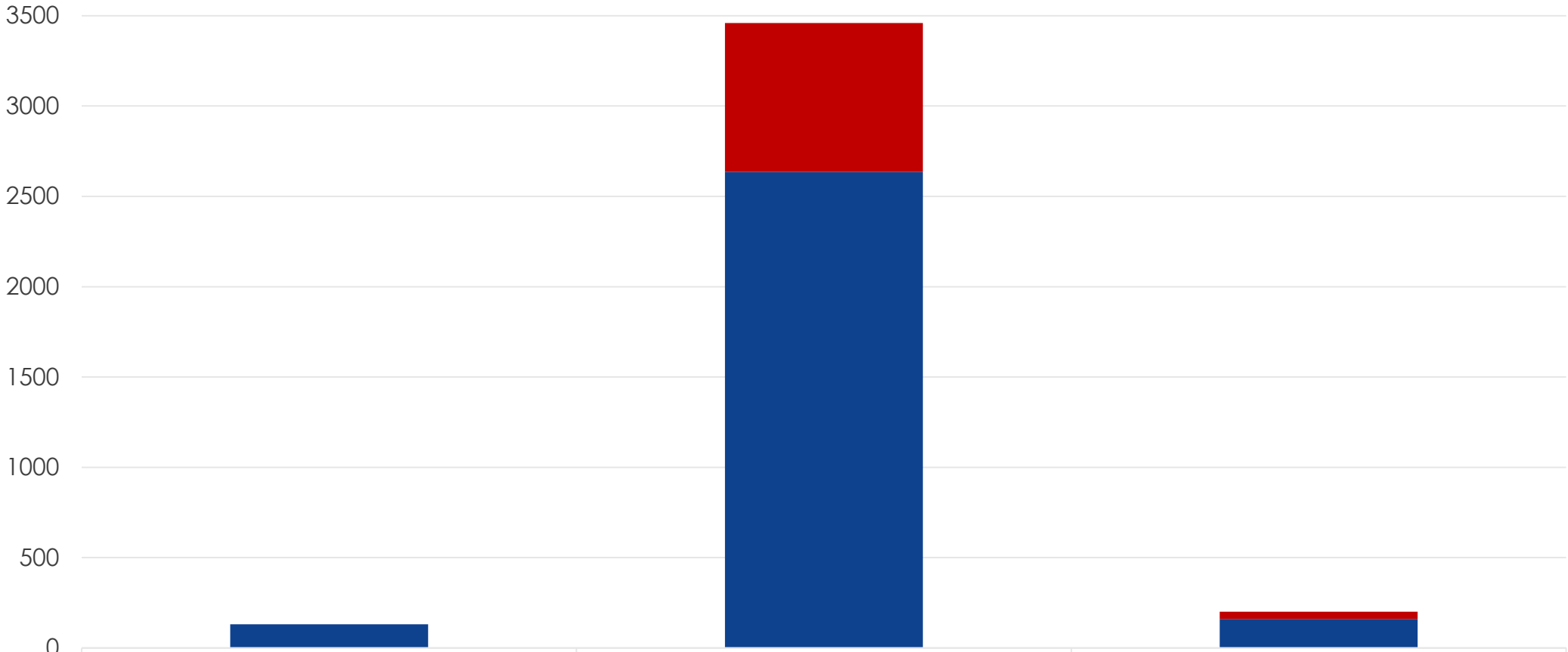
- The number of #A24 alerts increased during week 10 in Belgium; 90% of these alerts were due to OBPs
- The number of #A7 alerts increased in week 11; 50% of them were generated by IMTs from users outside Belgium

HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

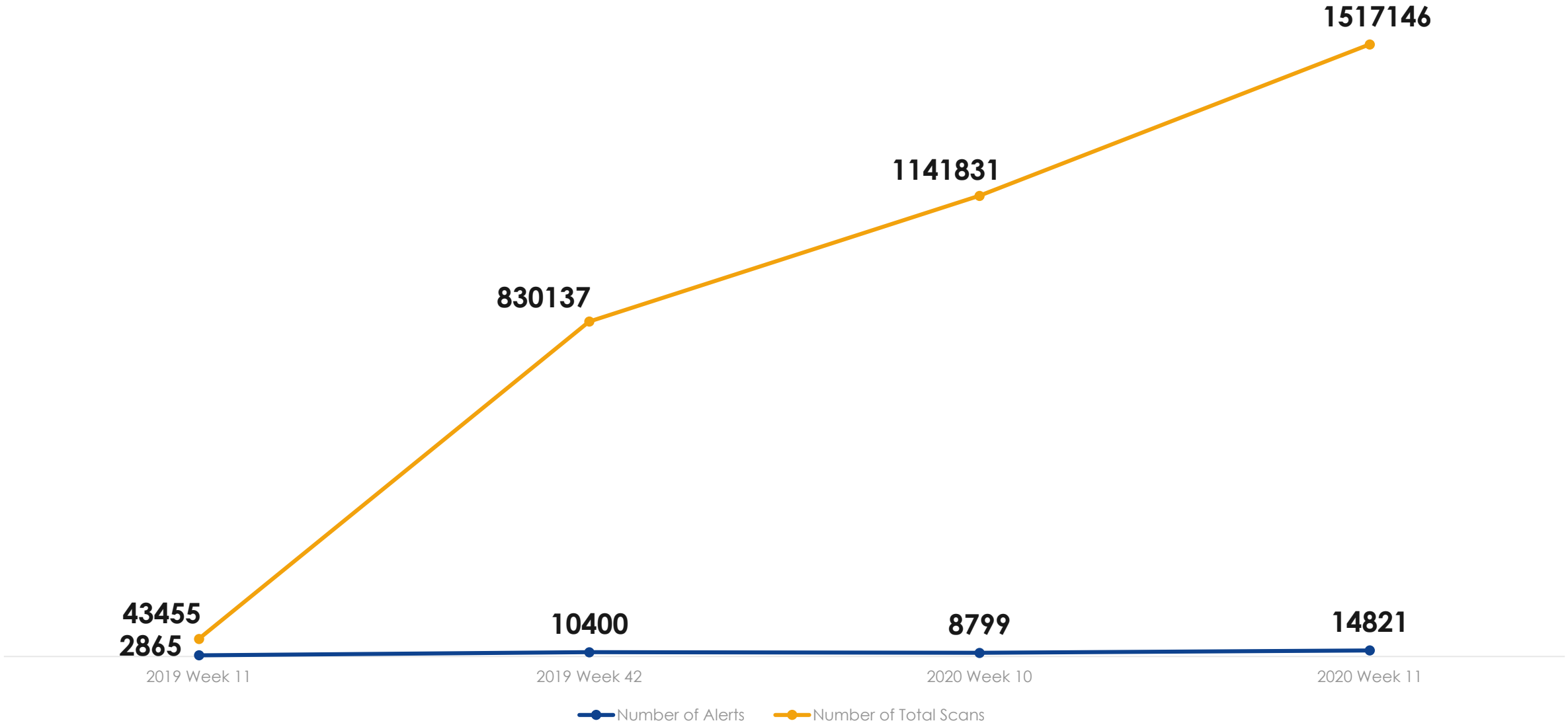
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

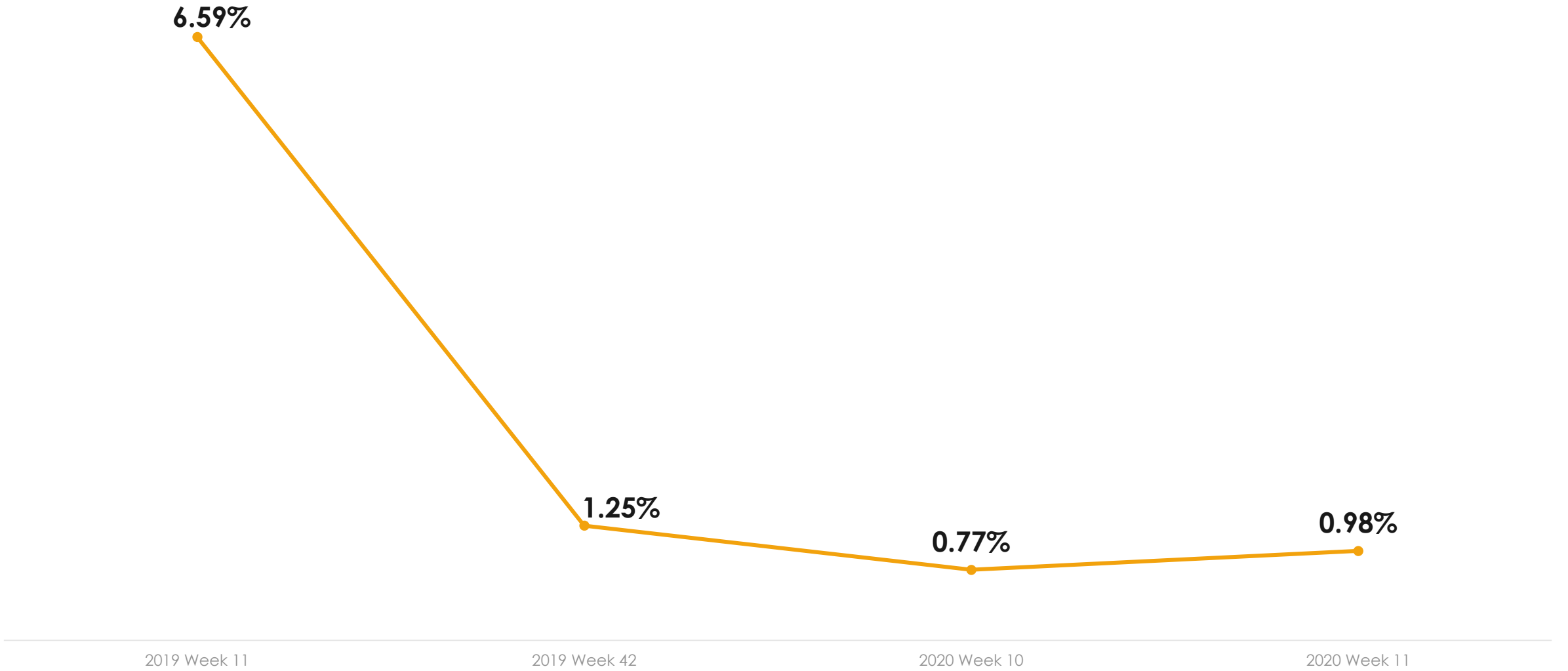


	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	0	825	40
Connected	131	2635	160
Percentage remaining	0.00%	23.84%	20.00%

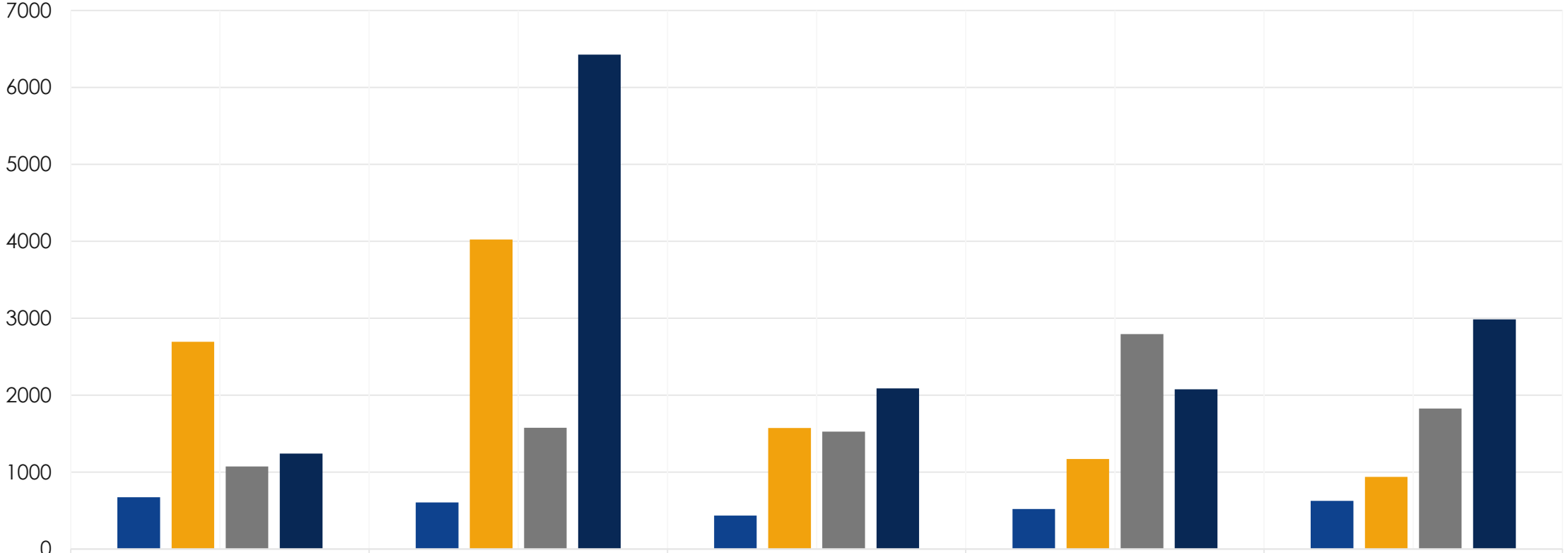
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	675	607	435	521	627
2019 Week 42	2695	4023	1573	1171	938
2020 Week 10	1075	1576	1528	2794	1826
2020 Week 11	1242	6428	2088	2078	2985

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

- Fines for non-compliance with the obligations under the Delegated Regulation will be implemented in Bulgaria after the approval of the changes in the Medicines Act by the Parliament. The expectations are the changes to be adopted by the end of H1/2020 but related to the COVID- 19 Emergency State the probability changes in the legislation to be postponed is high.
- During Week 9 and Week 10 the rates of alerts in Bulgaria was 0,9%-1,0%. Around 25-30% of the alerts are due to expiry date issues (A52 alerts) with several batches from one MAH. The issue has been communicated to the MAH but the batches are already released and distributed in the market so the alerts cannot be prevented.

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

The number of A24 & A7 alerts was significantly higher in week 11. The distribution is as follow:

- **A7 alerts**
  - **177** A7 alerts were generated from 4 different Parallel Importers and 5 different batches. The analysis shows that the root cause is the same: the multiple attempts by the same user to decommission packs with „Checked-out".
  - **461** A7 alerts were due to bulk verification – main root cause is because two local IT providers have issues with the bulk operations and delayed response. These alerts are generated by 3 end-users
  - **224** A7 alerts were due to End-users' software loops
  - **49** A7 alerts were generated by End-users from other EU markets
  - **397** A7 were generated in single transaction by local end-users and we are checking them case by case for double dispense (procedure errors by the same end-user) or second decommissioning attempt by a different end-user. We have increased numbers in local A7 due to the increased activity of pharmacies during the last week.

- **A24 alerts**
  - **112** A24 alerts were generated in bulk verifications, including 107 A24 alerts generated by one wholesaler during second attempt to decommission packs as Free-sample.

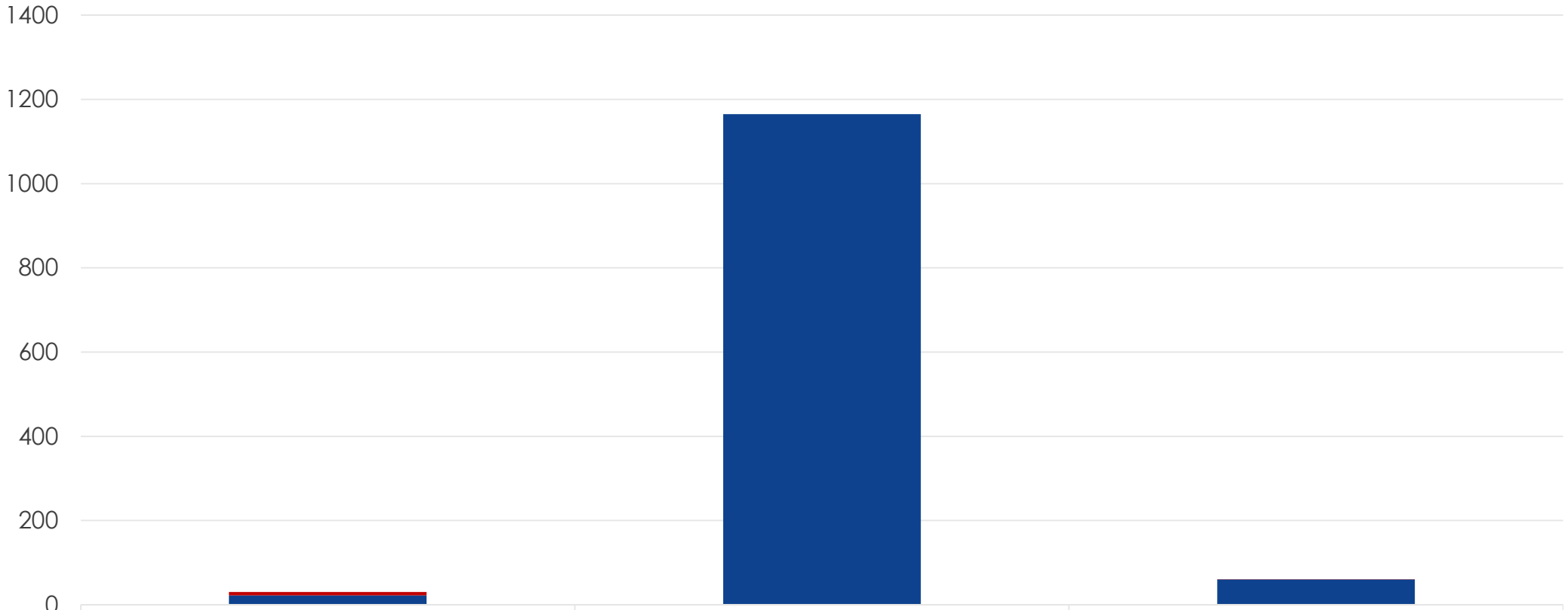
In the next couple of days BgMVO will contact the relevant users and IT providers to further specify the root cause and to agree with them on corrective and preventive actions. For more information, please do not hesitate to contact BgMVO.

HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

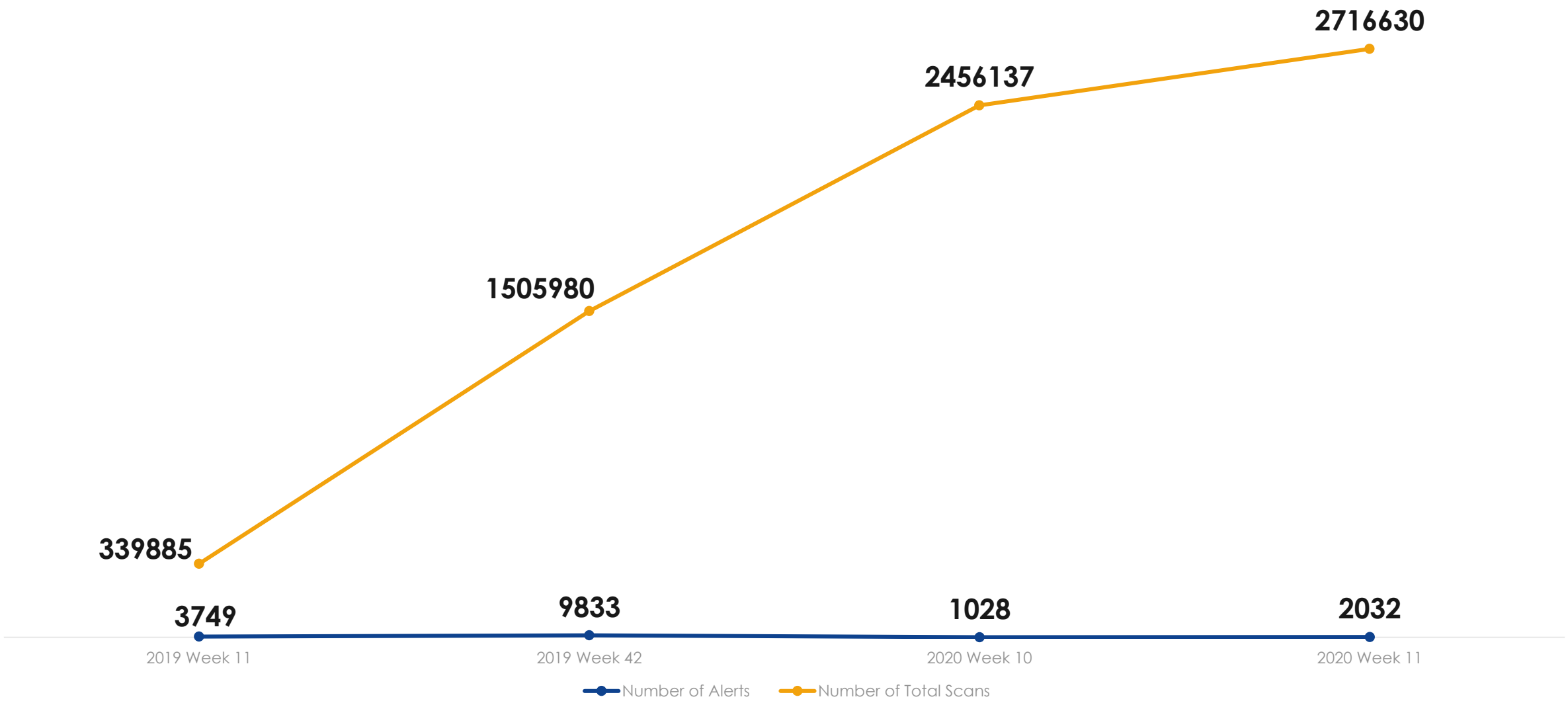
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

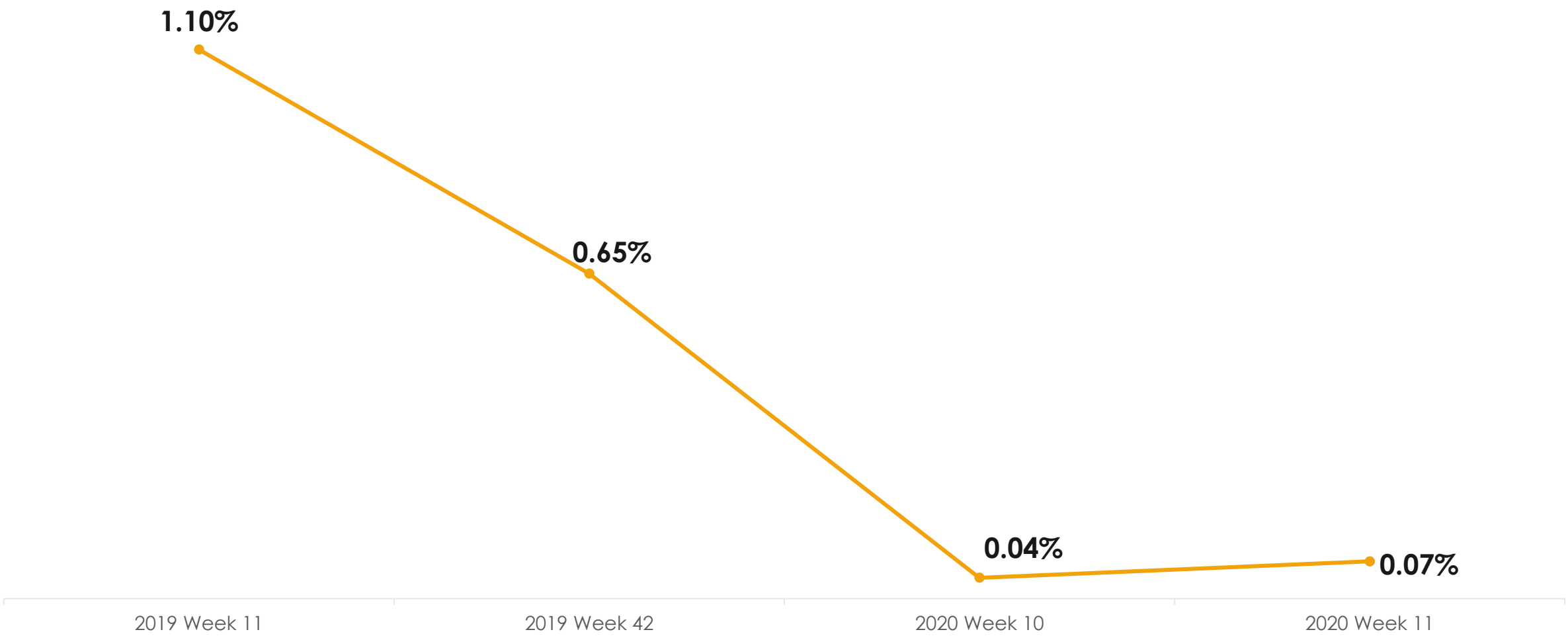


	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	8	0	1
Connected	22	1165	60
Percentage remaining	26.67%	0.00%	1.64%

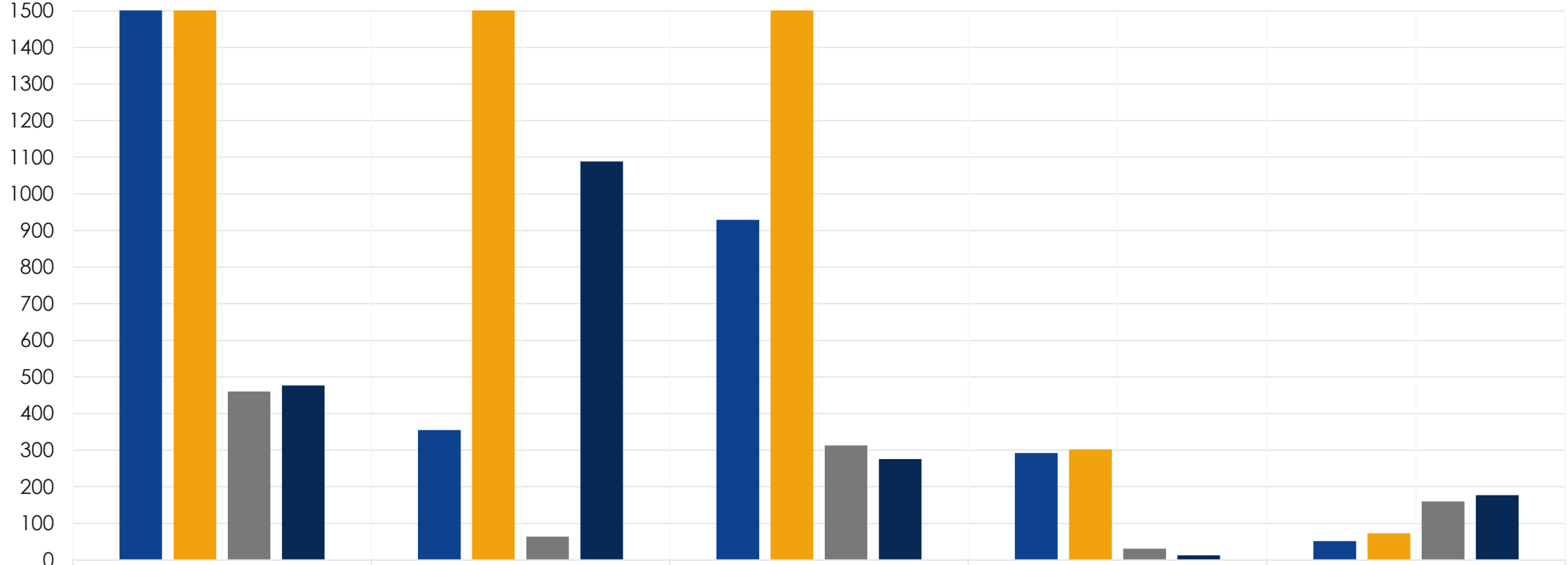
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 1.500



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	2121	355	929	292	52
2019 Week 42	6188	1733	1537	302	73
2020 Week 10	460	64	313	31	160
2020 Week 11	477	1089	276	13	177

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

There was an increase of A7 Alerts during week 8 caused by 'MAH PPSU Request' transactions. The OBP/MAH tried to change the state of the bulk of packs into an already existing state. Two different MAHs caused 5.140 alerts. As of February, MAH/OBP initiated alerts amount to exactly 50% of the total Alerts in the system (5.140 by MAH; 5.140 Alerts caused by end-users).

HISTORY OF HIGHLIGHTS COMMUNICATED

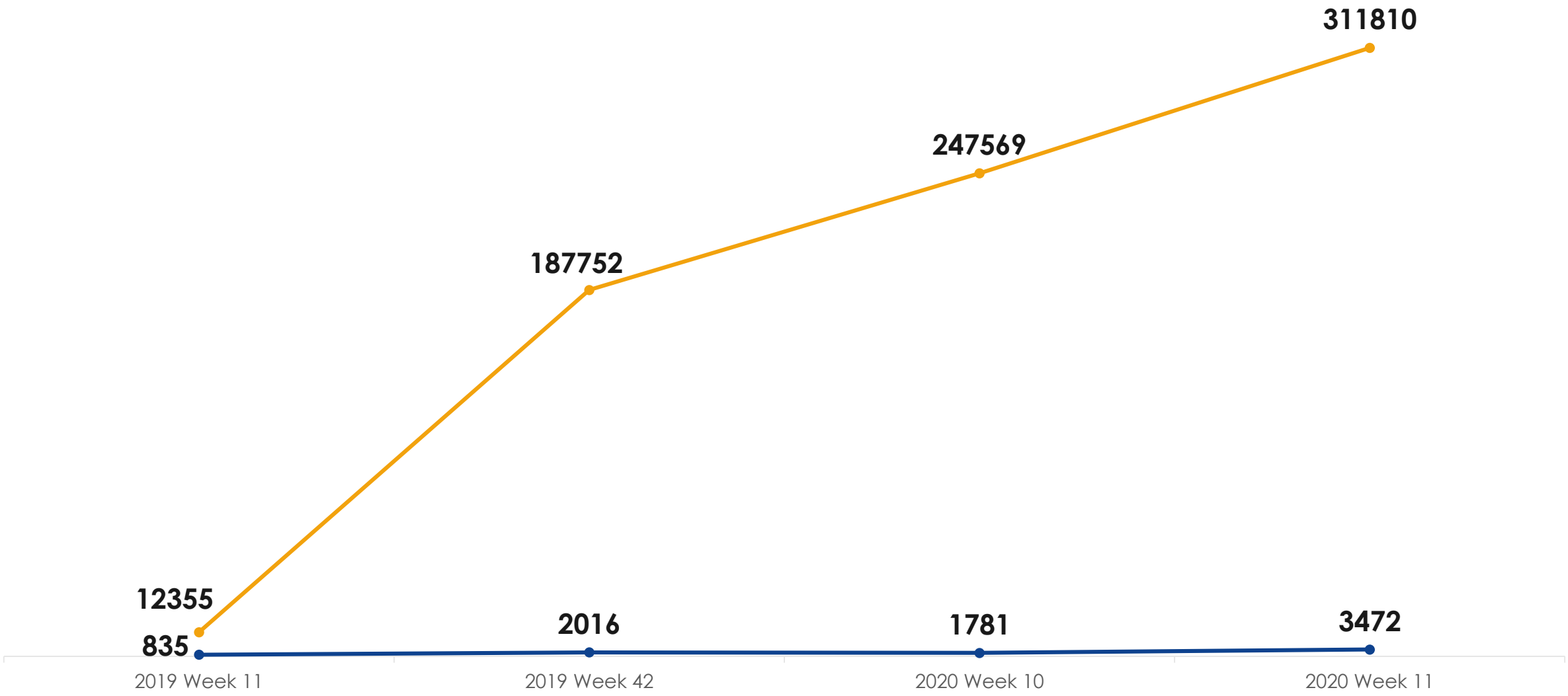
- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

Back to the EEA map

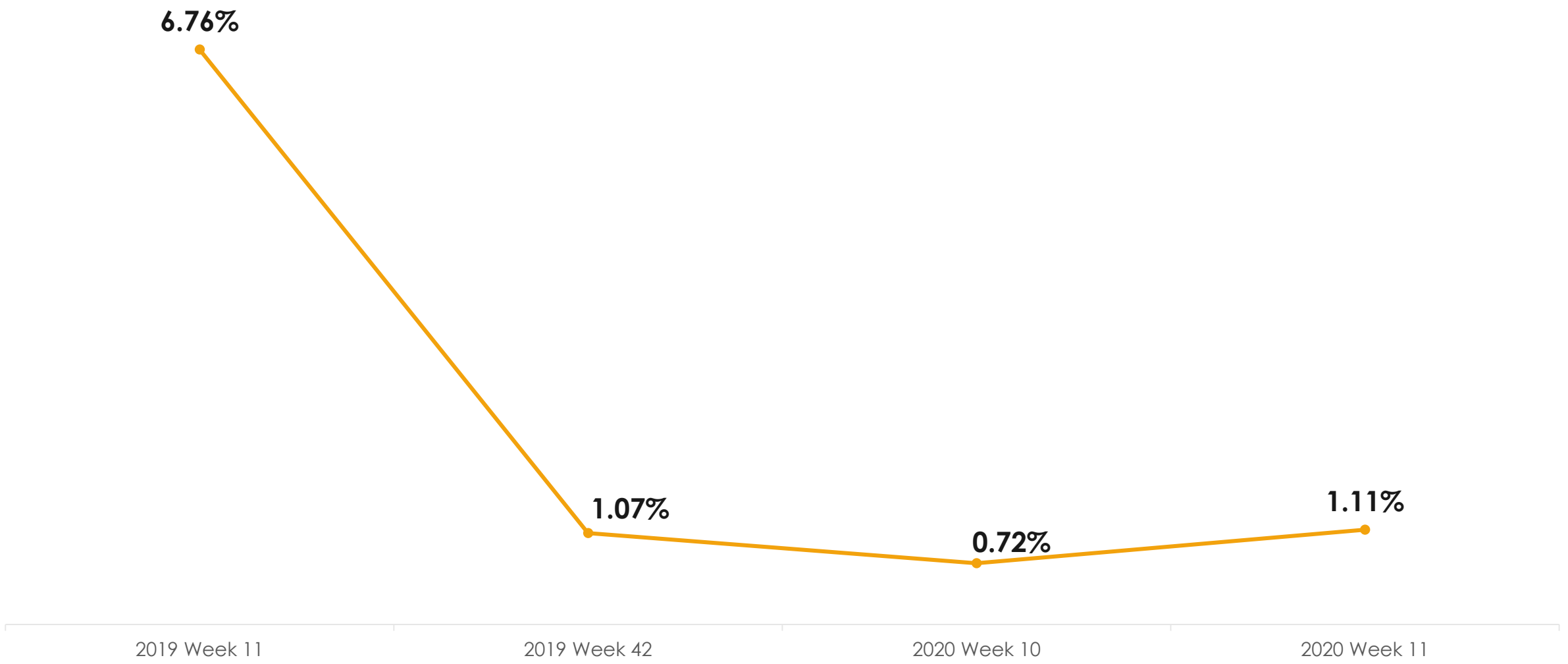
OVERVIEW OF END-USERS CONNECTION

	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	0	0	0
Connected	42	538	46
Percentage remaining	0.00%	0.00%	0.00%

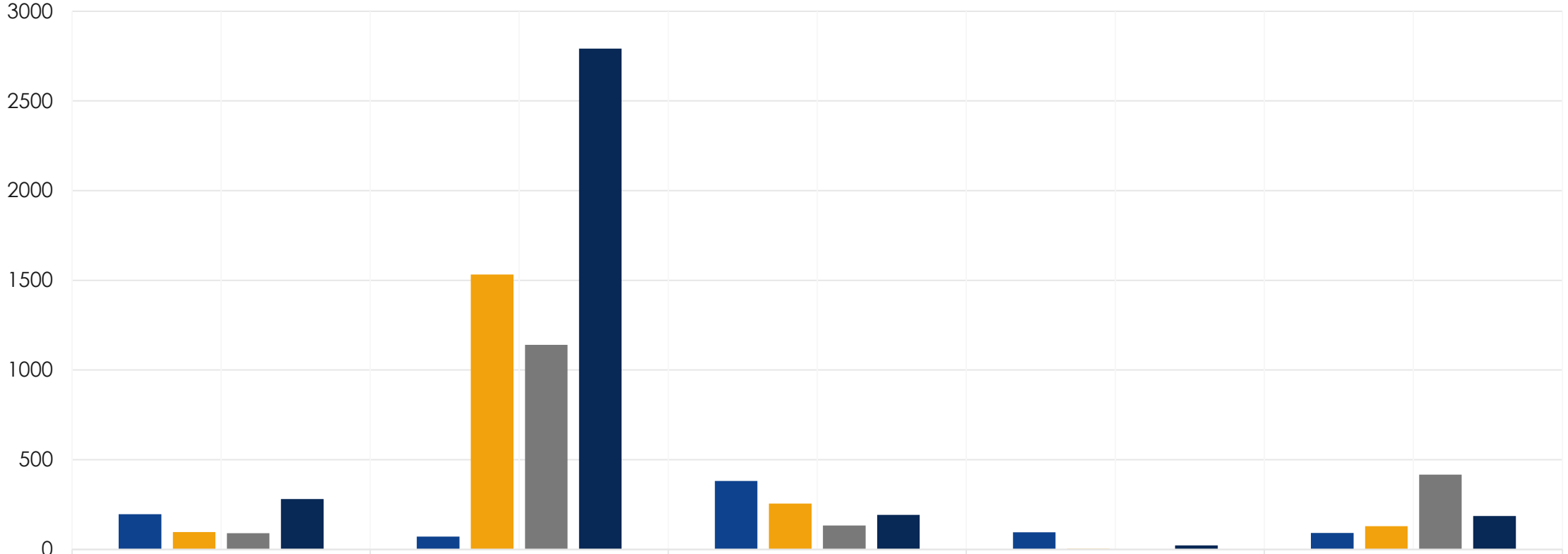
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK



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2019 Week 11	196	71	381	95	92
2019 Week 42	96	1532	255	3	130
2020 Week 10	90	1140	133	1	417
2020 Week 11	281	2791	192	22	186

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

The Cypriote NMVO has provided no particular insight for the past 4 weeks.

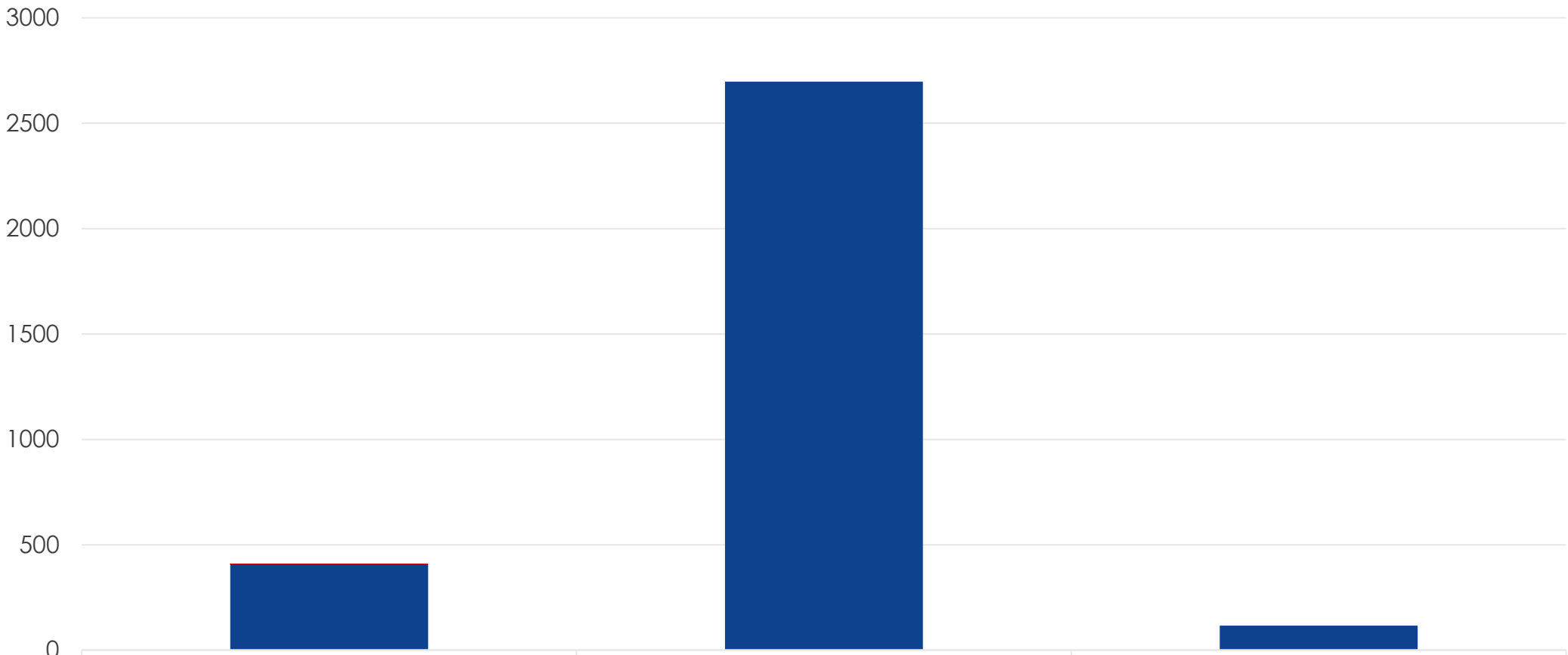
HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

CZECH REPUBLIC

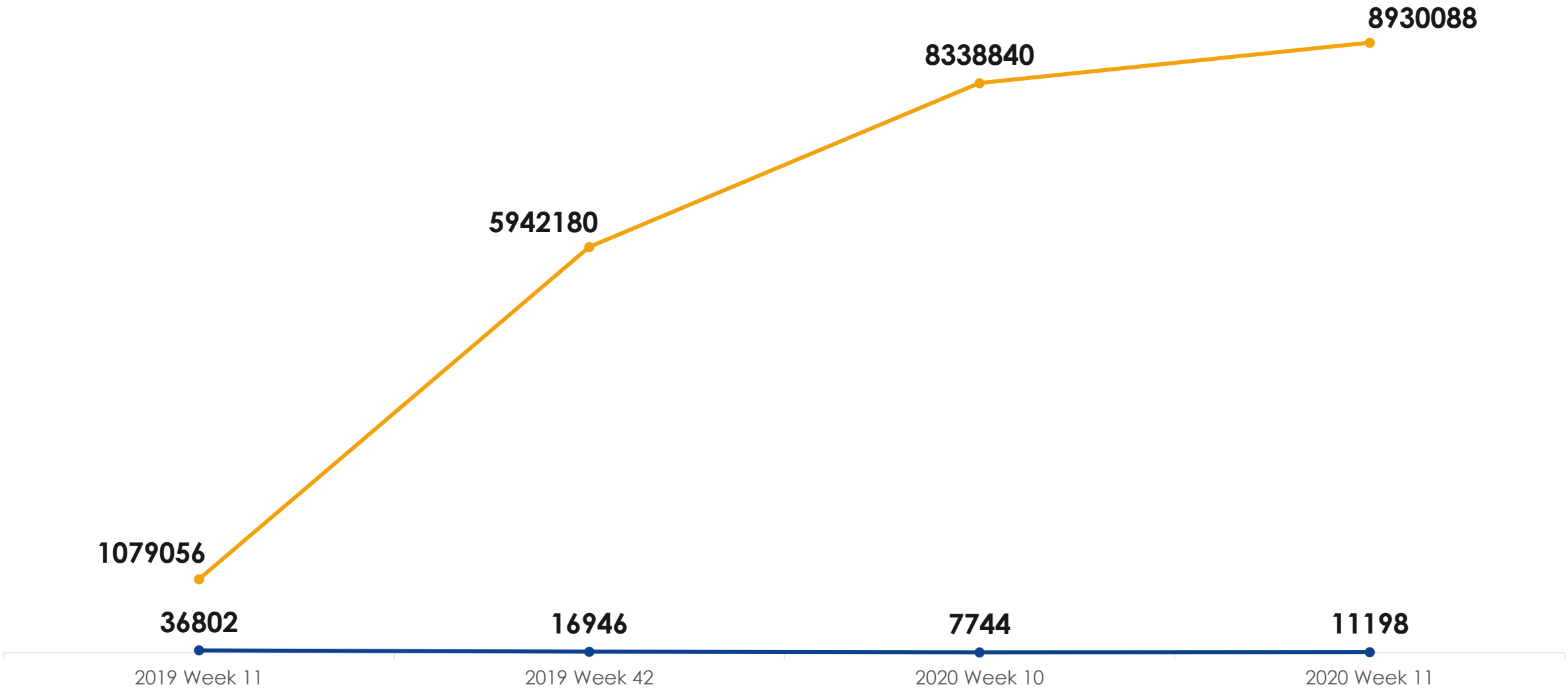
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

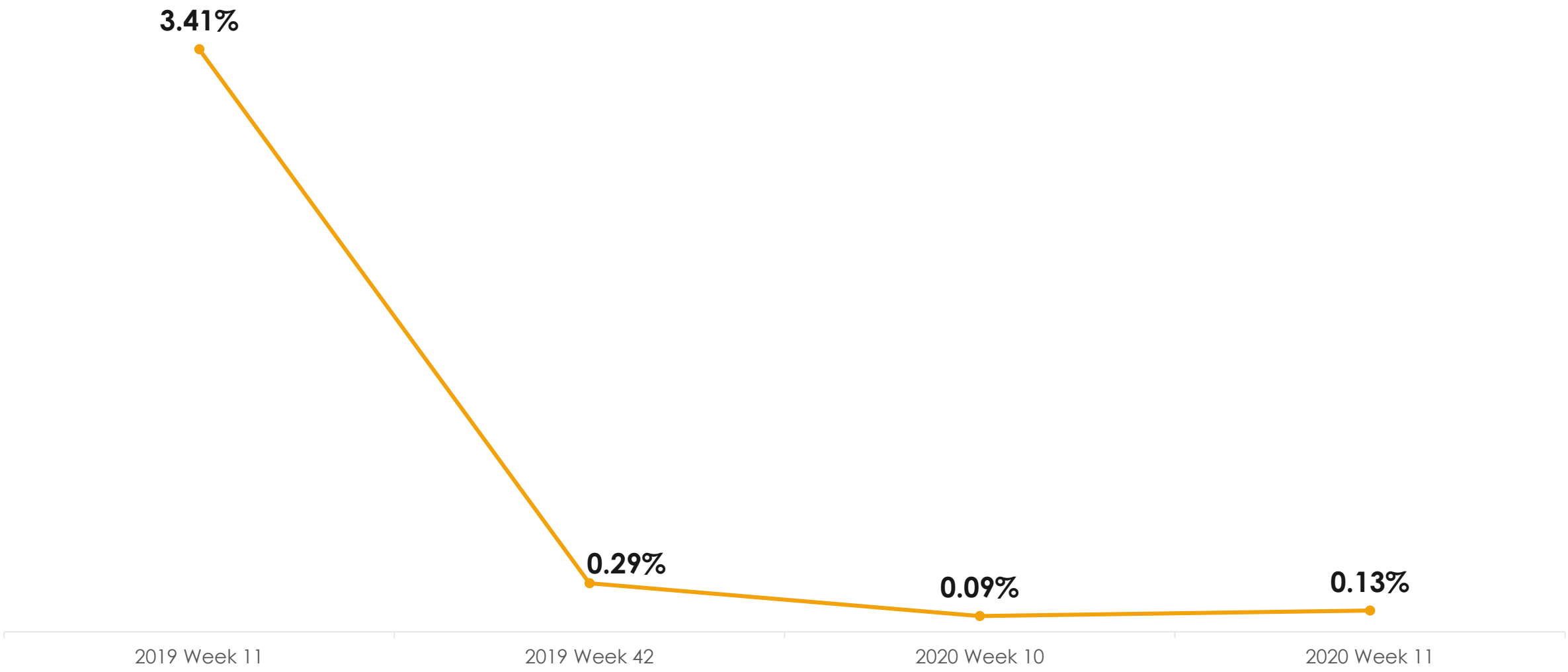


	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	2	0	0
Connected	409	2697	116
Percentage remaining	0.49%	0.00%	0.00%

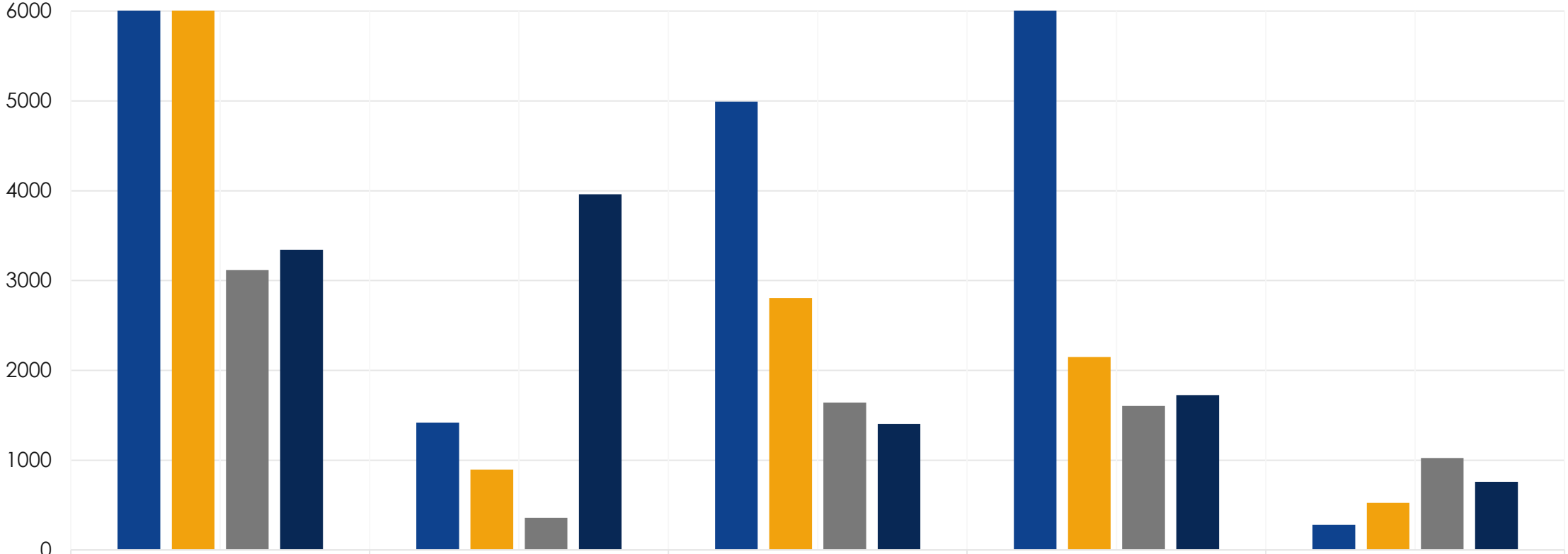
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 6.000



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	15091	1418	4993	15020	280
2019 Week 42	10570	897	2806	2149	524
2020 Week 10	3117	358	1641	1604	1024
2020 Week 11	3344	3962	1406	1726	760

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

During week 11 the increase in A7 (Pack already in requested state) was caused by a singe MAH/OBP operations who created 73% of these alerts during 1 day. The root cause might be the re-upload of data during a time out, as the successful upload was not notified to the OBP, the company tried it again and caused alerts.

The major increase in the number of alerts might also be due to the disruptions the EU Hub experienced from March 10 till March 12, as there was a problem uploading the data.

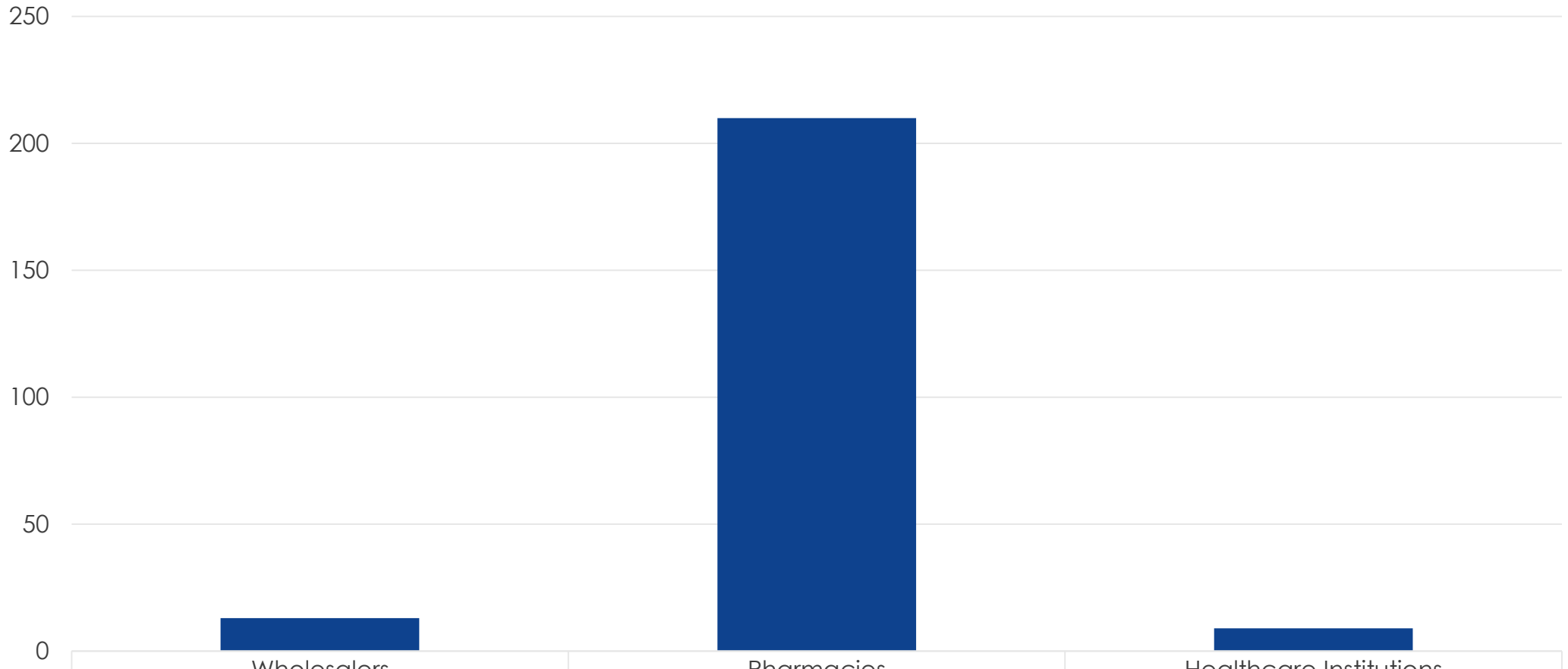
HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

DENMARK

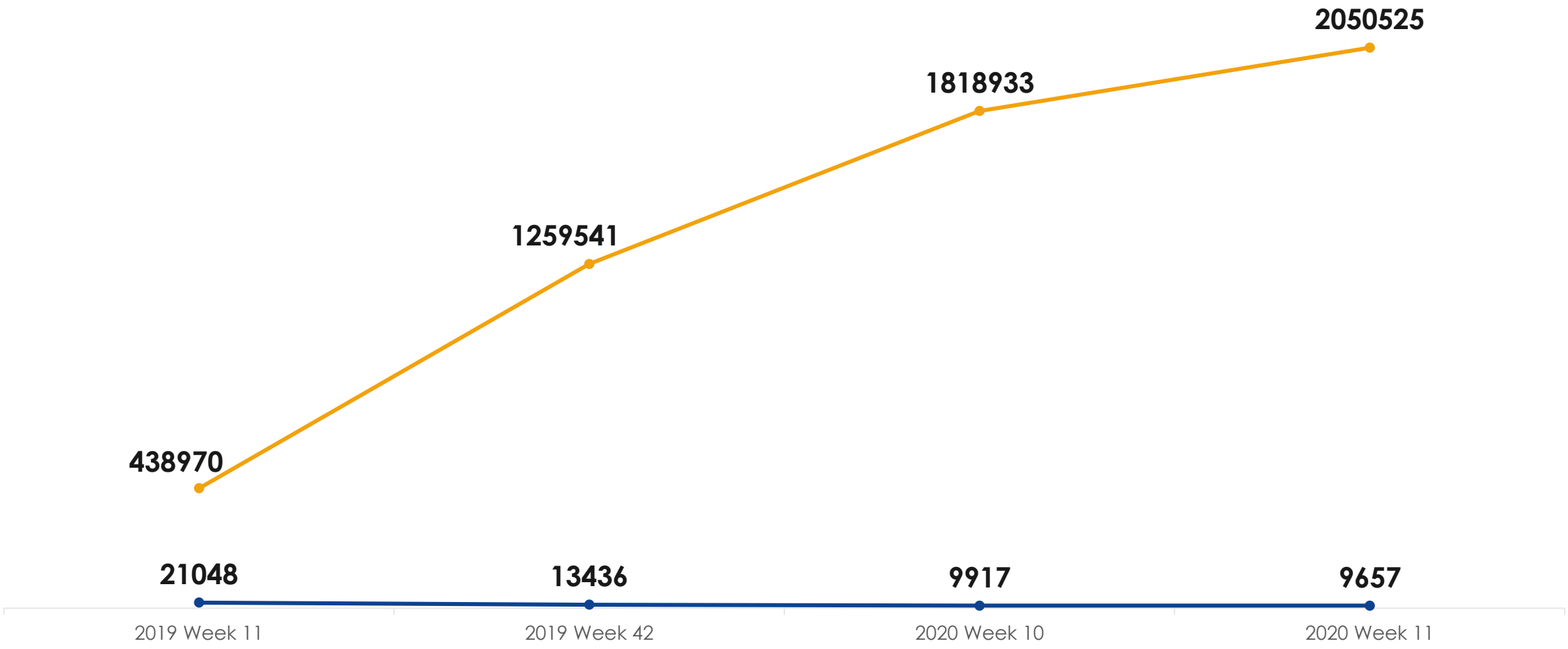
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

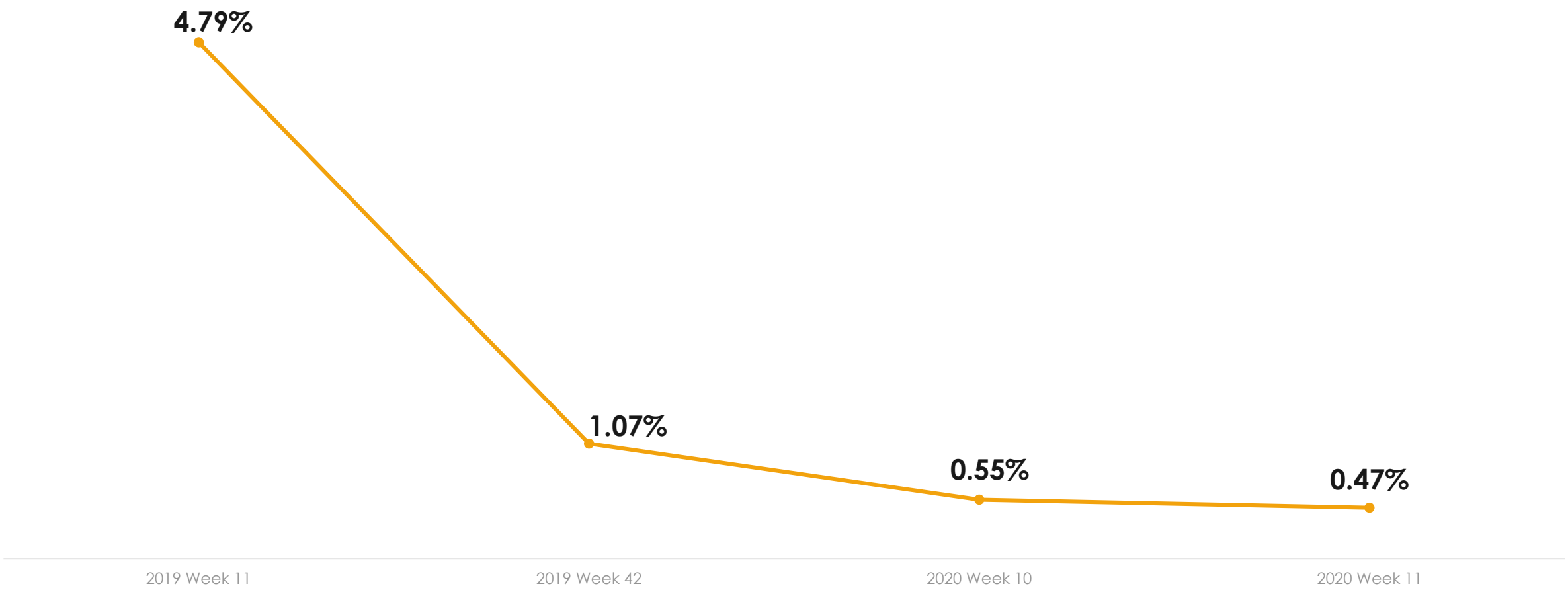


	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	0	0	0
Connected	13	210	9
Percentage remaining	0.00%	0.00%	0.00%

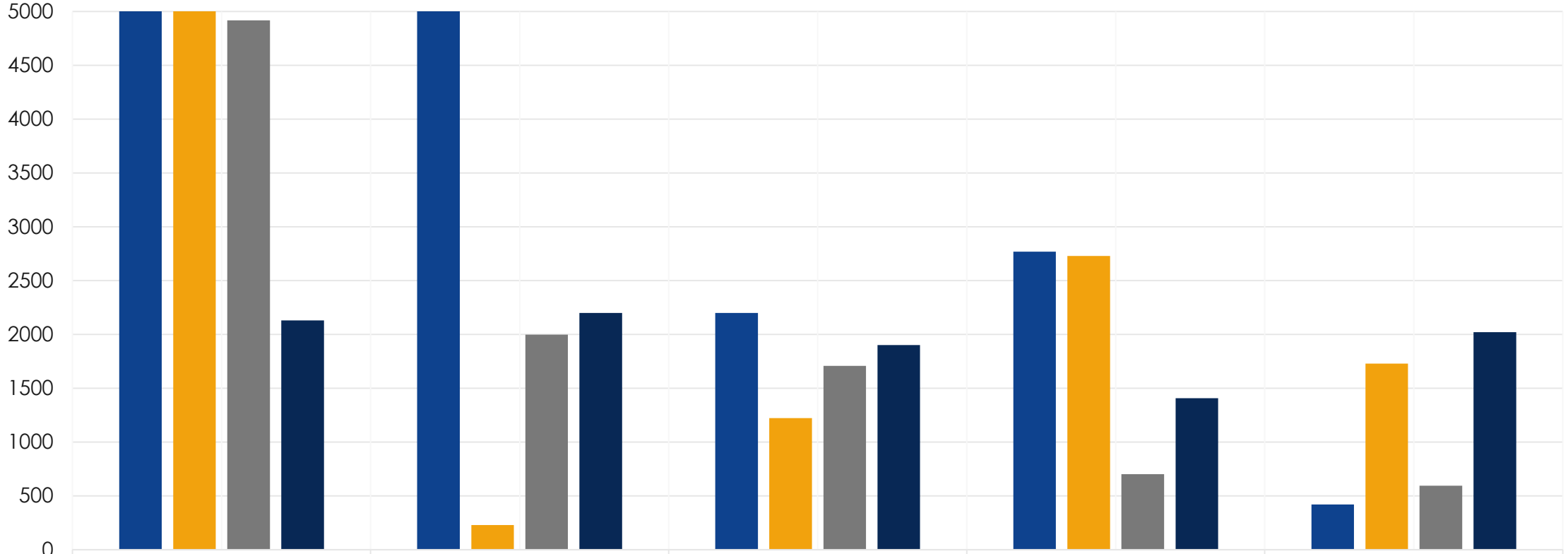
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 5.000



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	5848	9814	2198	2769	419
2019 Week 42	7528	229	1223	2728	1728
2020 Week 10	4918	1998	1708	700	593
2020 Week 11	2130	2198	1901	1407	2021

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

- DMVO experienced an A2 alert leap from week 8 to week 9 primarily due to a handful of OBPs that have not uploaded data to the HUB, others have encountered errors with the serialization numbers for (a) particular batch(es), hence a few OBPs have had/or are seeking dispensation from the Danish NCA.
- In addition, a number of A2 alerts were triggered due to products released prior to FMD being on the market.
- DMVO is continuously monitoring the incoming alerts, they are reaching out to OBPs when detecting incorrect – or lack of – data in order to correct the data and provide their for any question

HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

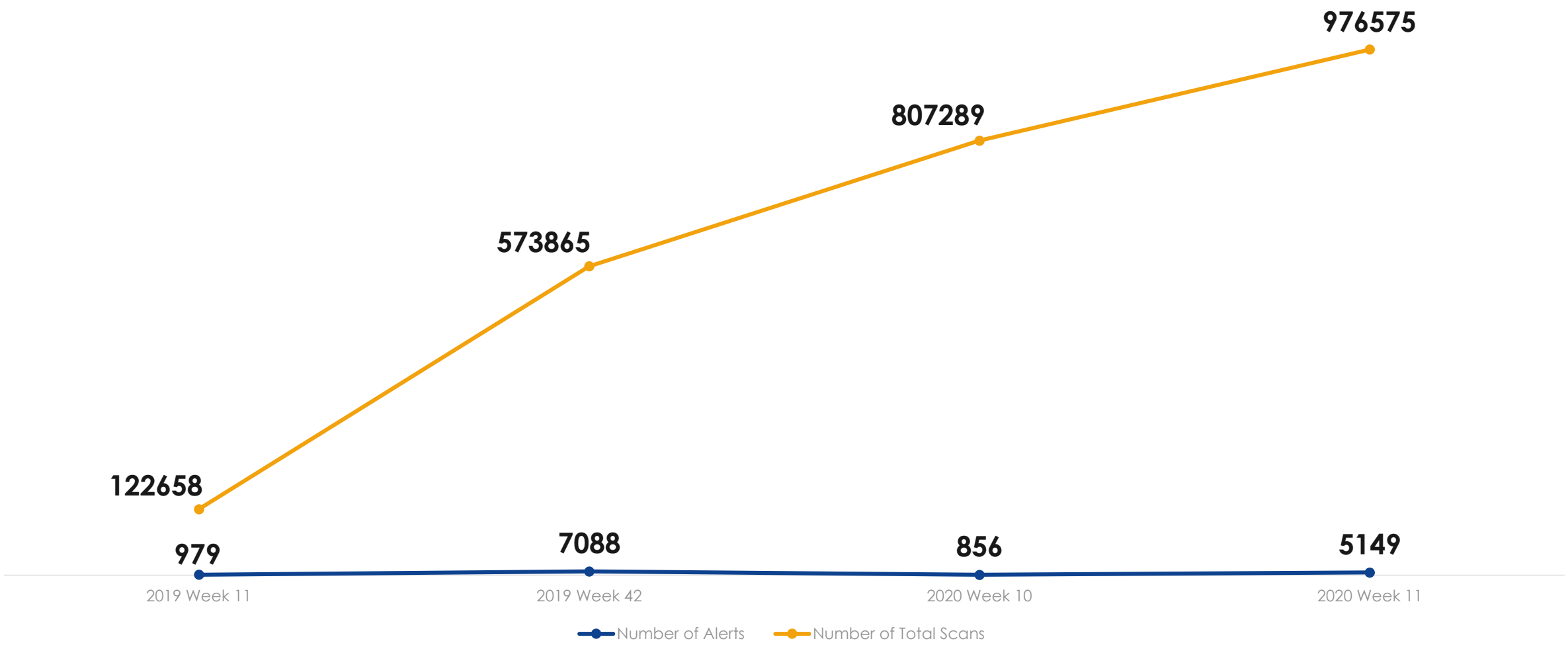
ESTONIA

Back to the EEA map

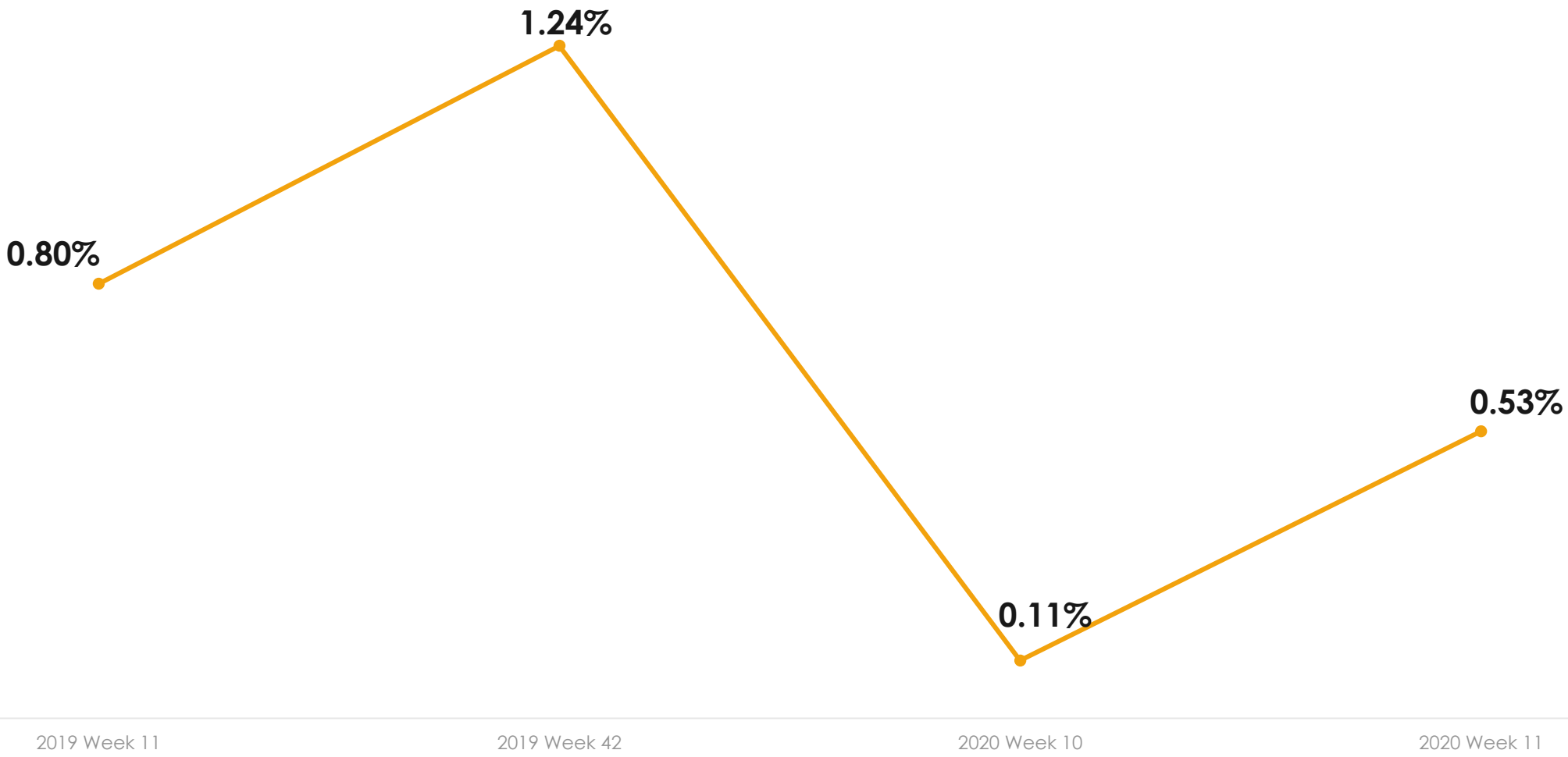
OVERVIEW OF END-USERS CONNECTION

	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	0	0	0
Connected	19	495	23
Percentage remaining	0.00%	0.00%	0.00%

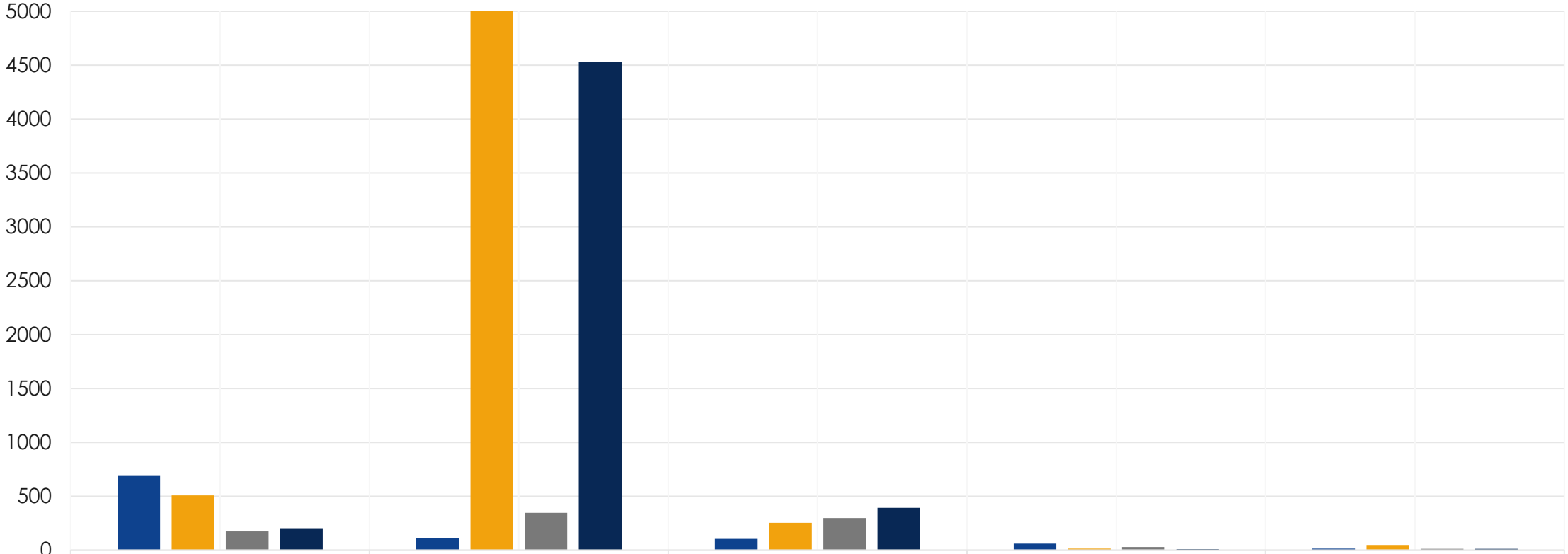
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 5.000



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	689	112	105	60	13
2019 Week 42	508	6266	254	13	47
2020 Week 10	173	346	298	28	11
2020 Week 11	203	4532	393	9	12

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

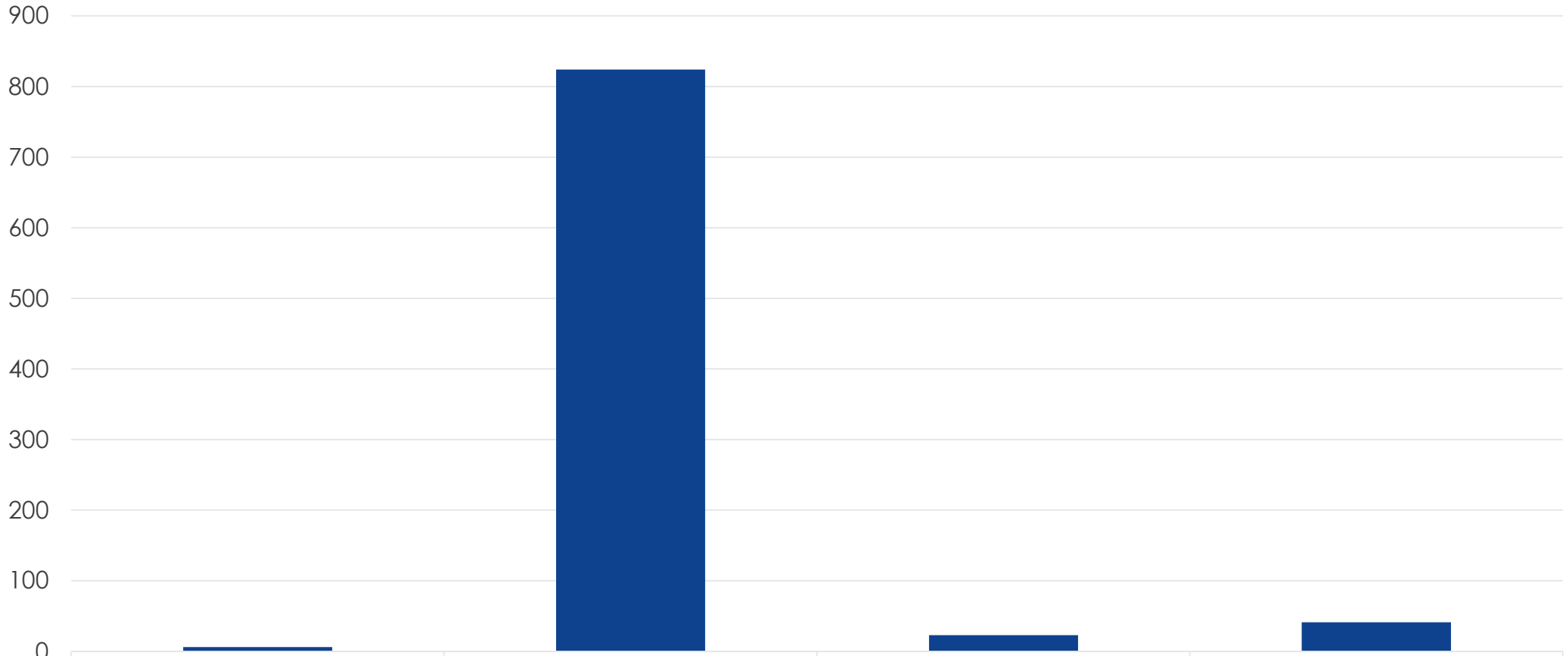
- There was an increase in Alerts A7 & A24 during weeks 8 and 9. This category increased in February about 60% in comparison with January. In February about 10% of these alerts are caused by end users and 90% by MAH's. 89% - 1606 out of 1787 - are caused by 4 different MAH's. One of them caused 1000 and another 555 alerts related to the error "Bulk check out packs for EU distribution".
- The number of A24 & A7 alerts increased ten-fold from week 10 to week 11. About 10% of these alerts were caused by end users and 90% by MAH's. Most of the alerts, 3405 out of 4454, are related to the error "Bulk check out packs for EU distribution".
- End-users causing alerts are mostly related to human mistakes and these cases are investigated by the Estonian NCA

HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

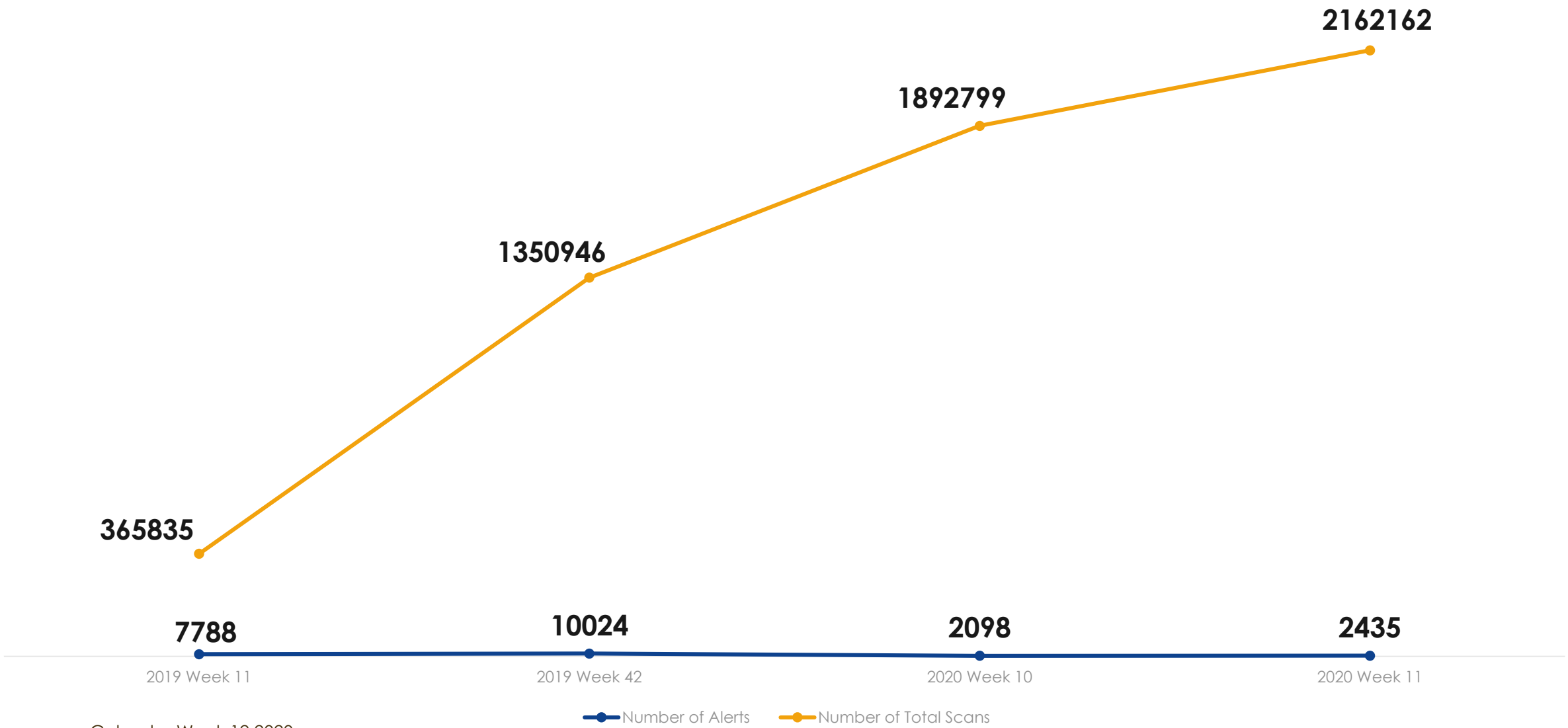
Back to the EEA map

OVERVIEW ON END-USERS CONNECTION

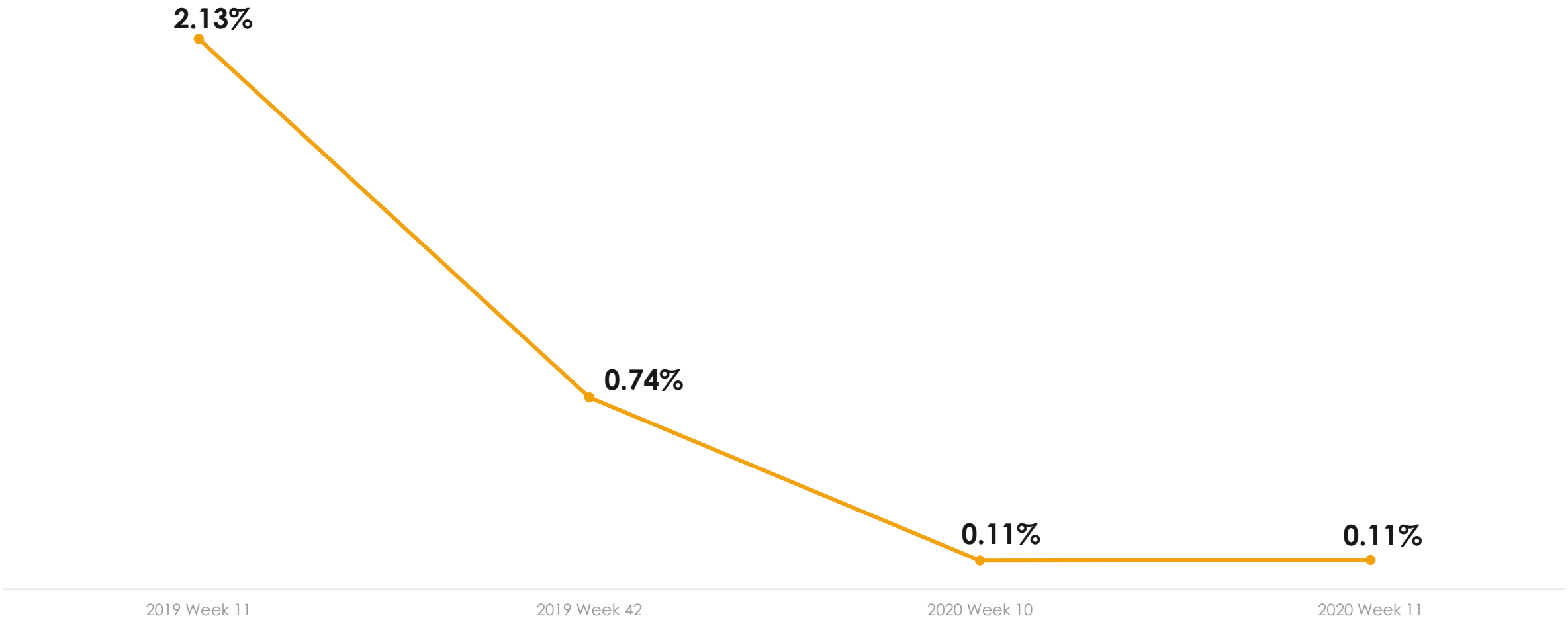


	Wholesalers	Pharmacies	Healthcare Institutions	Other Decommissioning Channels
Not connected	0	0	0	0
Connected Week	6	824	23	41
Percentage remaining	0.00%	0.00%	0.00%	0.00%

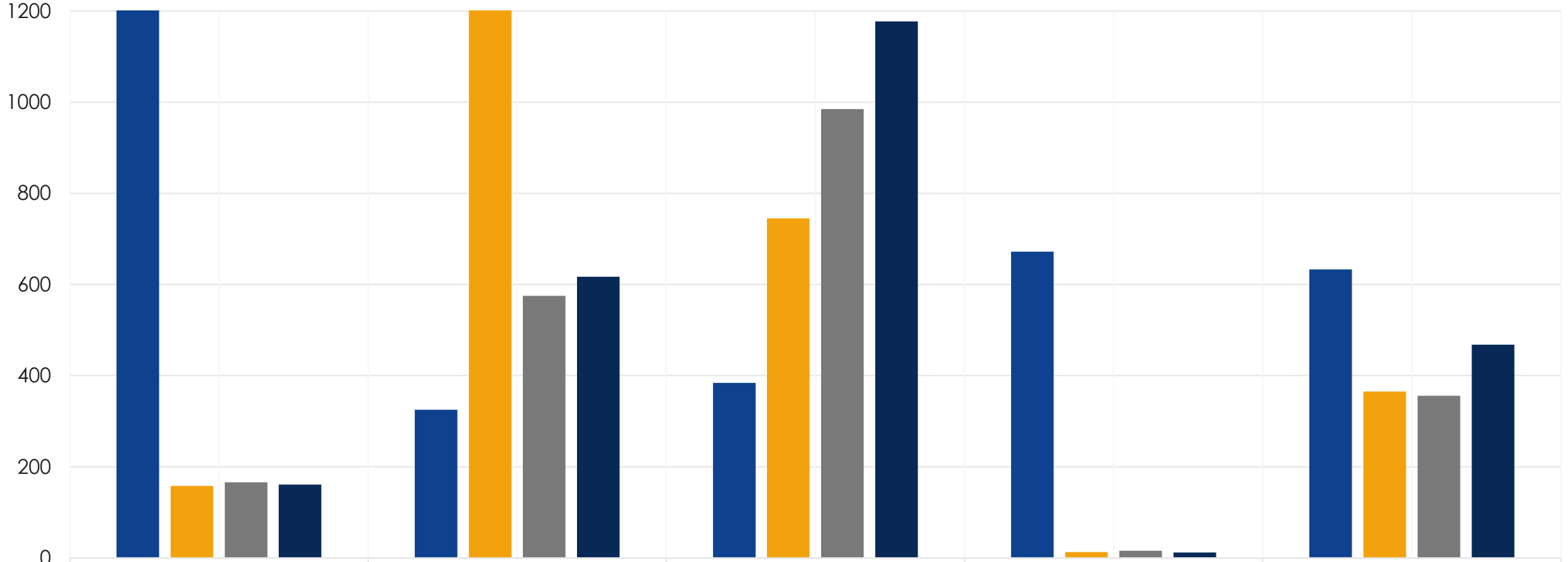
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 1.200



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	5774	325	384	672	633
2019 Week 42	158	8743	745	13	365
2020 Week 10	166	575	985	16	356
2020 Week 11	161	617	1177	12	468

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

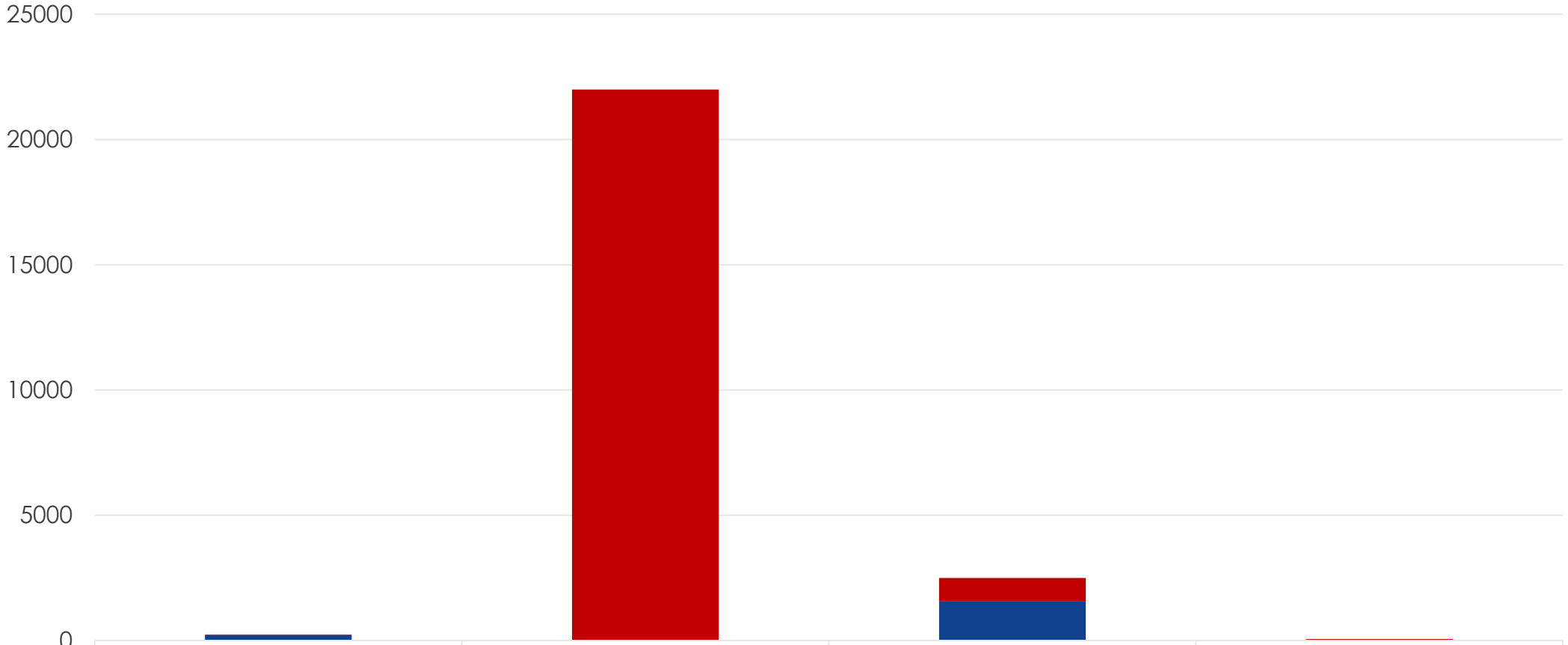
There was an increase in A2 alerts during week 9 caused by one single OBP performing a Bulk destroy packs transaction for 225 packs a couple of seconds before they had uploaded the respective batch data. This OBP-related error explains the difference between weeks 8 and 9.

HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

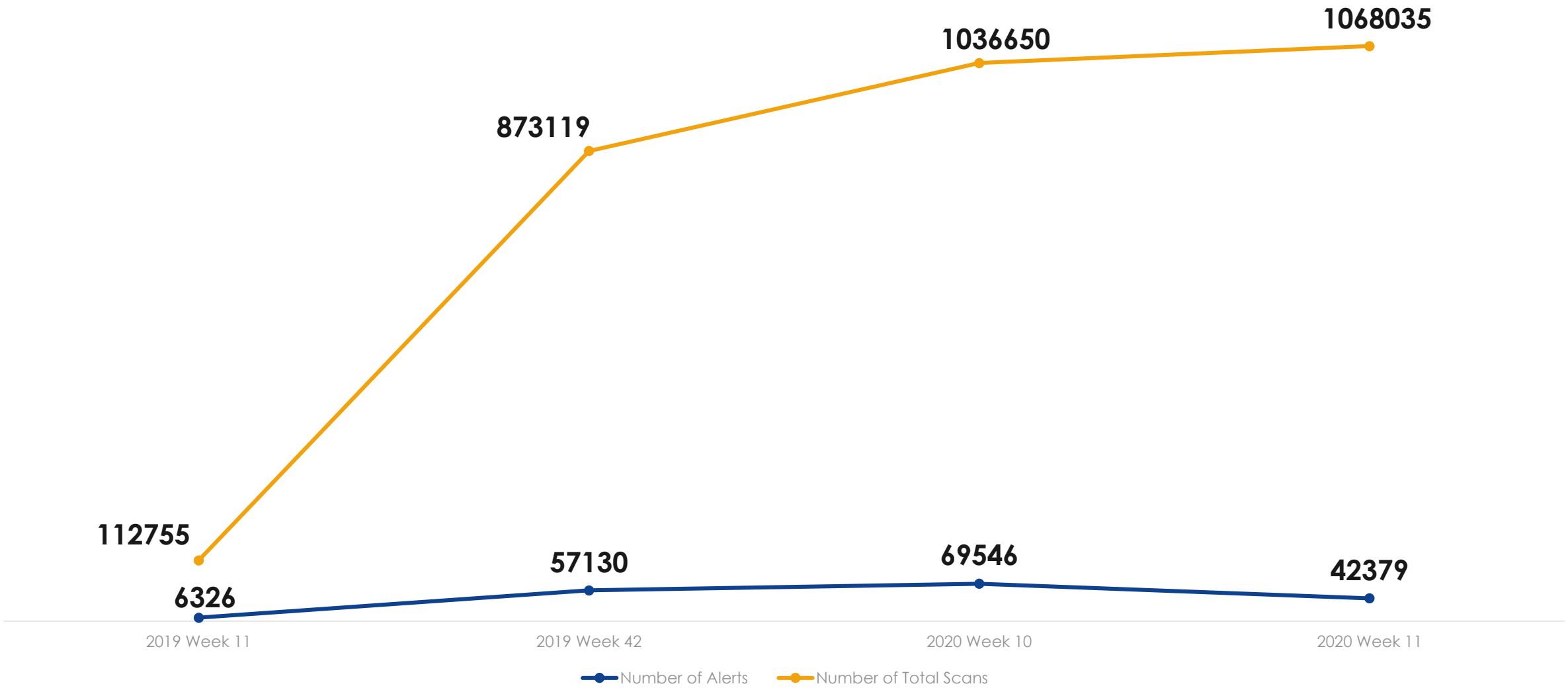
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

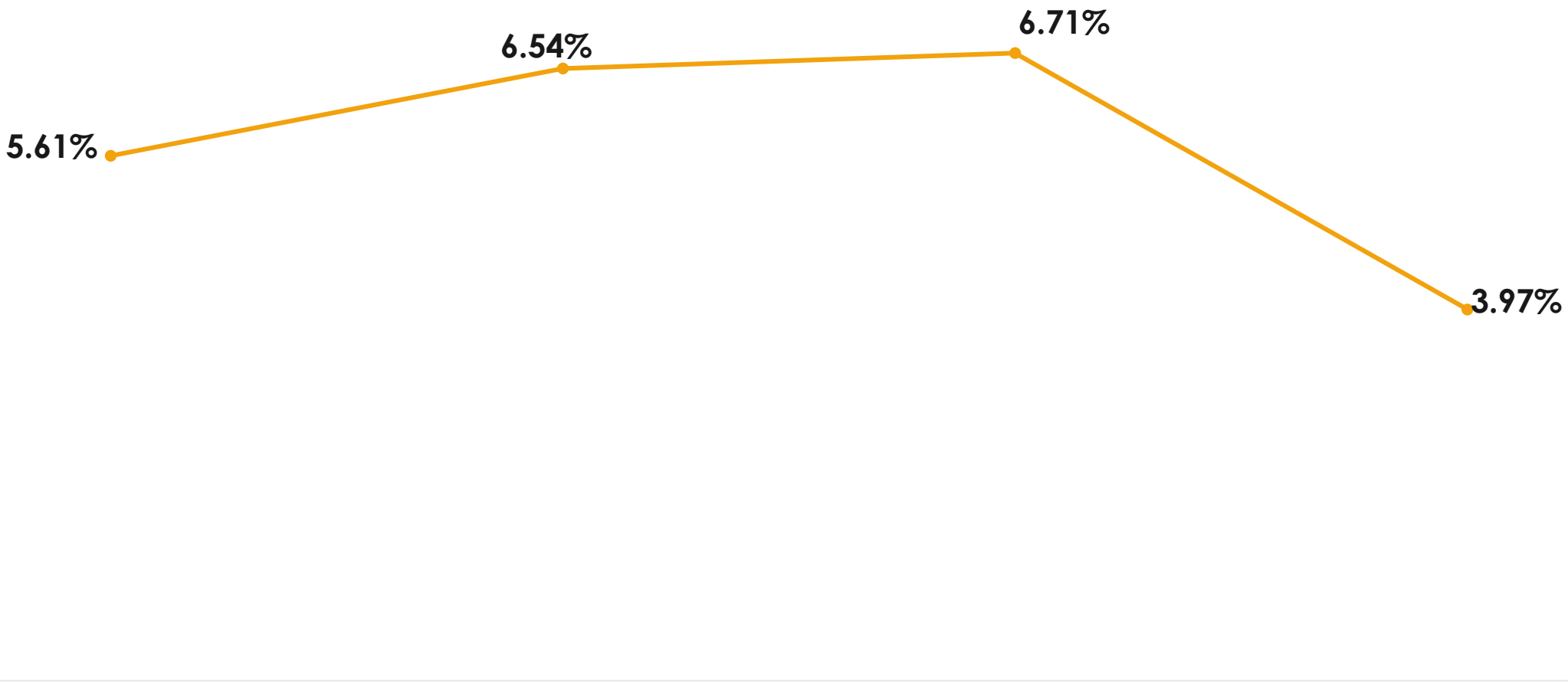


	Wholesalers	Pharmacies	Healthcare Institutions	Other Decommissioning Channels
Not connected	2	21991	918	60
Connected	238	9	1582	0
Percentage remaining	0.83%	99.96%	36.72%	100.00%

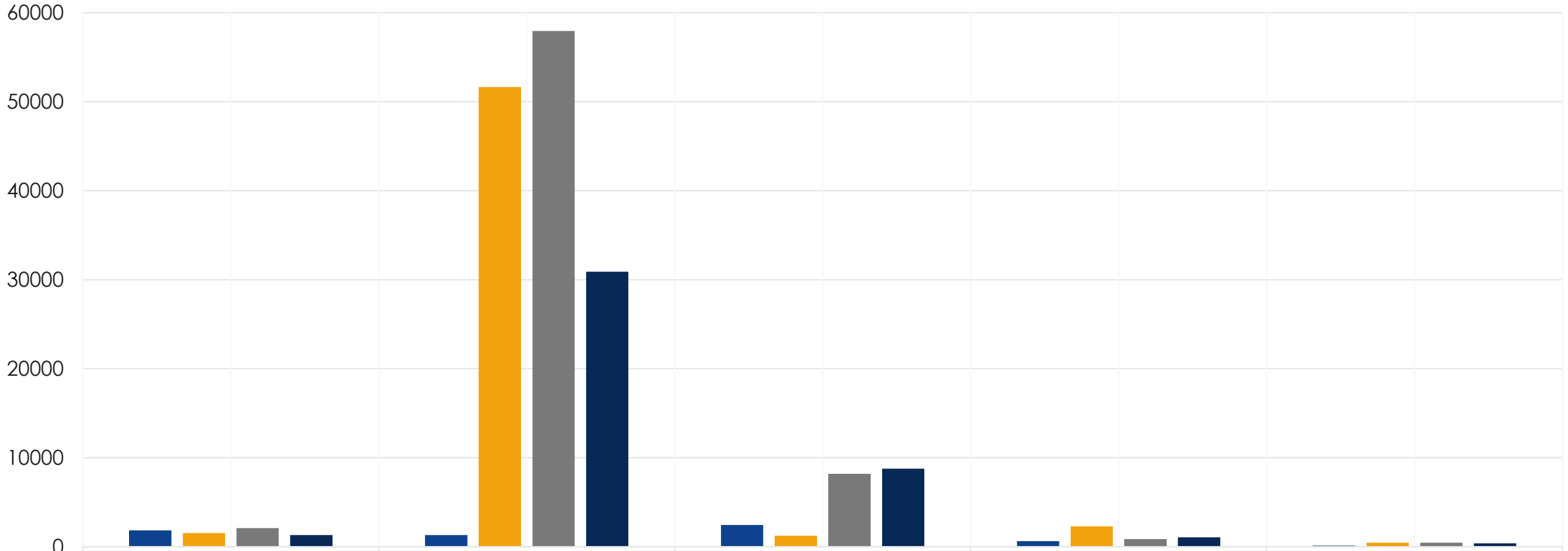
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	1841	1314	2439	615	117
2019 Week 42	1528	51653	1224	2282	443
2020 Week 10	2096	57955	8192	849	454
2020 Week 11	1315	30898	8764	1042	360

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

- There was an increase in A24 alerts from week 8 to 9. A wholesaler was identified who had never been involved in mass alerts before. This wholesaler triggered 19.734 alerts " A decommissioning was attempted for a pack that is already inactive ". Only one MAH is involved with 4 products. France MVO has asked the wholesaler for explanations.

- The increase in the alerts during weeks 9-10-11 is the consequence of an issue with one wholesaler which is identified. There are 2 problems: one with the software and the other with the process between him and the MAHs. France MVO have sent e-mails and are still waiting for their action plan

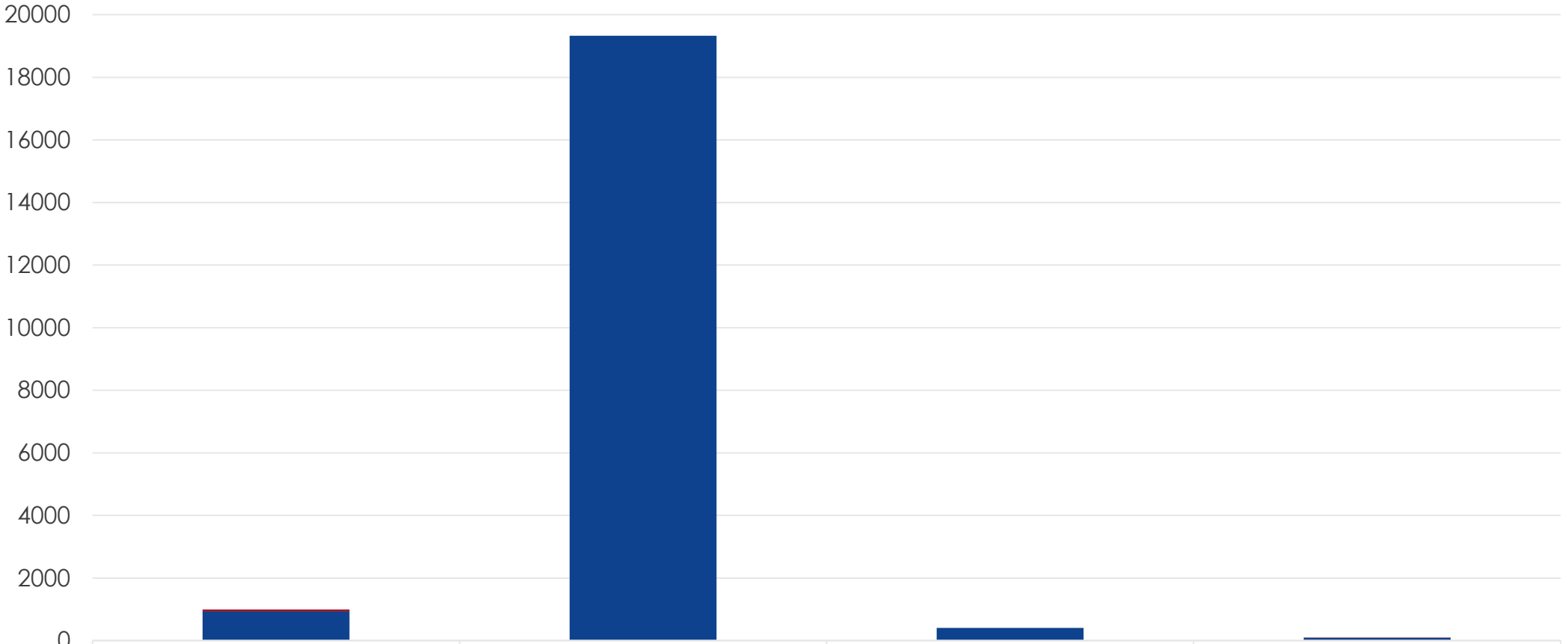
HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

GERMANY

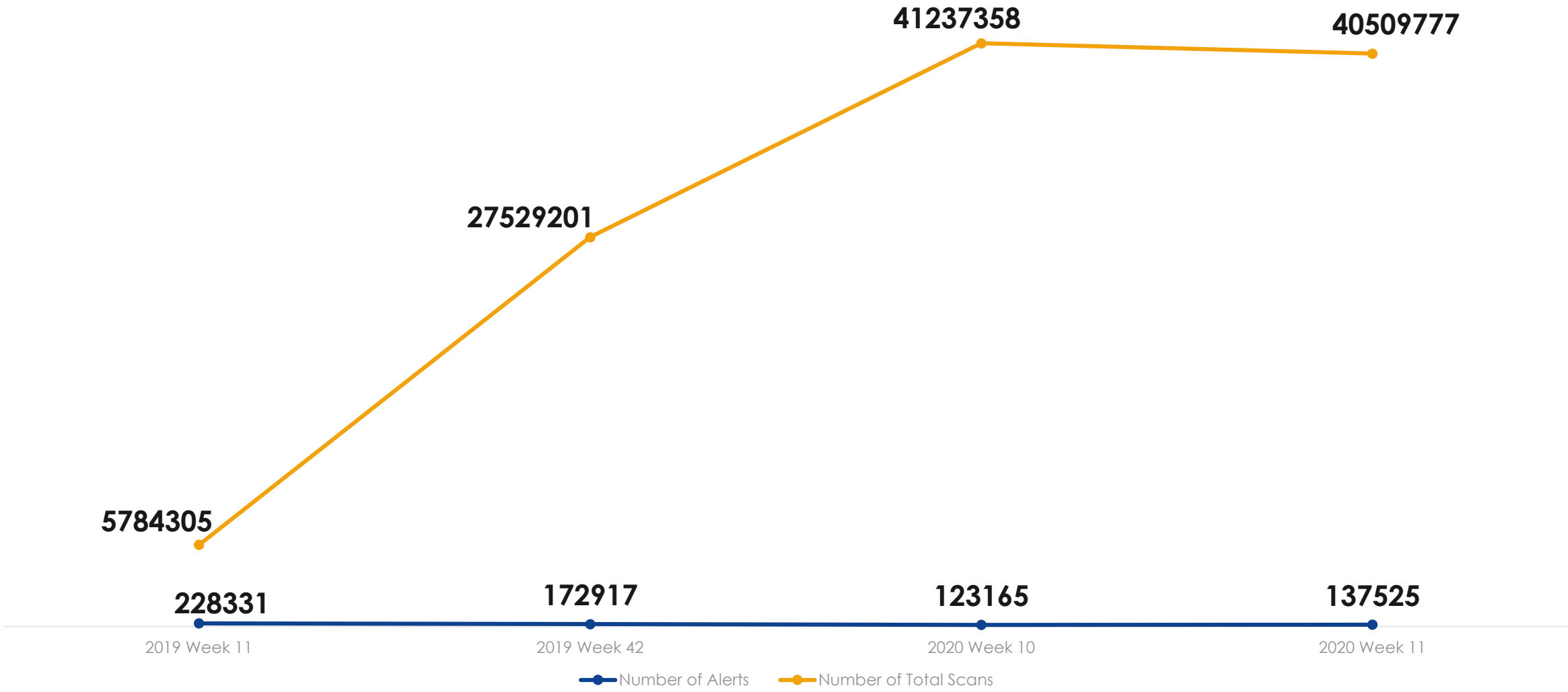
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

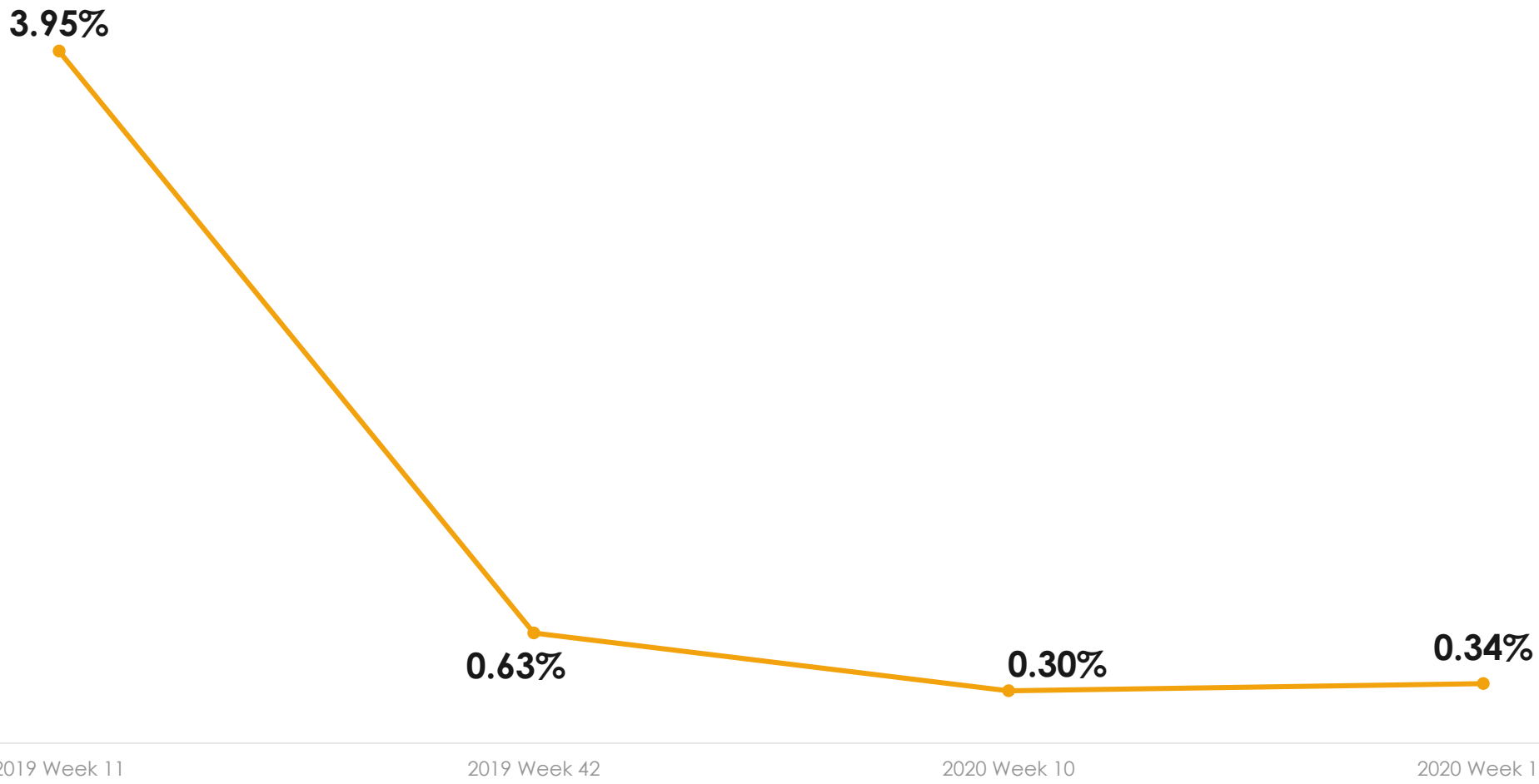


	Wholesalers	Pharmacies	Healthcare Institutions	Other Decommissioning Channels
Not connected	55	0	0	8
Connected	945	19330	408	94
Percentage remaining	5.50%	0.00%	0.00%	7.84%

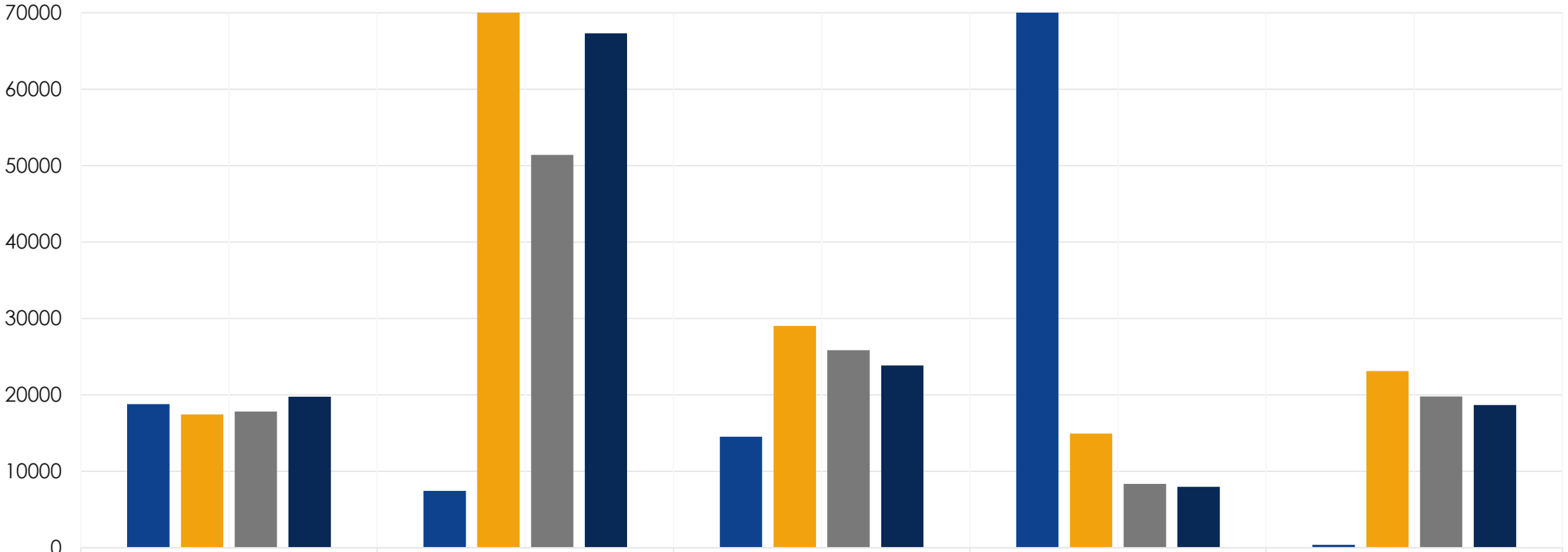
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 70.000



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	18791	7447	14510	187217	366
2019 Week 42	17428	88405	29033	14938	23113
2020 Week 10	17807	51411	25838	8337	19772
2020 Week 11	19759	67302	23831	7960	18673

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

- The increase of A24 alerts in week 8 was caused by a handling error of one MAH. Due to a second attempt to set packs as free samples, more than 27.000 alerts were generated. The MAH was informed.
- During week 9, one MAH generated 79.744 A24 alerts by putting those packs as "locked" instead of "recalled" on the market. This triggered alerts for all packs that had been dispensed by End-users. The MAH and EMVO were informed.
- During week 11, the NMVS observed approx. 3.500 alerts (A24) generated by Parallel Distributor(s) trying to bulk check out packs for EU distribution several times. Since the initiator of the alerts cannot be found without EMVO assistance cases were provided to EMVO helpdesk. Investigation is still running.

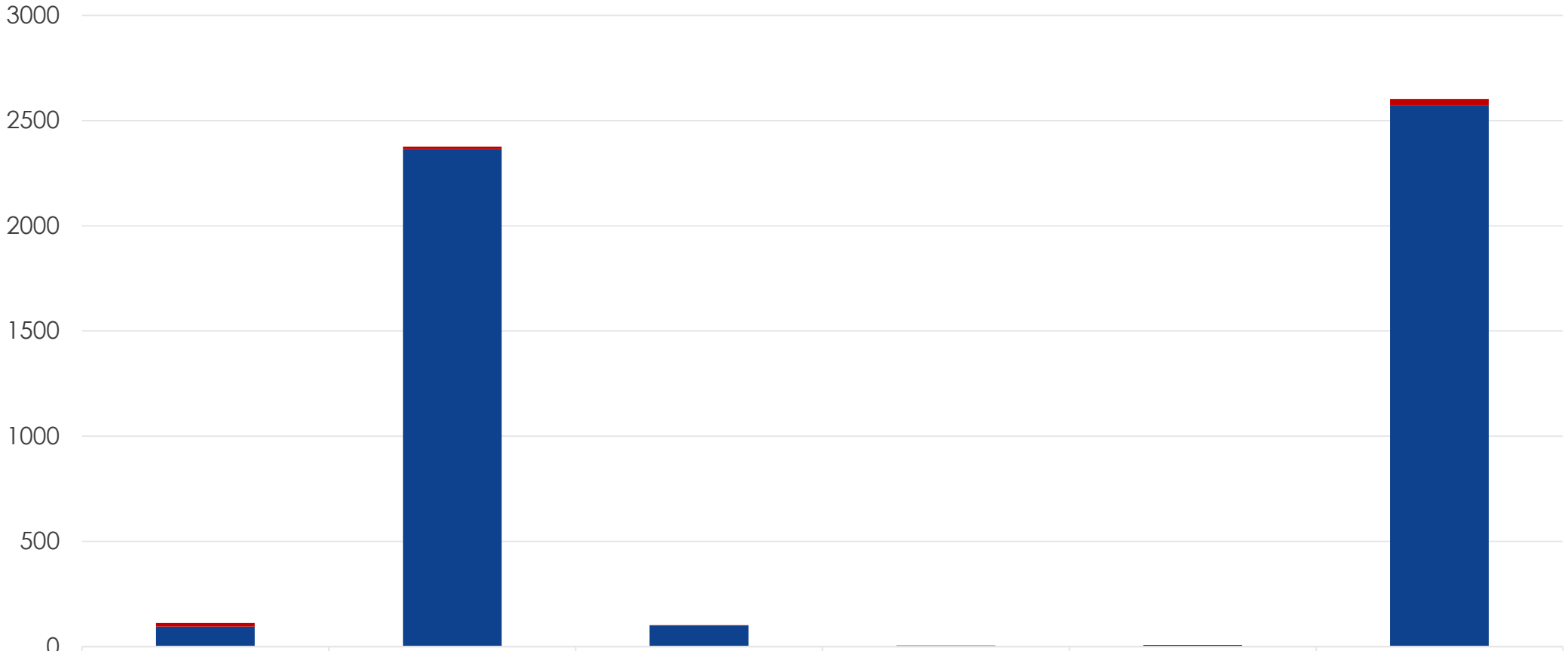
HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

HUNGARY

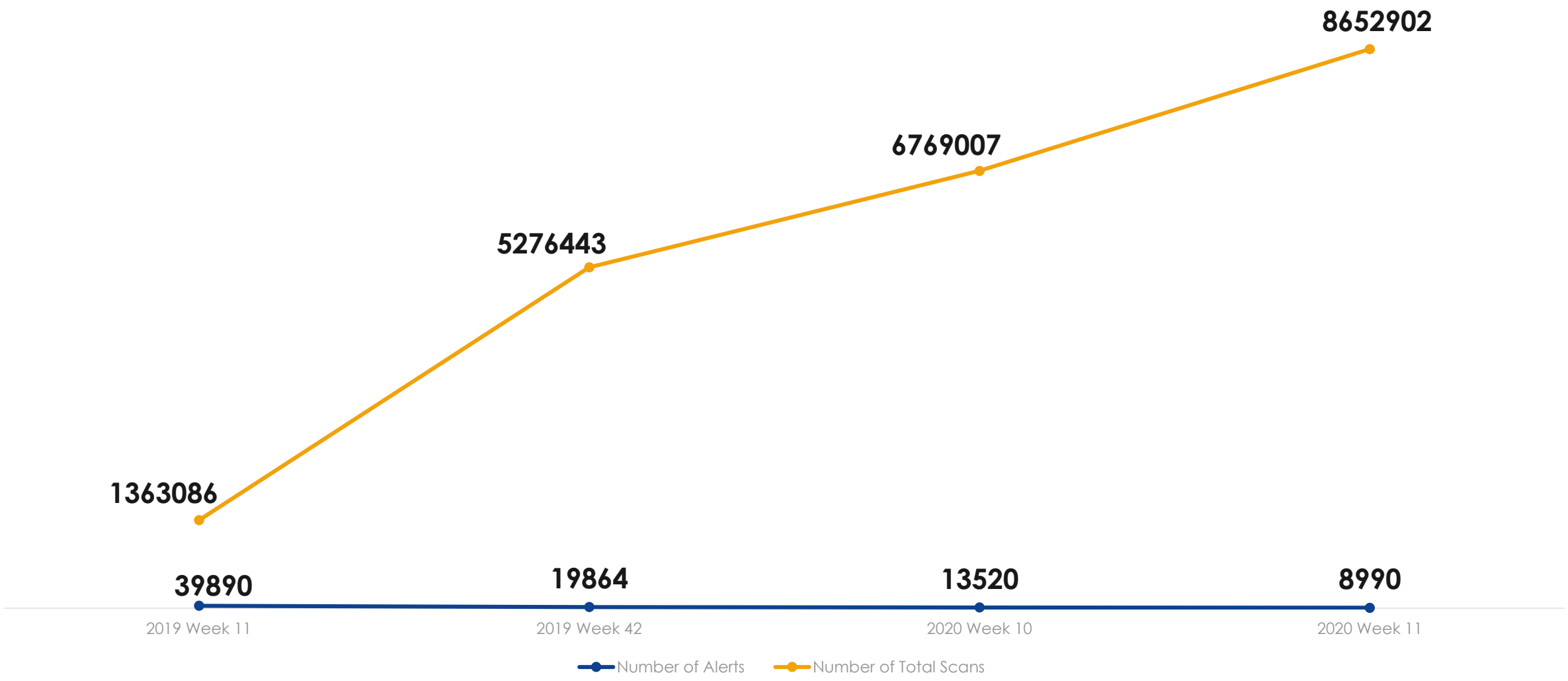
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

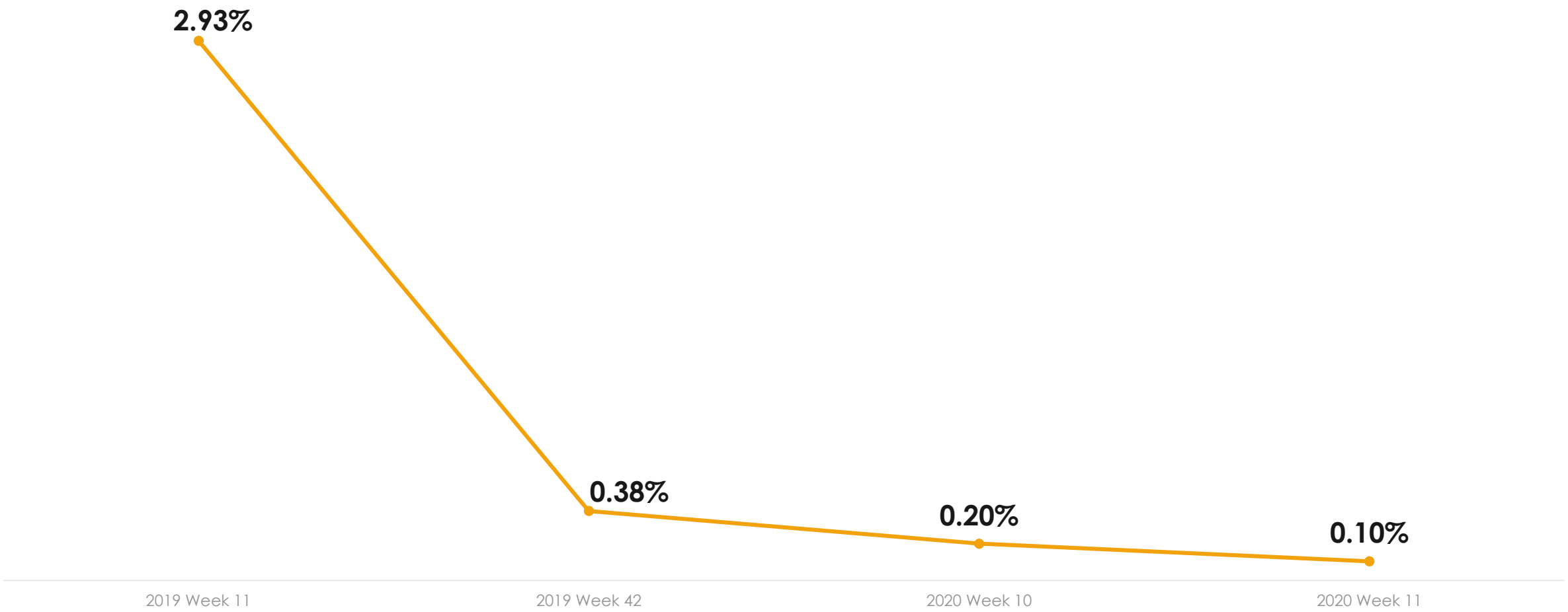


	Wholesalers	Pharmacies	Healthcare Institutions	Dispensing Doctors	Other Decommissioning Channels	Total End-users
Not connected	17	12	1	1	0	31
Connected	95	2364	101	4	8	2572
Percentage remaining	15.18%	0.51%	0.98%	20.00%	0.00%	1.19%

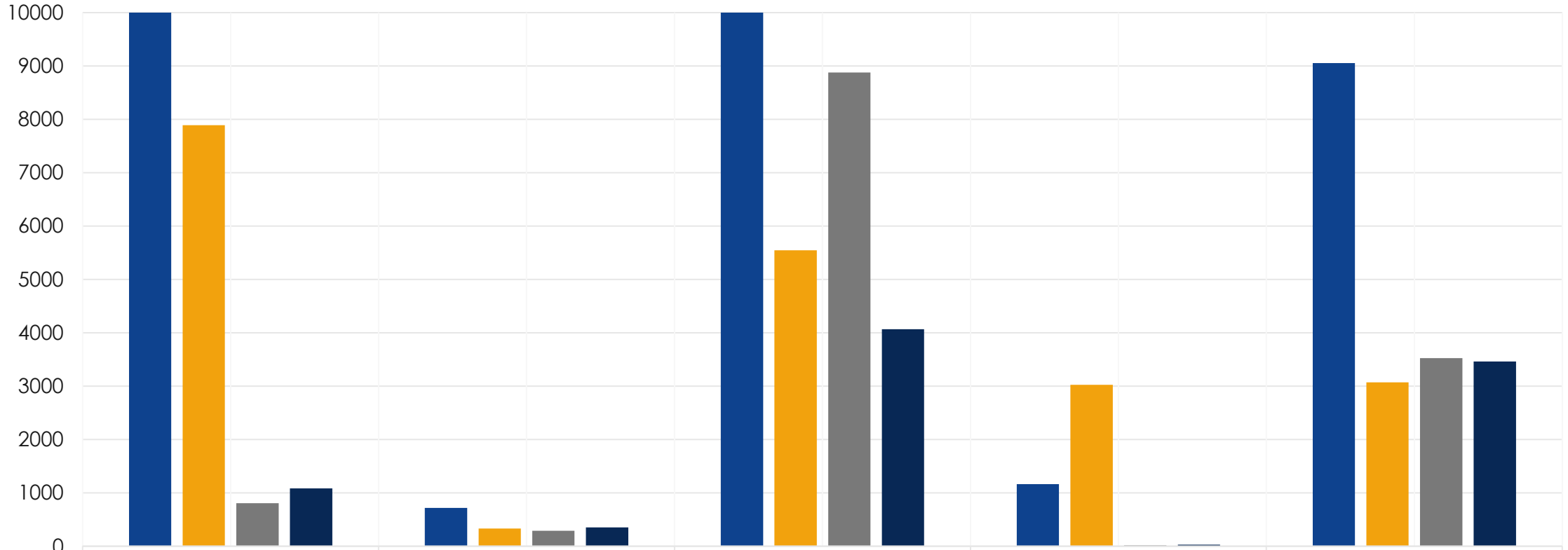
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 10.000



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	12580	719	16373	1163	9055
2019 Week 42	7889	333	5545	3024	3073
2020 Week 10	807	290	8879	19	3525
2020 Week 11	1083	352	4066	28	3461

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

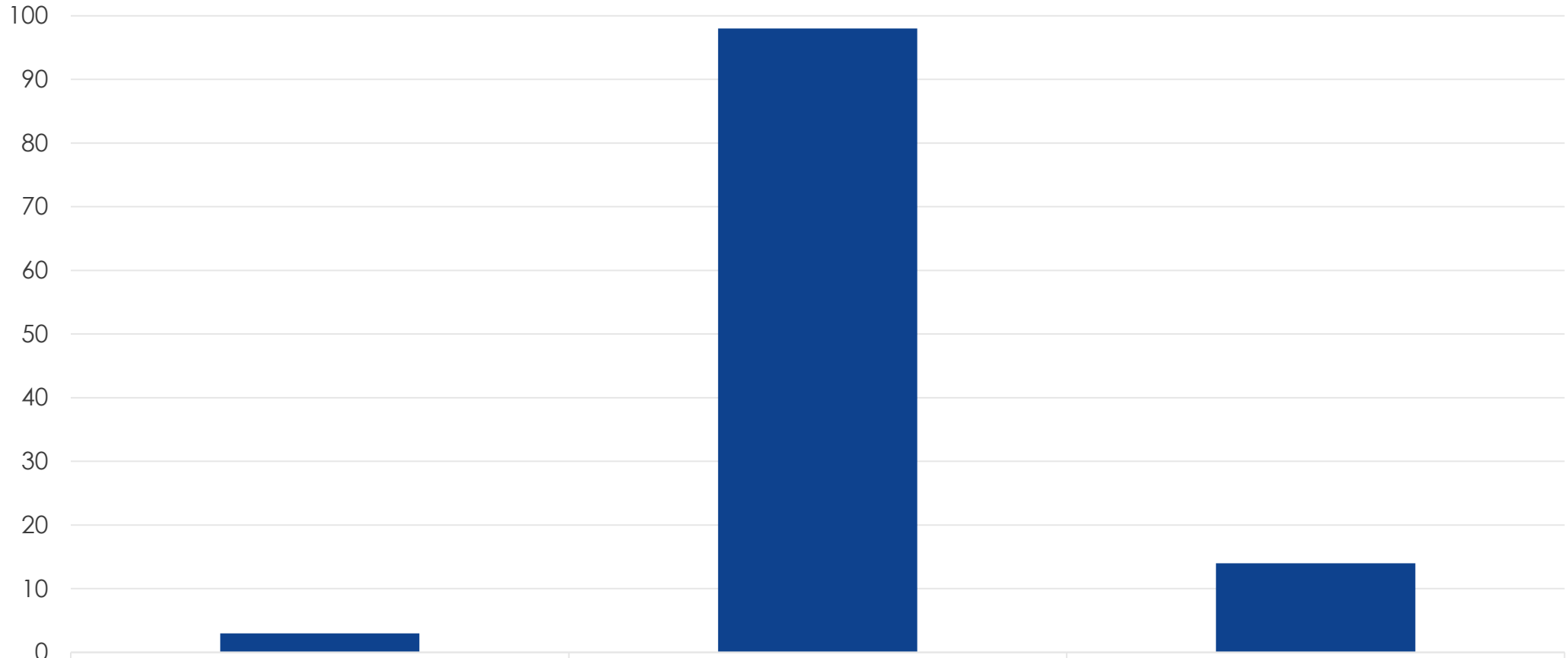
The Hungarian NMVO has provided no particular insight for the past 4 weeks.

HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

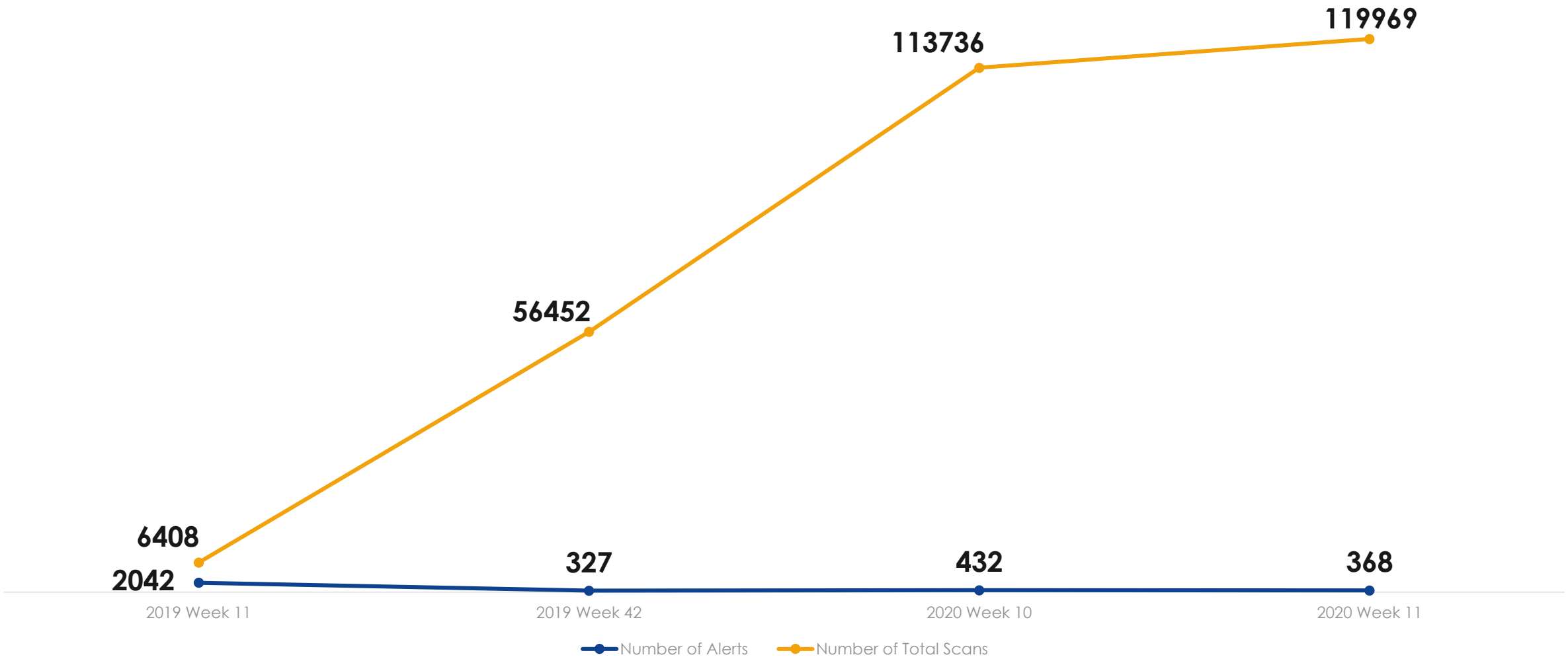
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

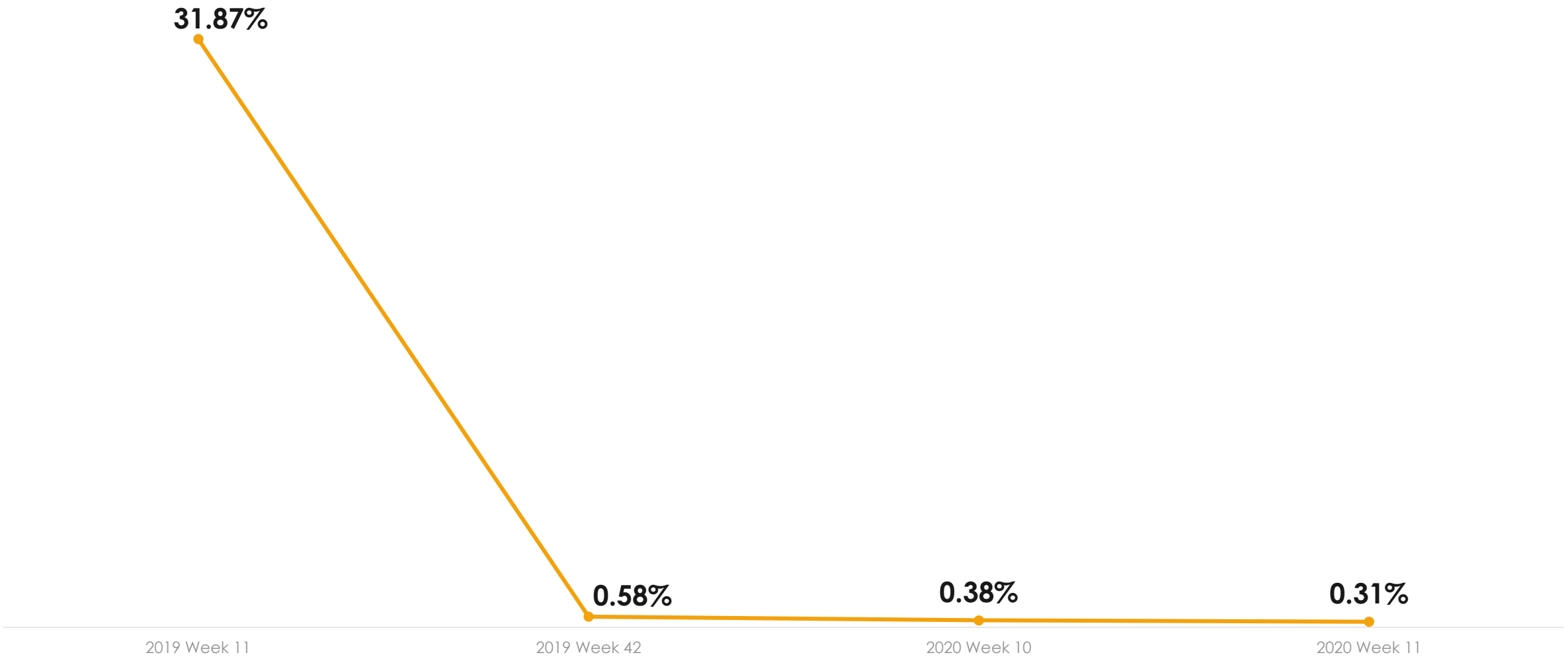


	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	0	0	0
Connected	3	98	14
Percentage remaining	0.00%	0.00%	0.00%

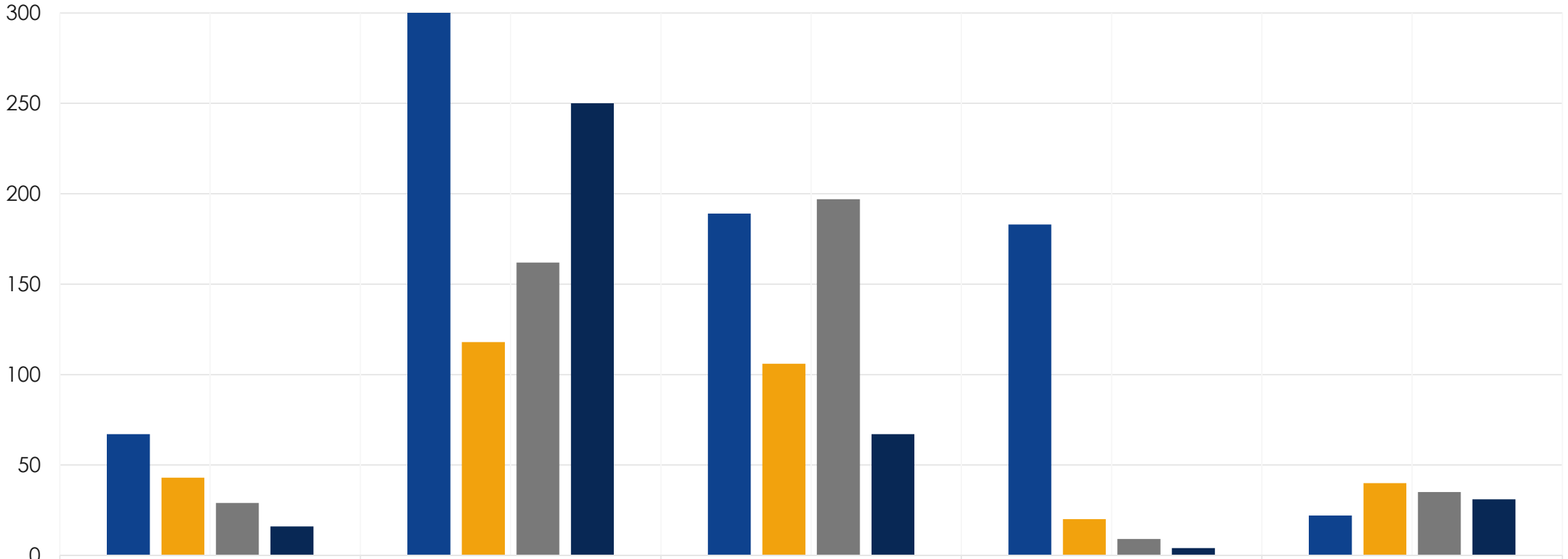
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 300



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	67	1581	189	183	22
2019 Week 42	43	118	106	20	40
2020 Week 10	29	162	197	9	35
2020 Week 11	16	250	67	4	31

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

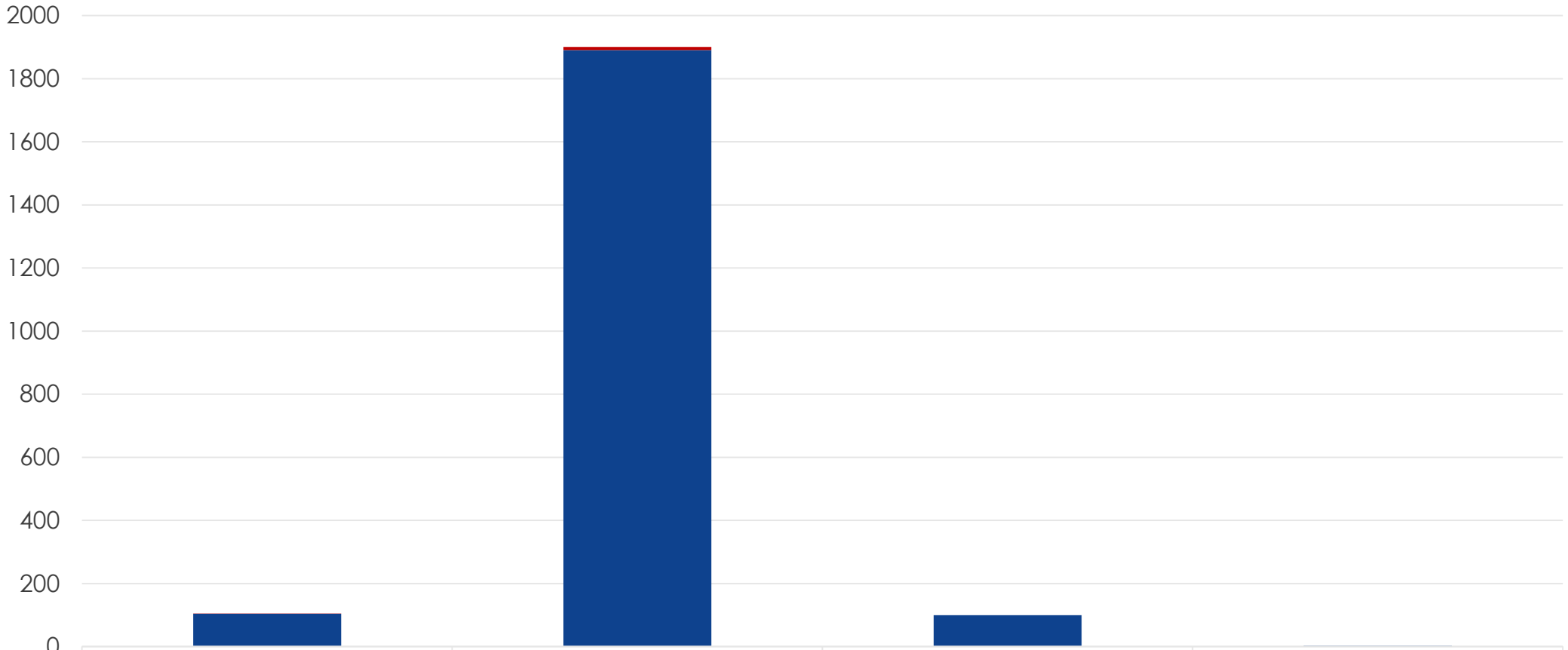
The Islandic NMVO has provided no particular insight for the past 4 weeks.

HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

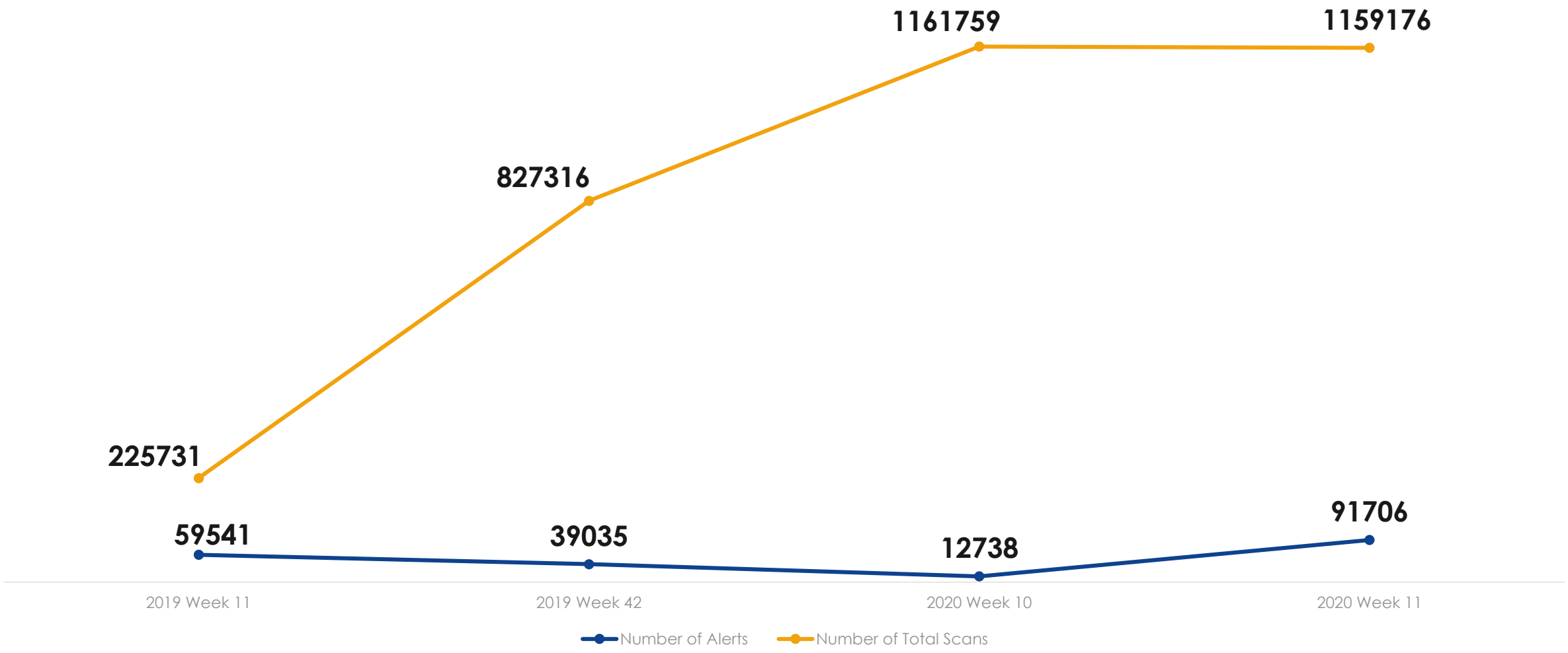
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

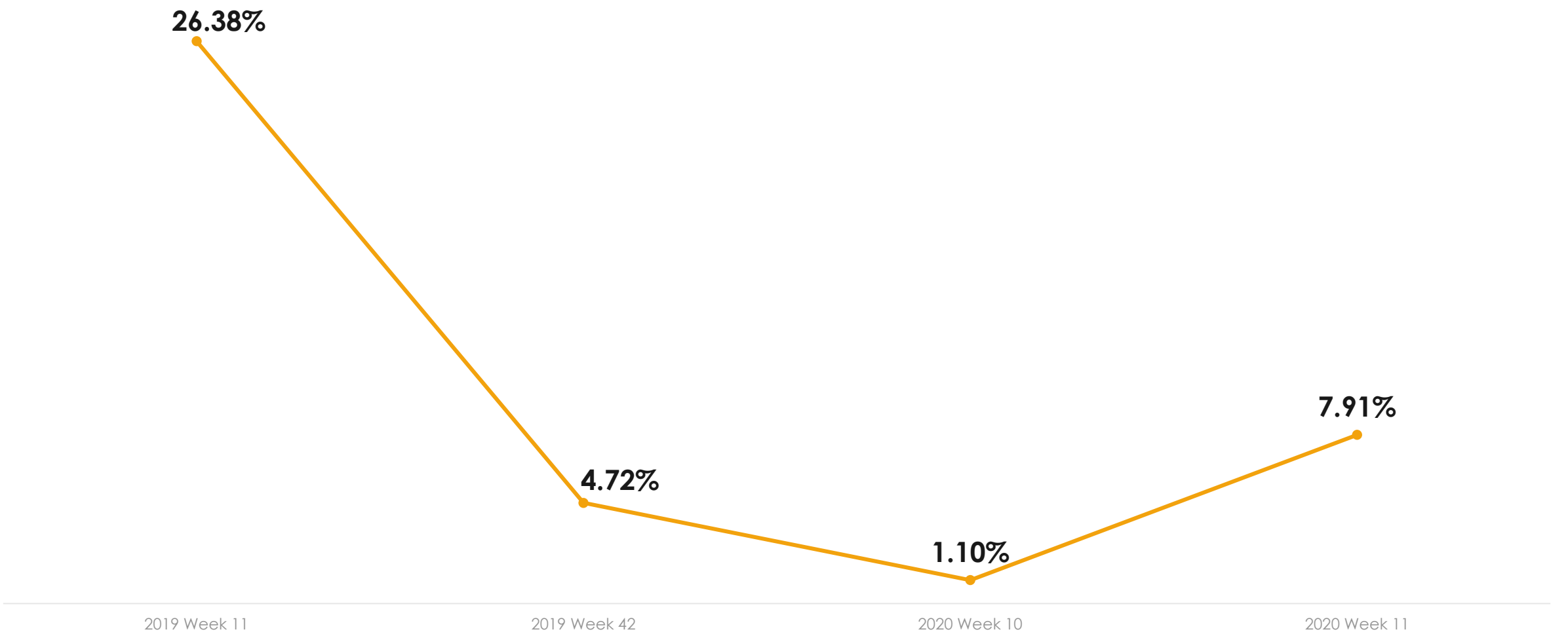


	Wholesalers	Pharmacies	Healthcare Institutions	Other Decommissioning Channels
Not connected	1	10	0	0
Connected	104	1891	100	3
Percentage remaining	0.95%	0.53%	0.00%	0.00%

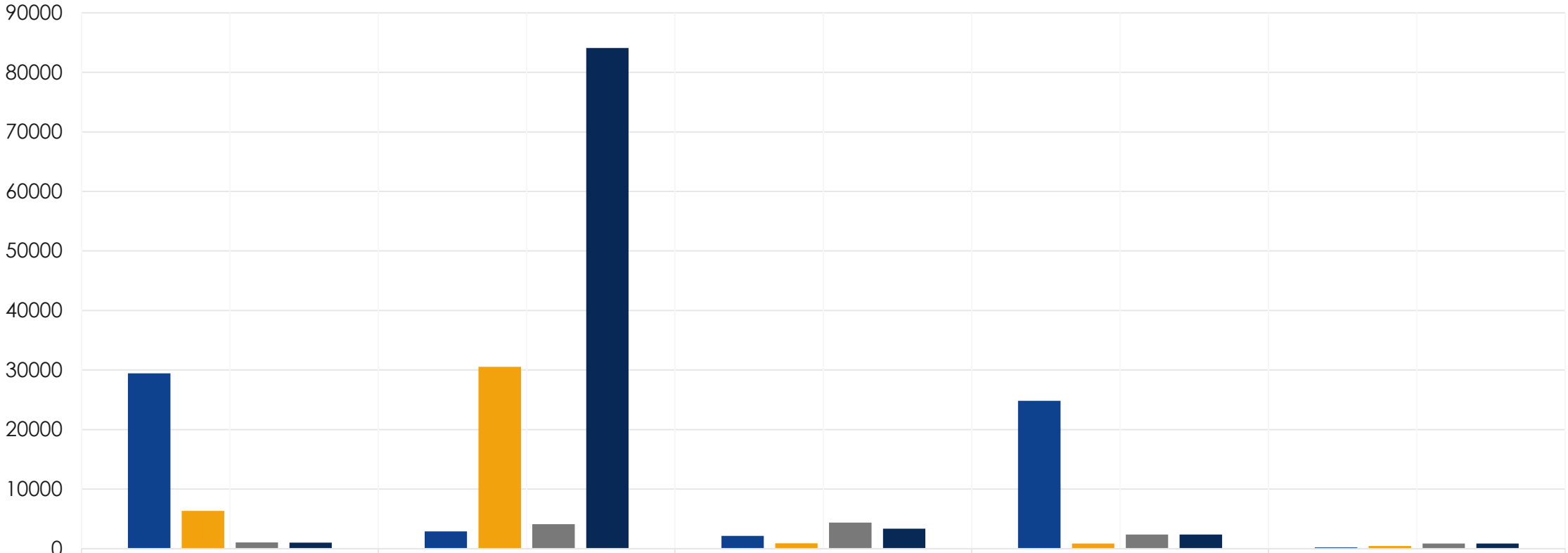
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	29446	2898	2161	24819	217
2019 Week 42	6337	30540	885	844	429
2020 Week 10	1035	4100	4394	2357	852
2020 Week 11	994	84097	3362	2378	875

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

There was a significant increase in A7/A24 alerts in week 11 (84.098 in total).

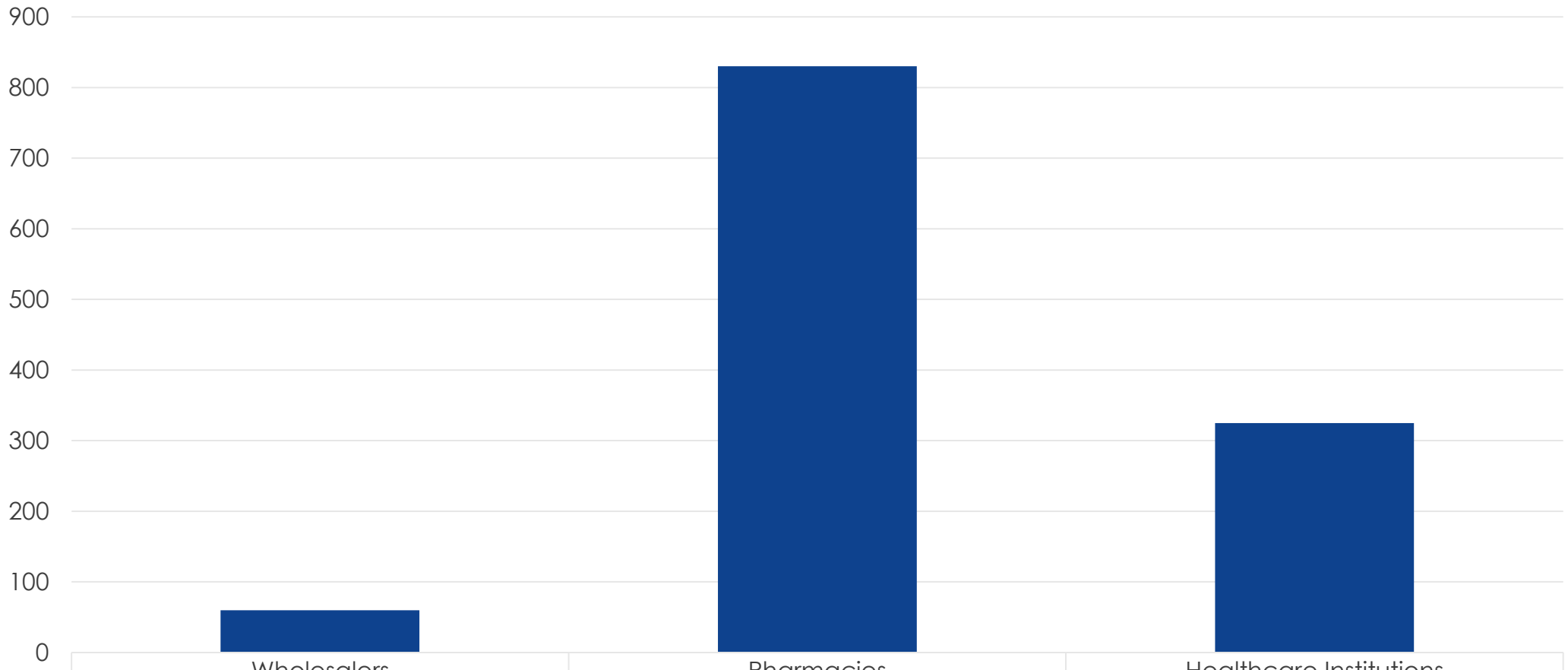
- Three incidents caused 81.653 A7 alerts of these alerts - approx. 80.000 arose from one MAH trying to 'lock' packs and the remainder from check-out operations by 2 parallel distributors. Each of the actors decommissioned the packs on 10th March while there were EU Hub issues and then tried to do so again on 11th March, causing the alerts. It appears that in all cases, the original decommissioning request was successful but the MAH/parallel distributor did not get the necessary confirmation and retrying the operation caused the alerts.
- Approx. 600 A7/A24 alerts were due to locations within the health services designated as Article 23 decommissioning packs again on receipt. The health services FMD project team is working with the relevant sites and wholesalers to ensure that this dual decommissioning does not continue and the numbers of these alerts have fallen by 50% over the last 4 weeks.

HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

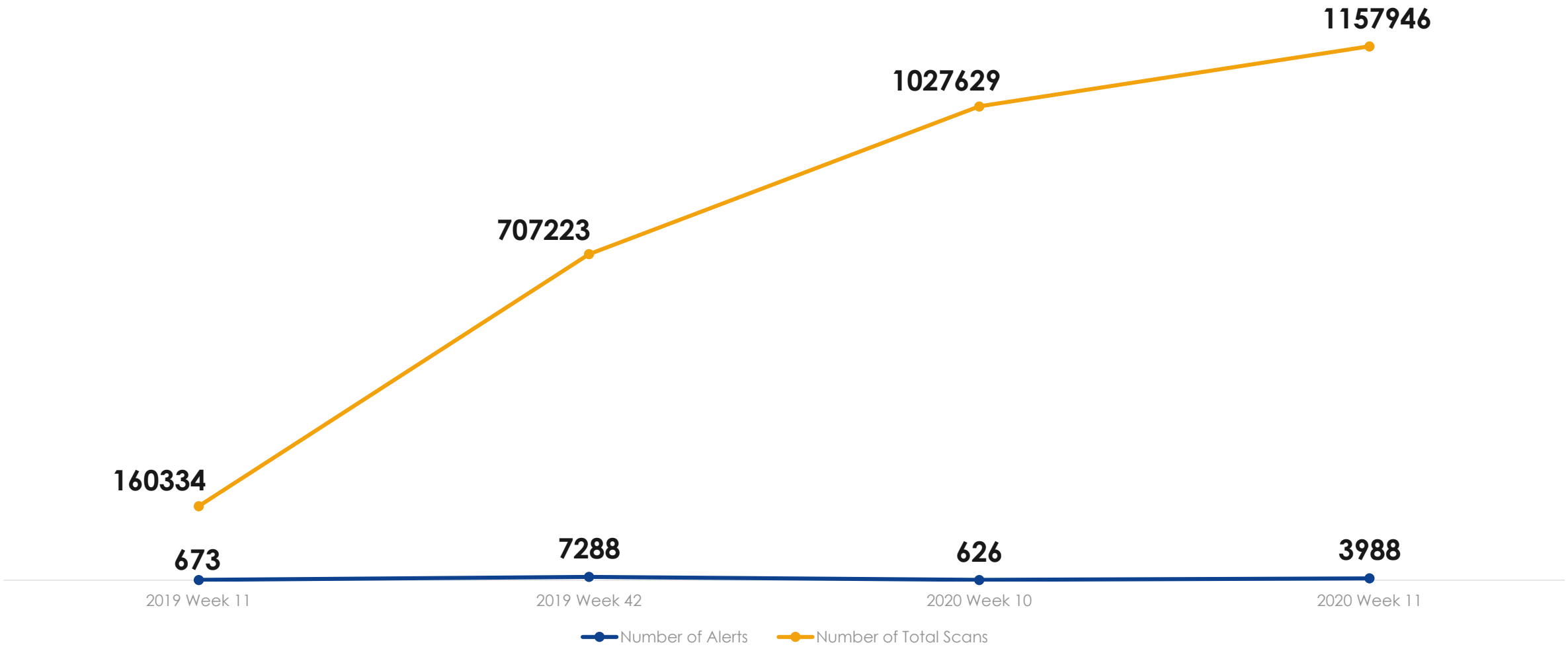


	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	0	0	0
Connected	60	830	325
Percentage remaining	0.00%	0.00%	0.00%

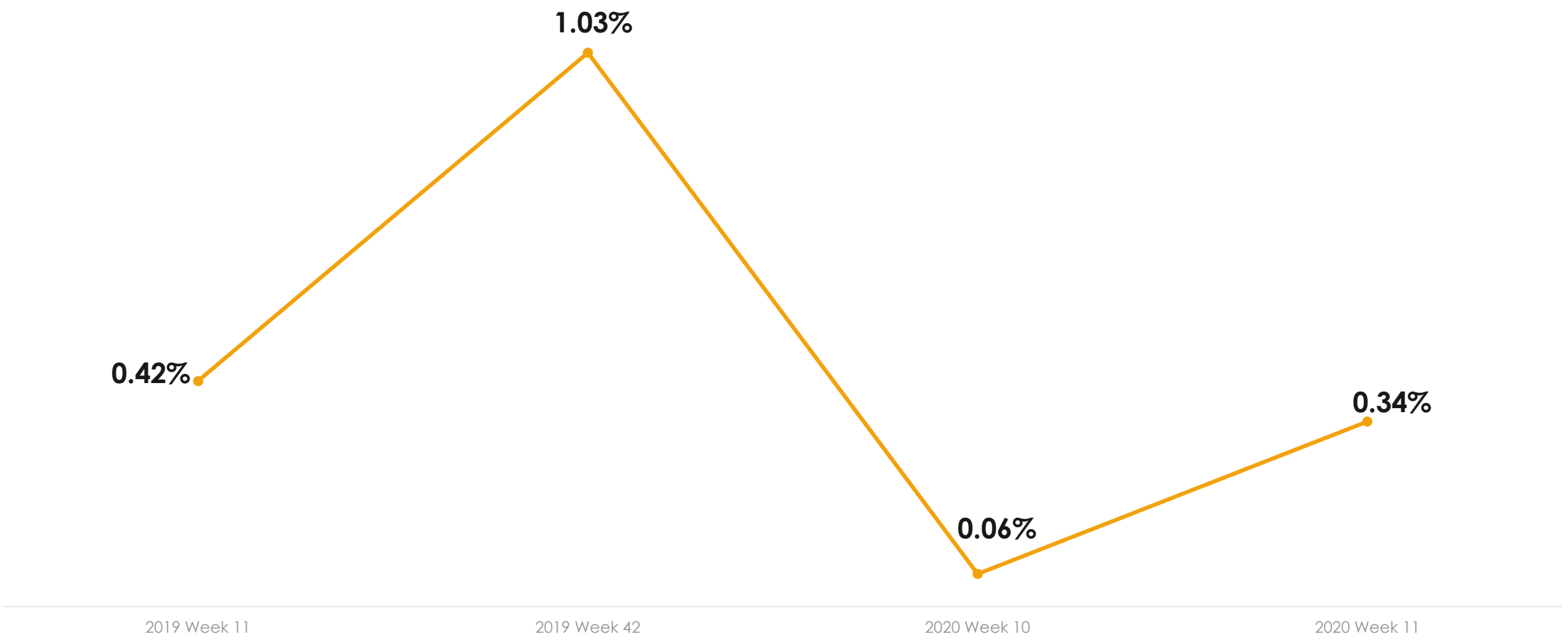
emvo European Medicines Verification Organisation

Note: As of November, dispensing doctors in Latvia have been added to the healthcare institutions report as legally they all are healthcare institutions.

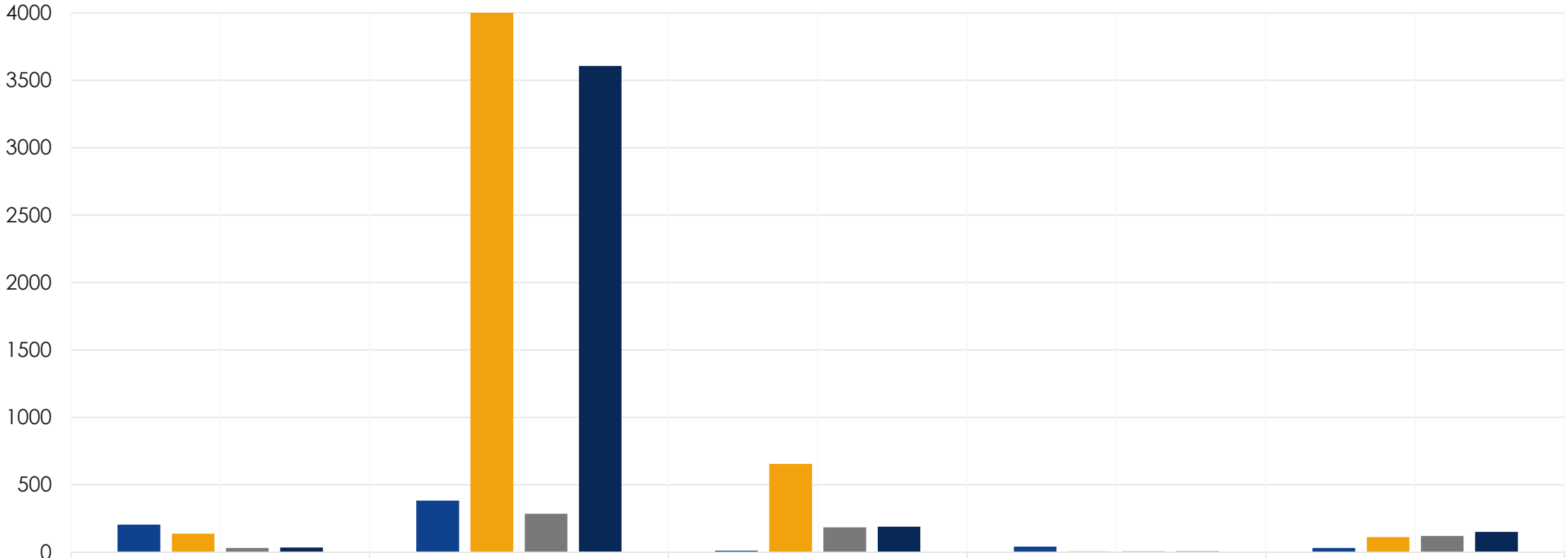
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 4.000



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	205	383	11	42	32
2019 Week 42	137	6376	656	7	112
2020 Week 10	31	285	184	6	120
2020 Week 11	35	3607	189	6	151

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

- During week 9 there was an increase in A24 Alert caused by one OBP (Parallel Distributor) with 2 products (number of packs 1000 & 555) who did repacking of these products. The OBP confirmed it was due to technical/procedural issues.
- The number of A24 & A7 alerts rose during week 11. All the cases identified (most part of all the OBP alerts) were related to the repeated check out and lock activities done by parallel distributors. For some of the cases, the OBPs confirmed that repeated activities were done because of the issues with the EU hub (missing response).

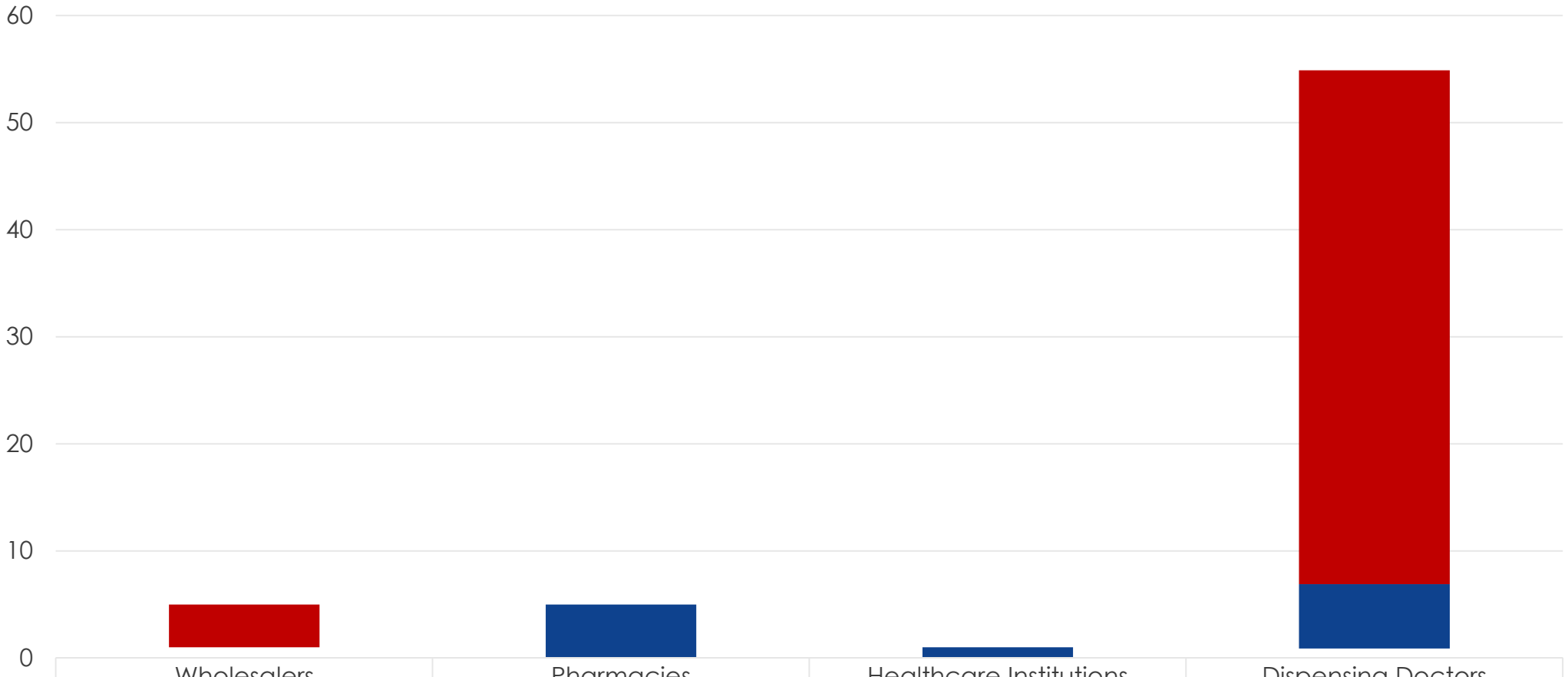
HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

LIECHTENSTEIN

Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

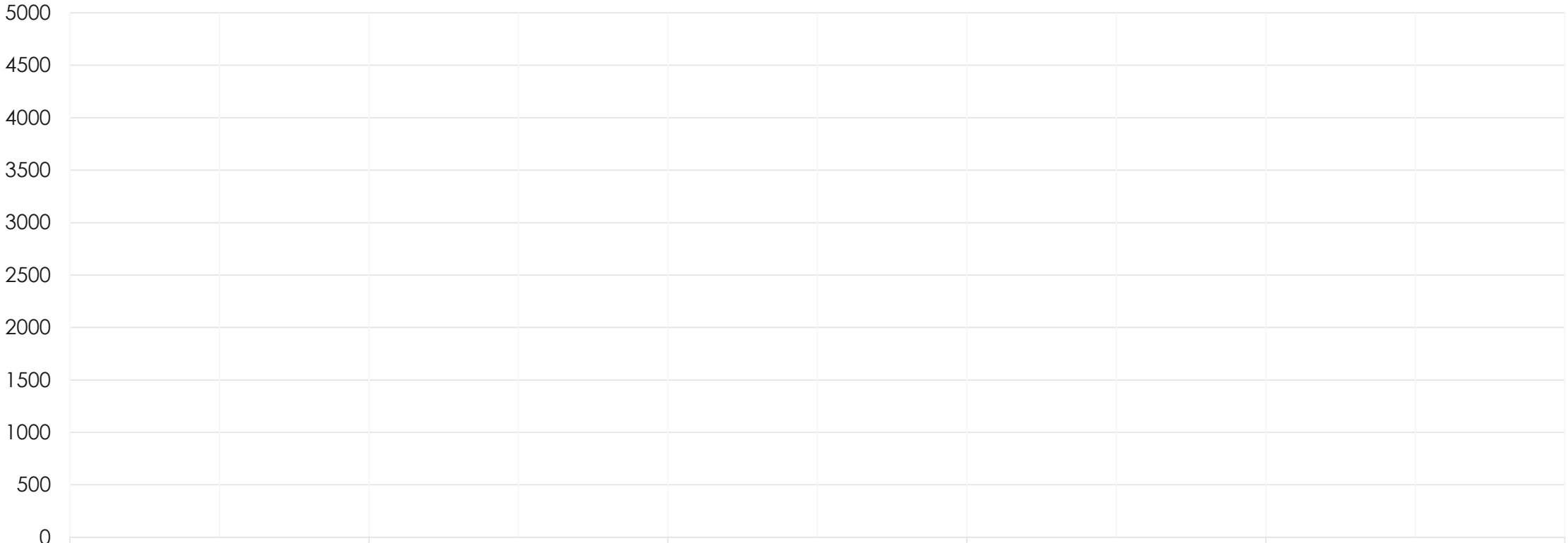


	Wholesalers	Pharmacies	Healthcare Institutions	Dispensing Doctors
Not connected	4	0	0	48
Connected	0	5	1	6
Percentage remaining	100.00%	0.00%	0.00%	88.89%

OVERVIEW OF TOTAL OF ALERTS AND SCANS & TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS

Due to Intermarket transactions the data related to alerts and scans in Liechtenstein are not meaningful and will therefore not be displayed in this report.

ABSOLUTE: ALERTS PER CATEGORY PER WEEK



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	3	0	0	0	0
2019 Week 42	3	0	0	0	0
2020 Week 10	2	1	0	0	0
2020 Week 11	0	2	0	1	0

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

Liechtenstein's NMVO has provided no particular insight for the past month.

HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
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- Highlights of November
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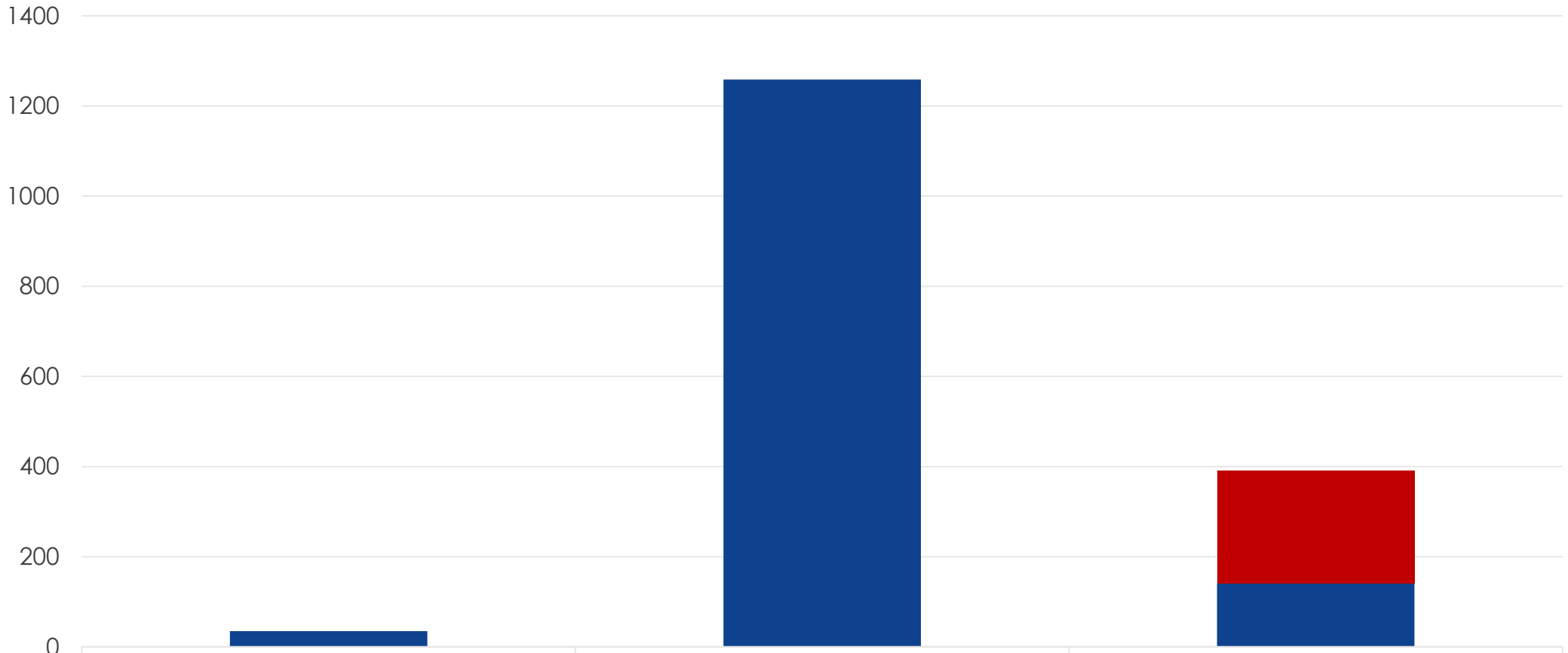
- Highlights of February

LITHUANIA

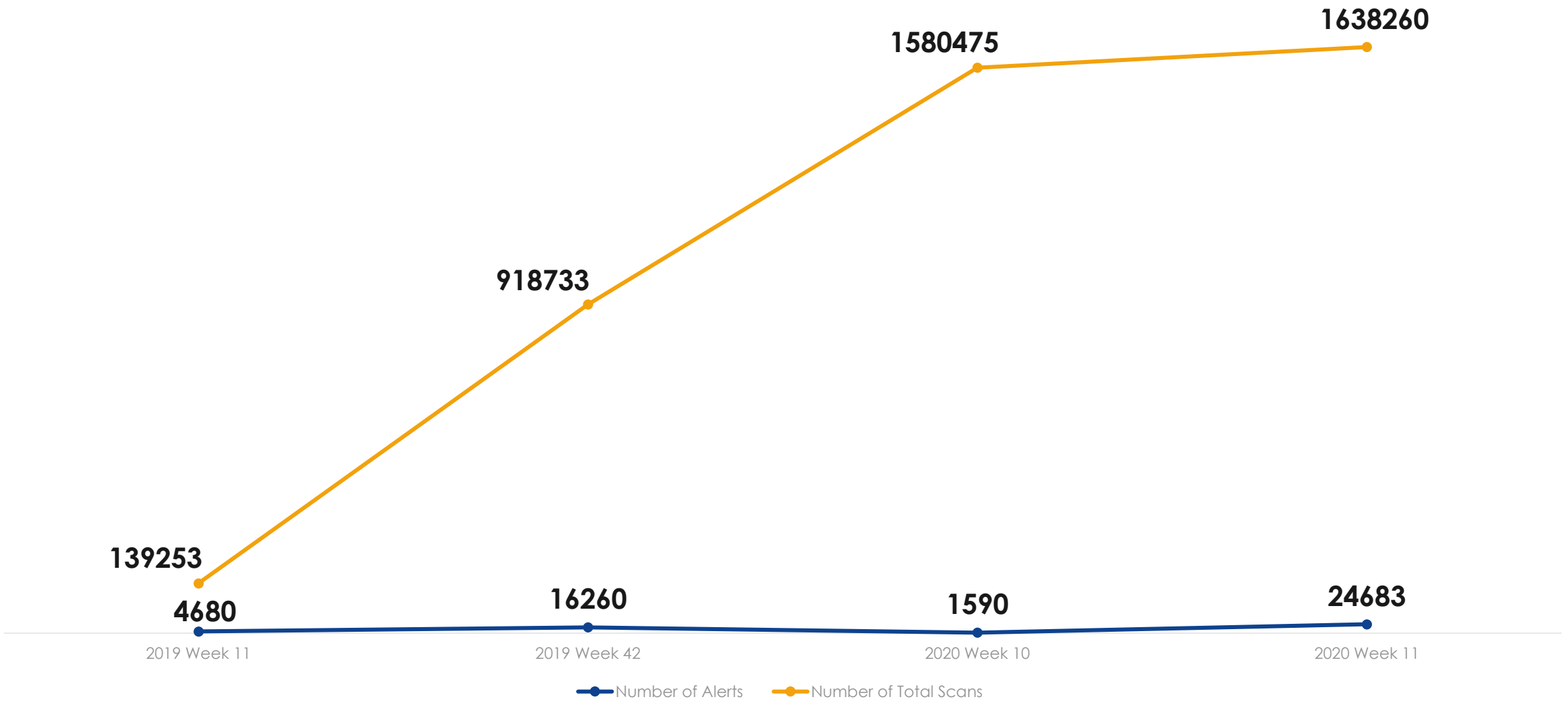
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

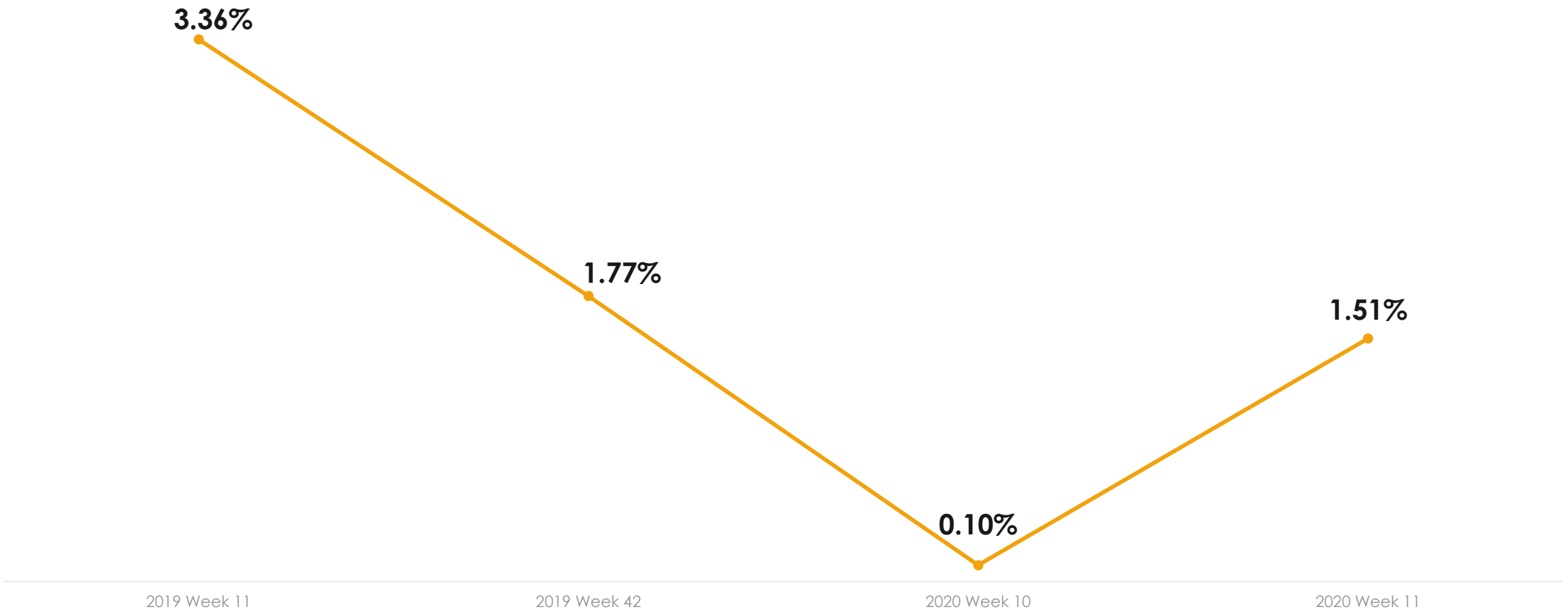


	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	0	0	250
Connected	35	1259	140
Percentage remaining	0.00%	0.00%	64.10%

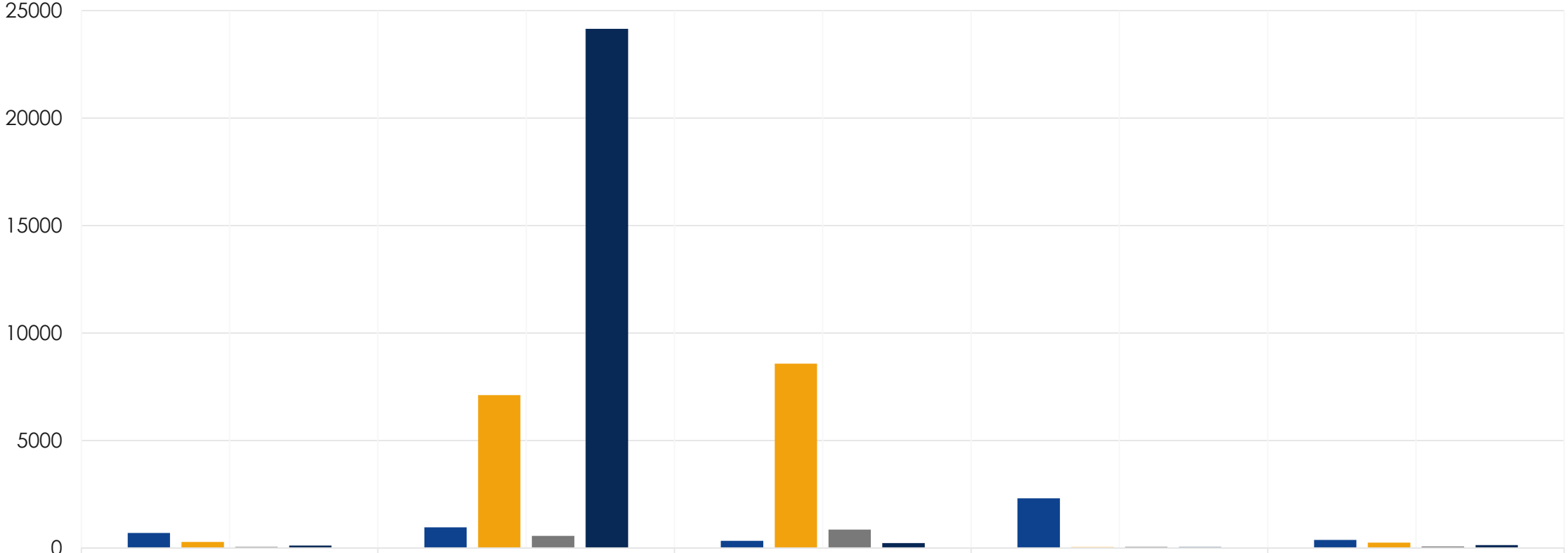
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK



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2019 Week 11	702	957	328	2315	378
2019 Week 42	282	7112	8579	36	251
2020 Week 10	49	562	855	52	72
2020 Week 11	118	24154	229	44	138

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

- During week 9, there was an increase in A7 which was caused by mainly 3 products, as parallel traders were trying to set "Checked out" status for already checked out products. These products caused a total of 1.657 alerts. The rest of A7 were due to regular mistakes by the end users.
- During week 11 the number of A24 & A7 alerts rose significantly as different parallel traders attempted several times to change the status during a timeout on the HUB level when MAH could not get the response from the HUB.
- Due to COVID-19, the stabilization period has been reinstituted, until the end of the quarantine set in Lithuania+30 days. Currently this would be till 21st of April.

HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
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- Highlights of November
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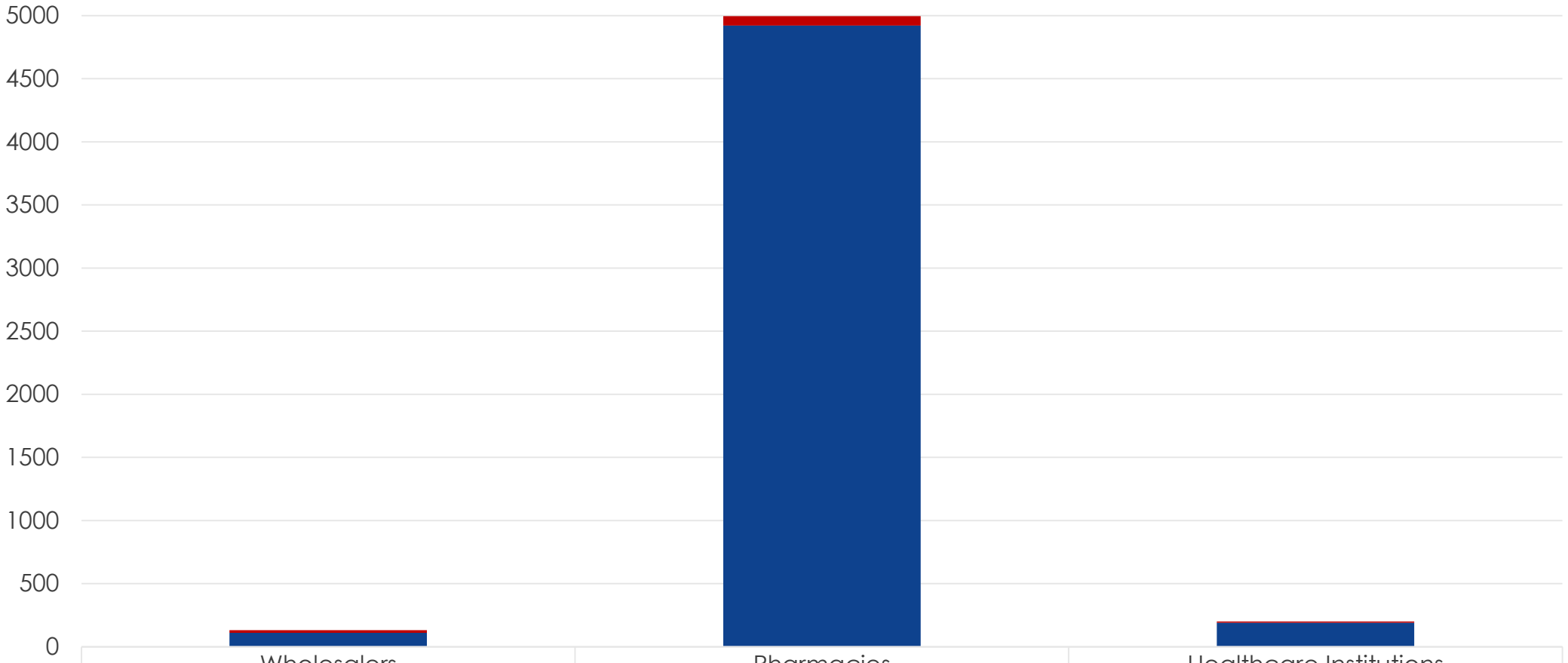
- Highlights of February

LUXEMBOURG

Back to the EEA map

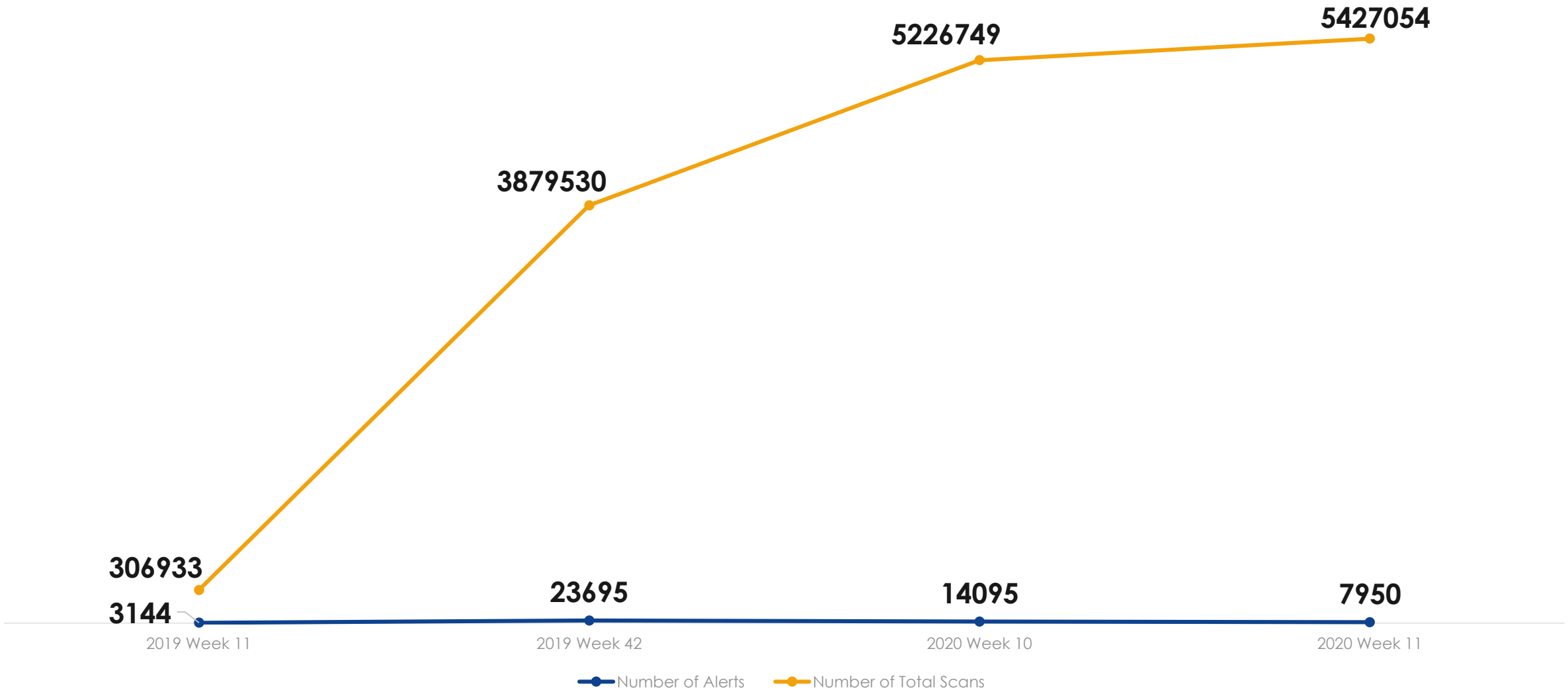
OVERVIEW OF END-USERS CONNECTION



	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	21	75	10
Connected	111	4921	191
Percentage remaining	15.91%	1.50%	4.98%

This reflects the data for End-Users connection in Luxembourg and in Belgium

OVERVIEW OF TOTAL OF ALERTS AND SCANS

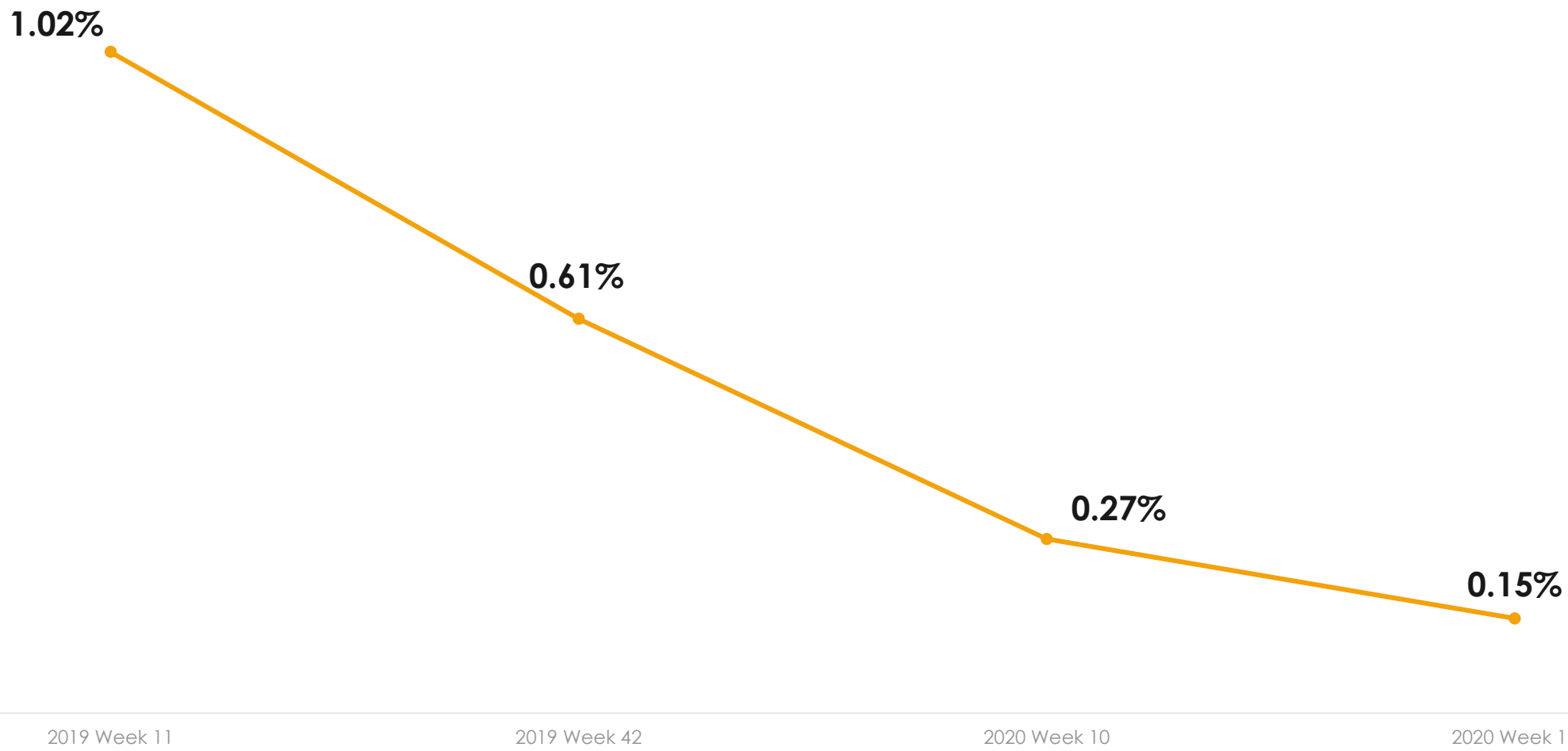


Calendar Week 12 2020
EMVO MONITORING REPORT

This reflects the data for alerts in Luxembourg and in Belgium

emvo European Medicines Verification Organisation

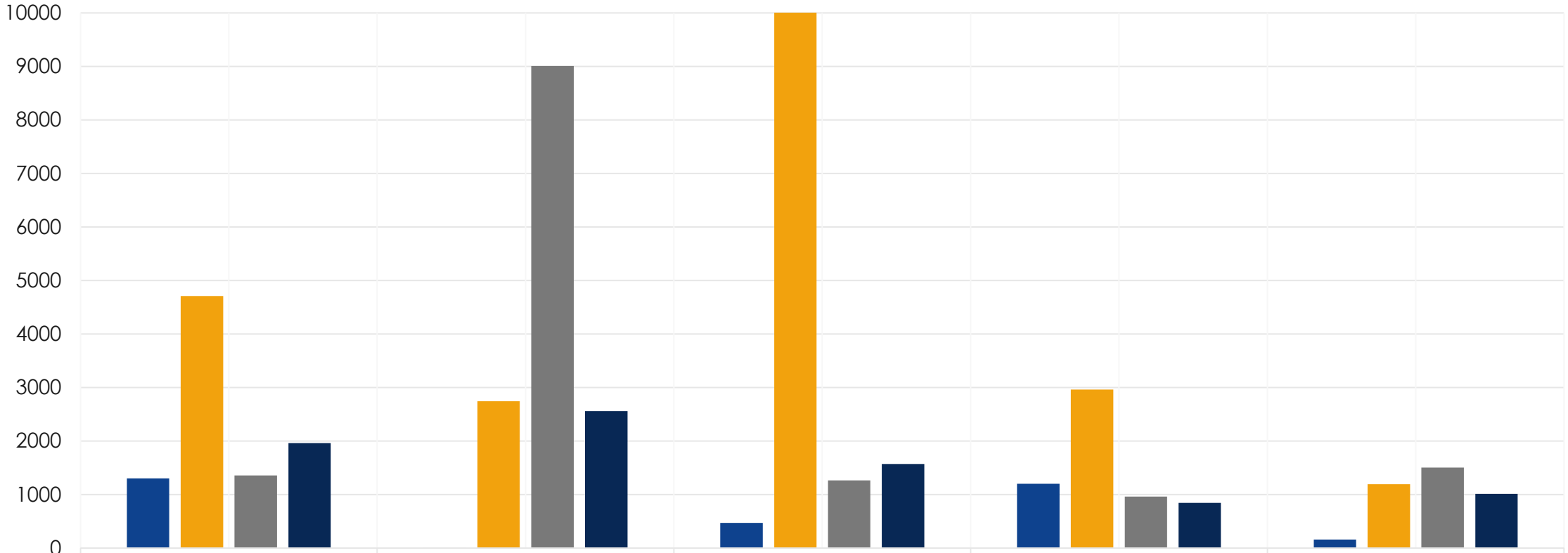
TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



emvo European Medicines Verification Organisation

This reflects the data for alerts in Luxembourg and in Belgium

ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 10.000



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	1302	10	472	1201	159
2019 Week 42	4708	2745	12089	2961	1192
2020 Week 10	1358	9007	1263	963	1504
2020 Week 11	1964	2560	1570	844	1012

This reflects the data for alerts in Luxembourg and in Belgium

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

The Luxembourgian NMVO has provided no particular insight for the past month.

HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
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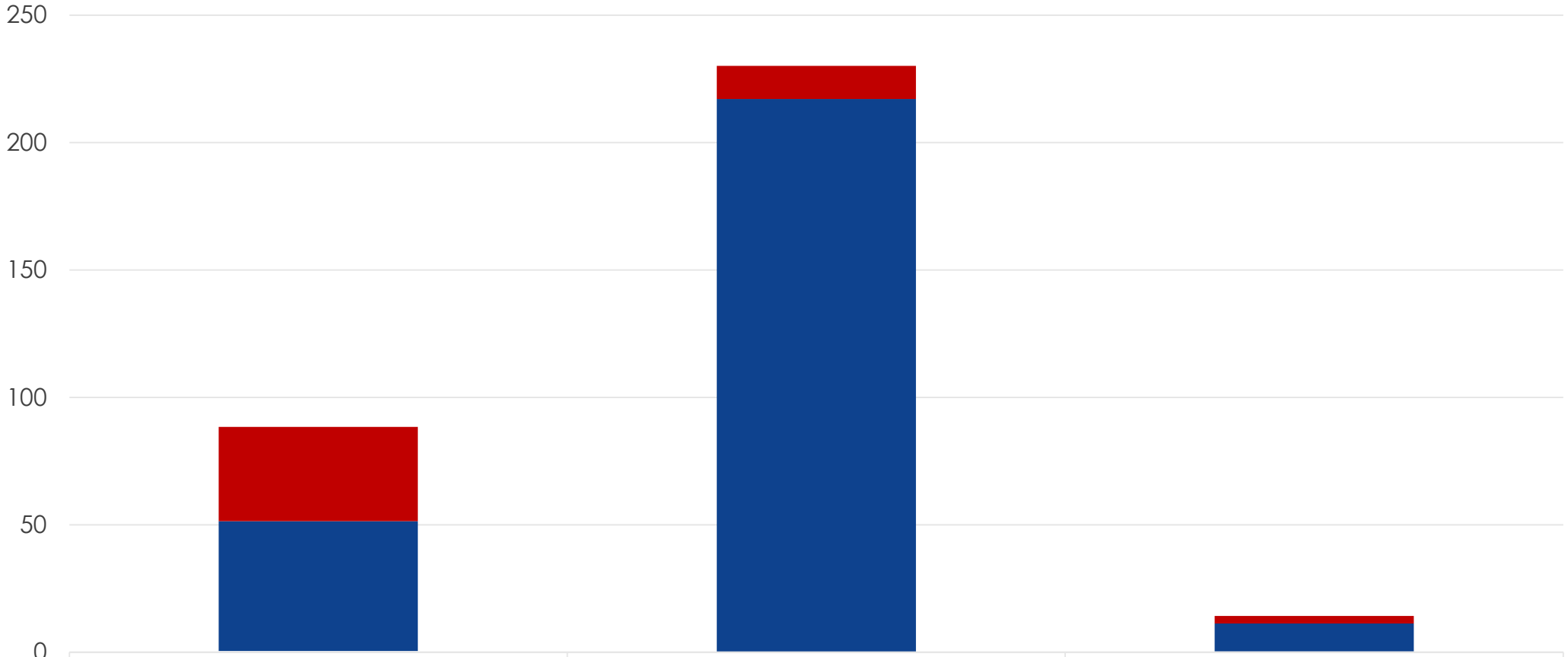
- Highlights of January
- Highlights of February

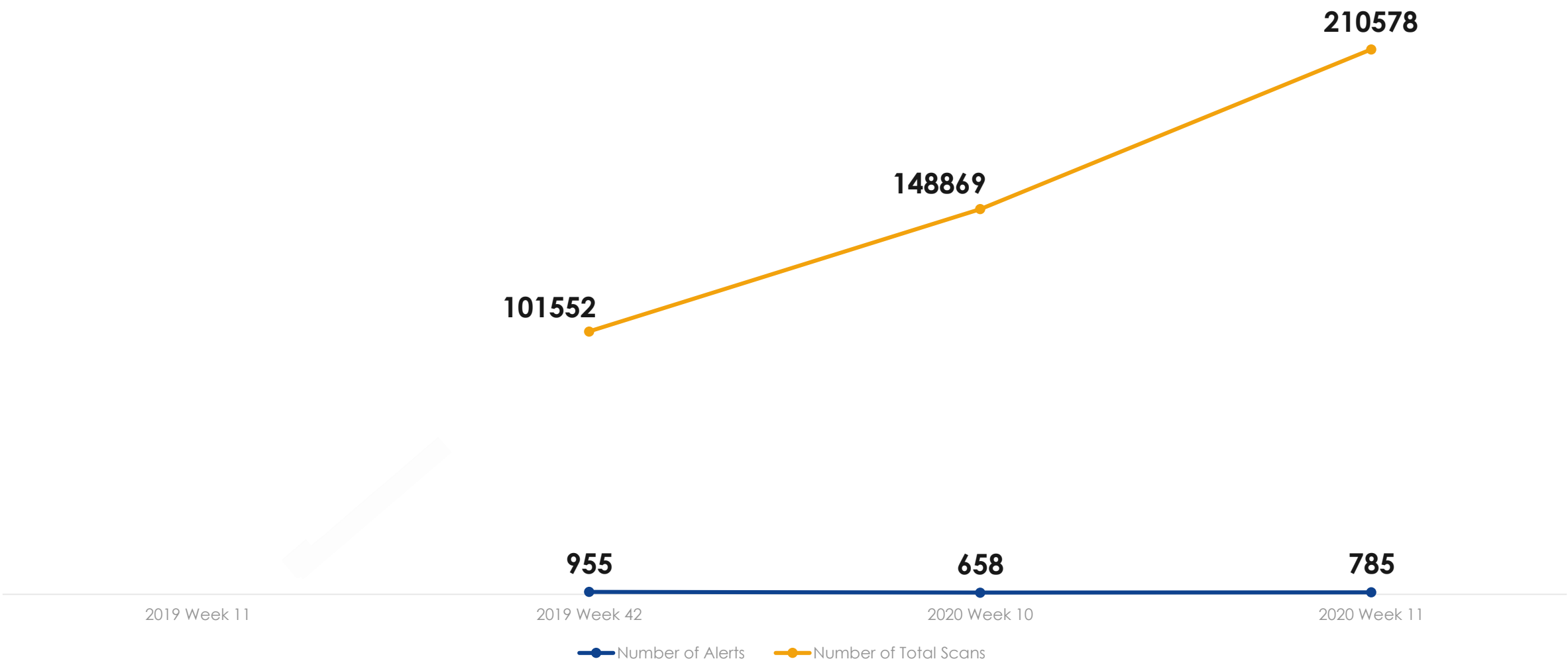
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION



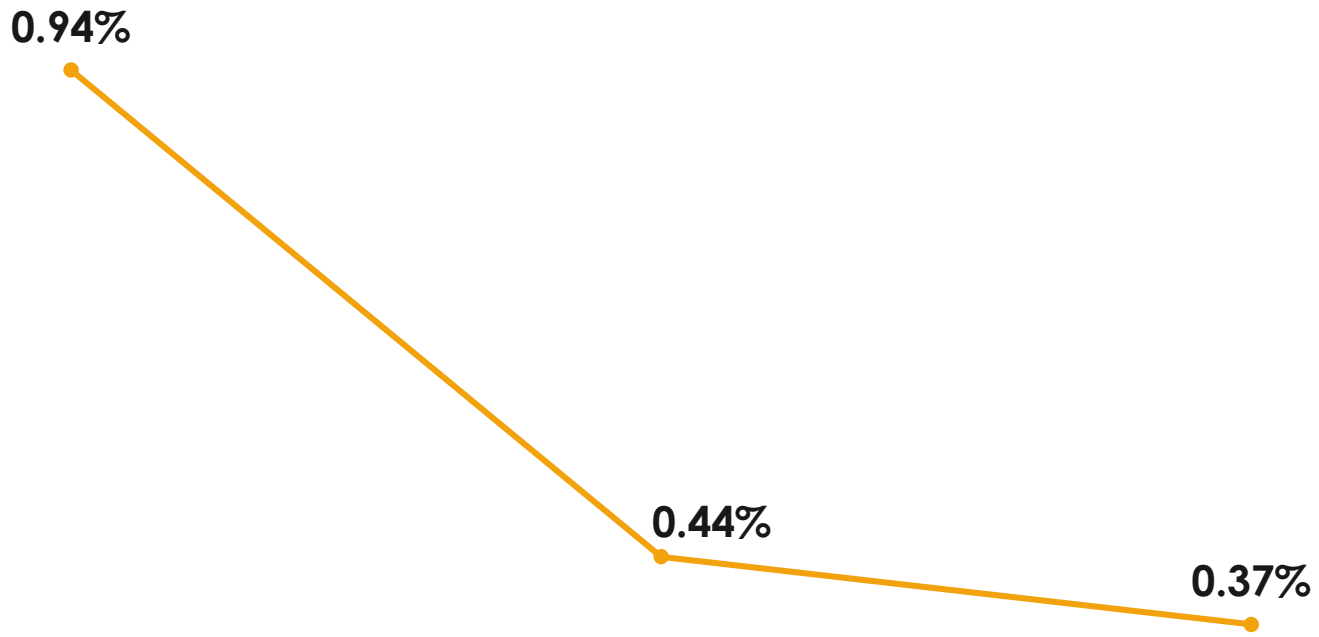
	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	37	13	3
Connected	51	217	11
Percentage remaining	42.05%	5.65%	21.43%

OVERVIEW OF TOTAL OF ALERTS AND SCANS



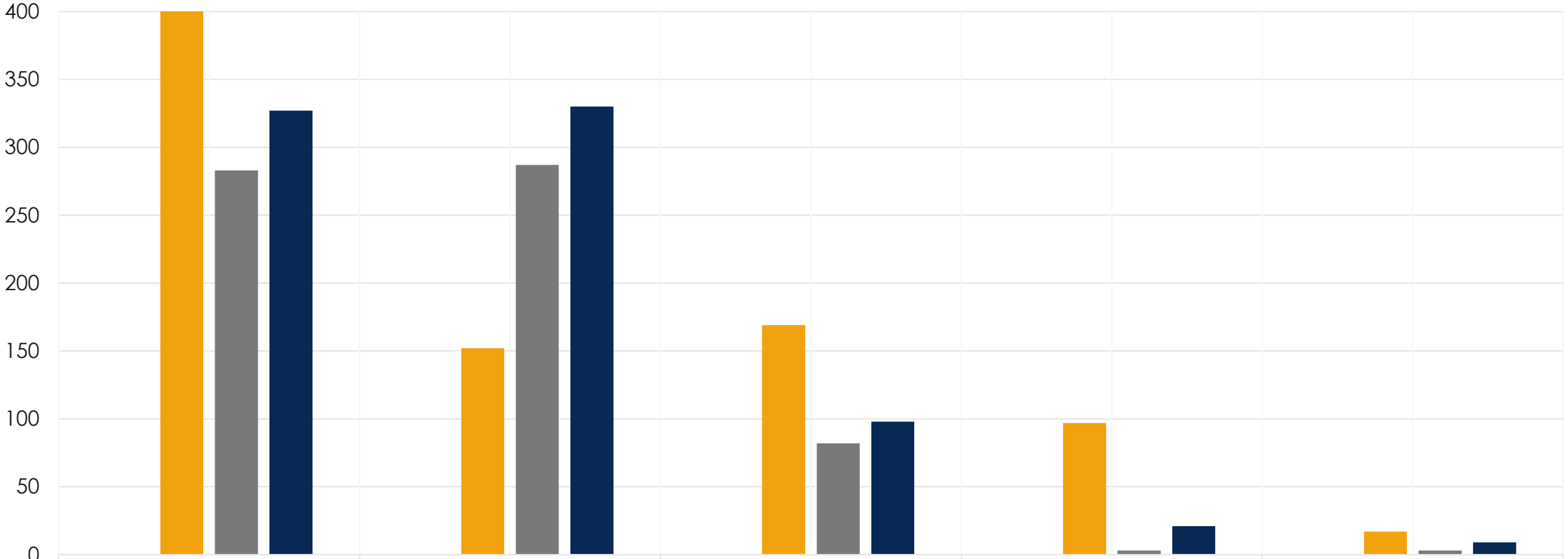
TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS

NB: Alert rates for Malta are strictly number of alerts caused by scans by local End-Users, expressed as a percentage of total number of local scans.



2019 Week 11 | 2019 Week 42 | 2020 Week 10 | 2020 Week 11

ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 400



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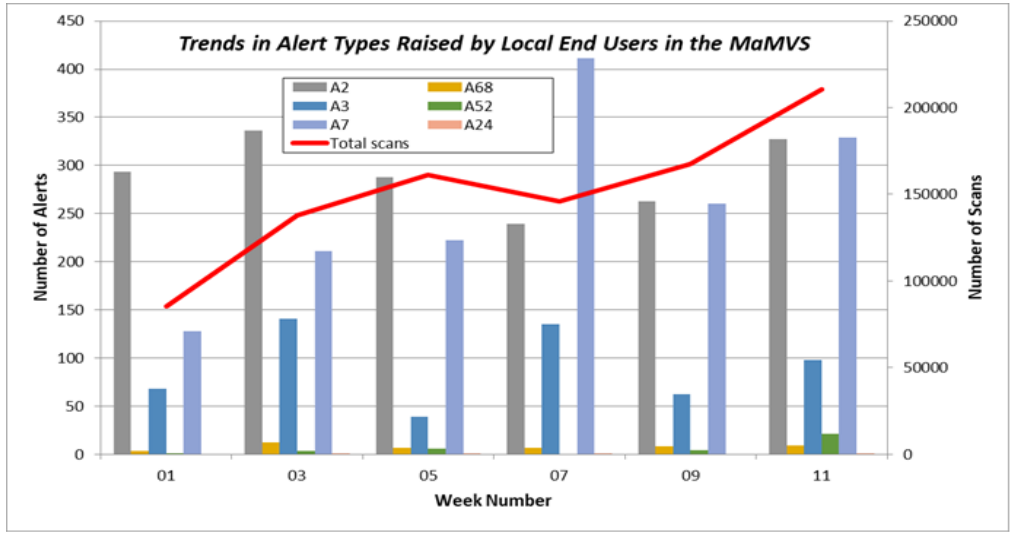
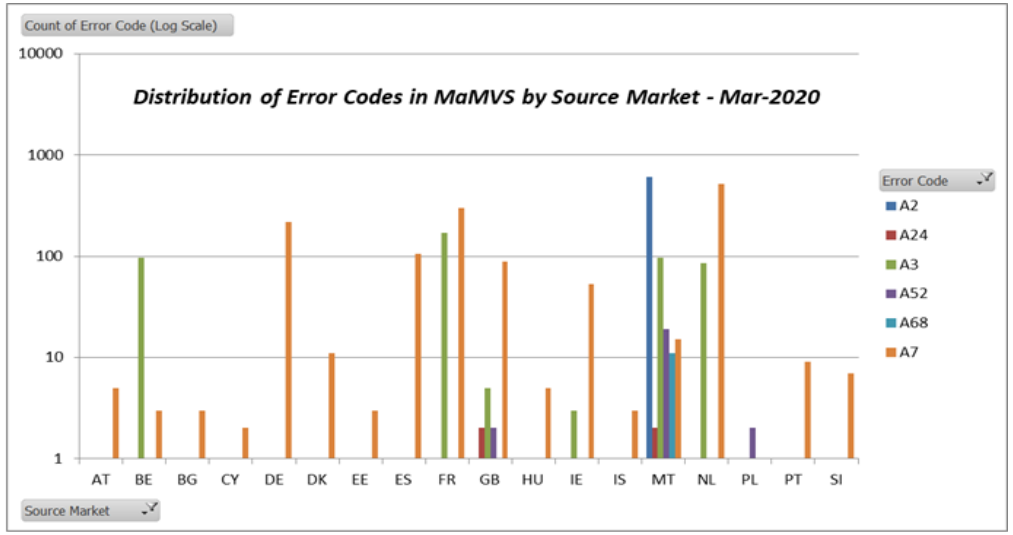
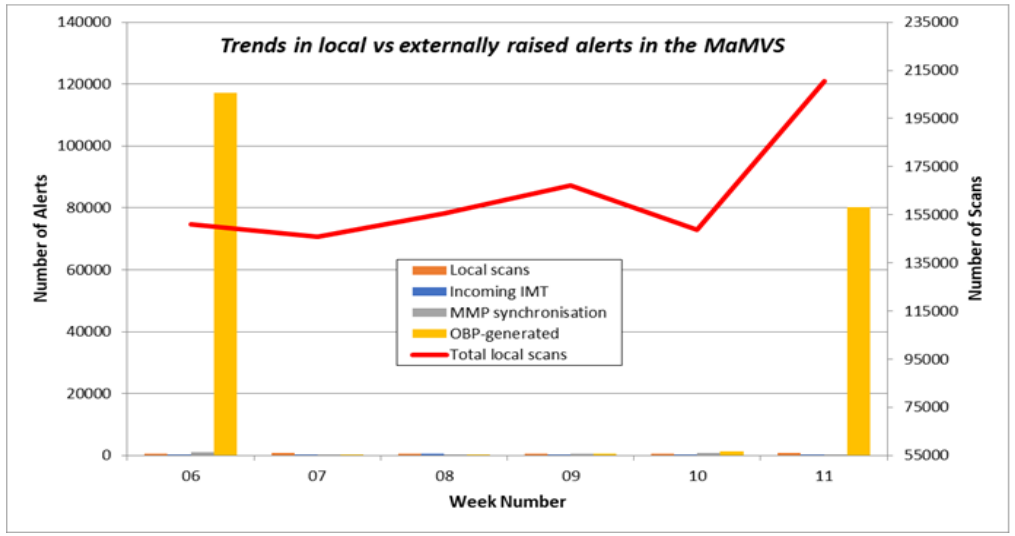
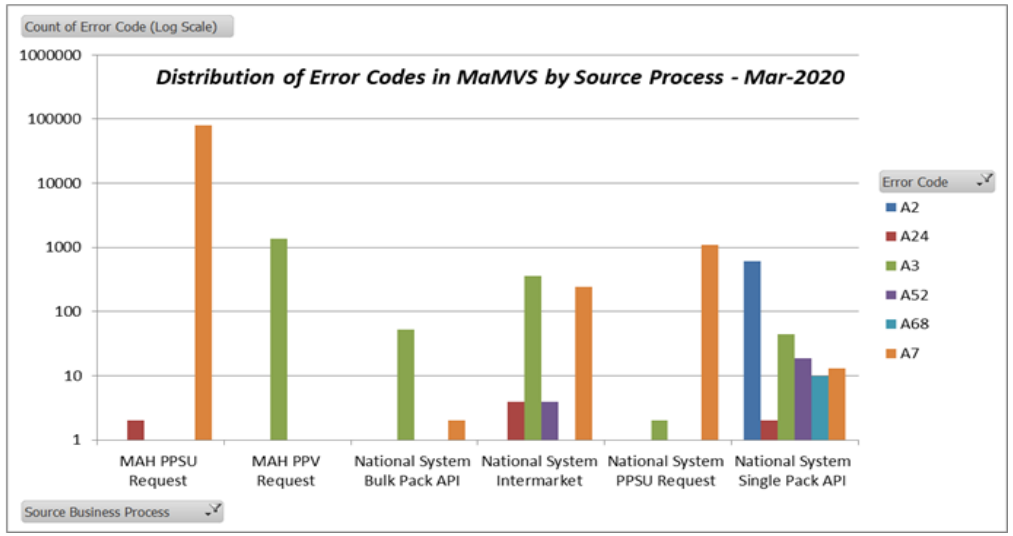
2019 Week 11					
2019 Week 42	520	152	169	97	17
2020 Week 10	283	287	82	3	3
2020 Week 11	327	330	98	21	9

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS









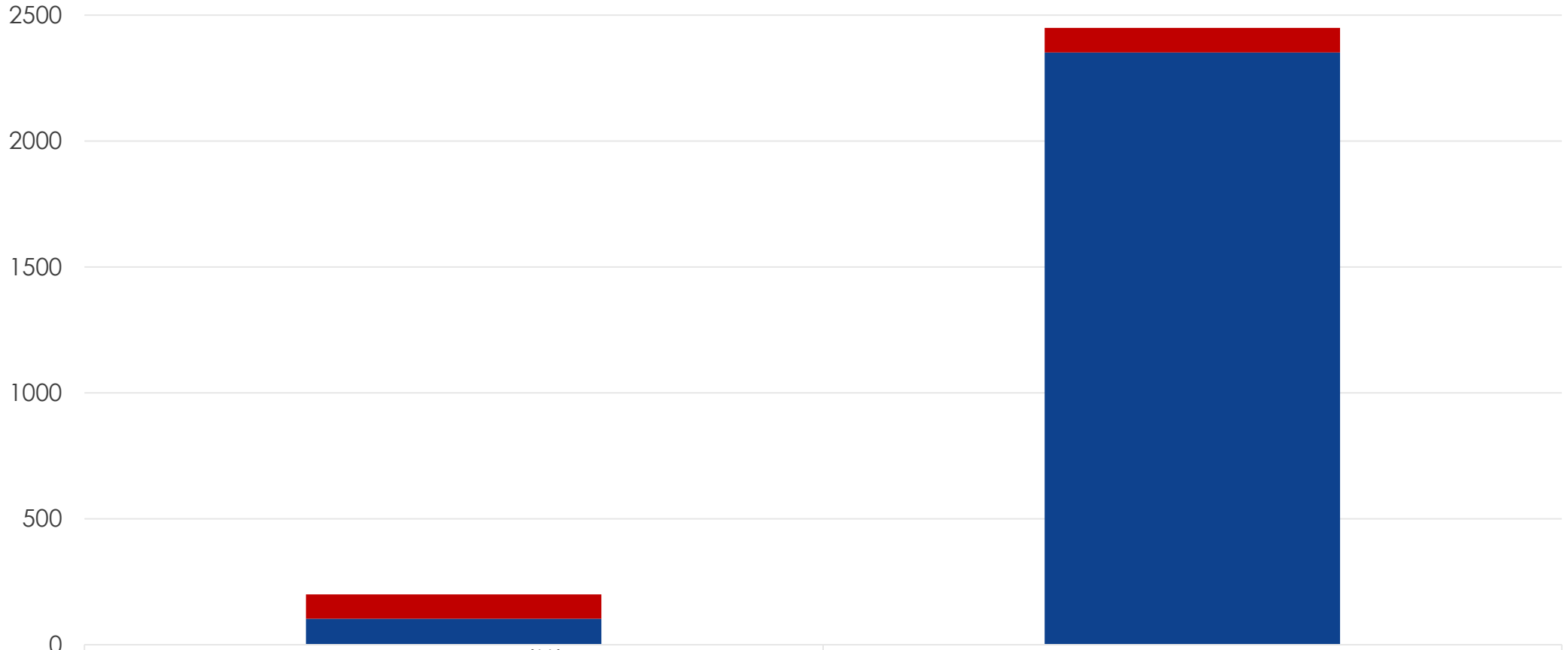
HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

NETHERLANDS

Back to the EEA map

OVERVIEW OF END-USERS CONNECTION(*)

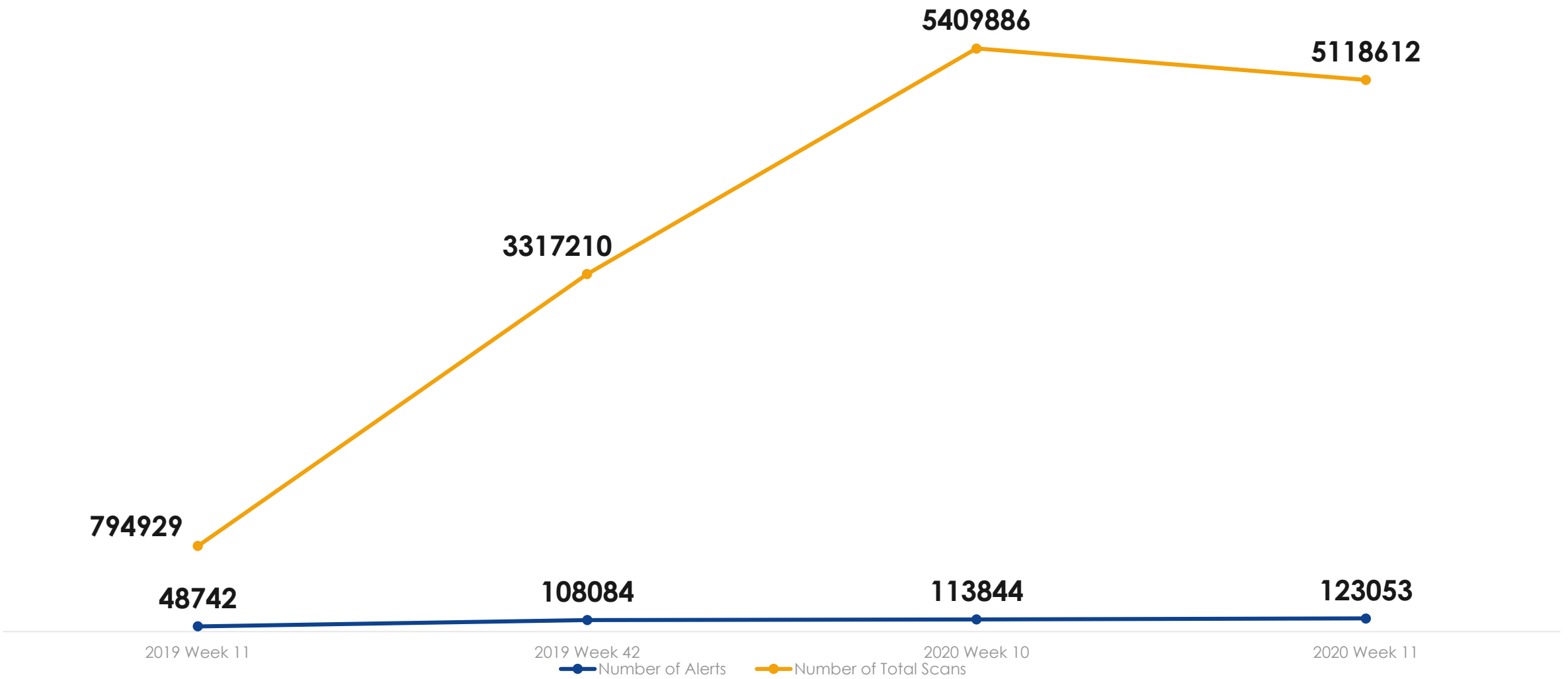


	Wholesalers (**)	Pharmacies
Not connected	97	98
Connected	103	2352
Percentage remaining	48.50%	4.00%

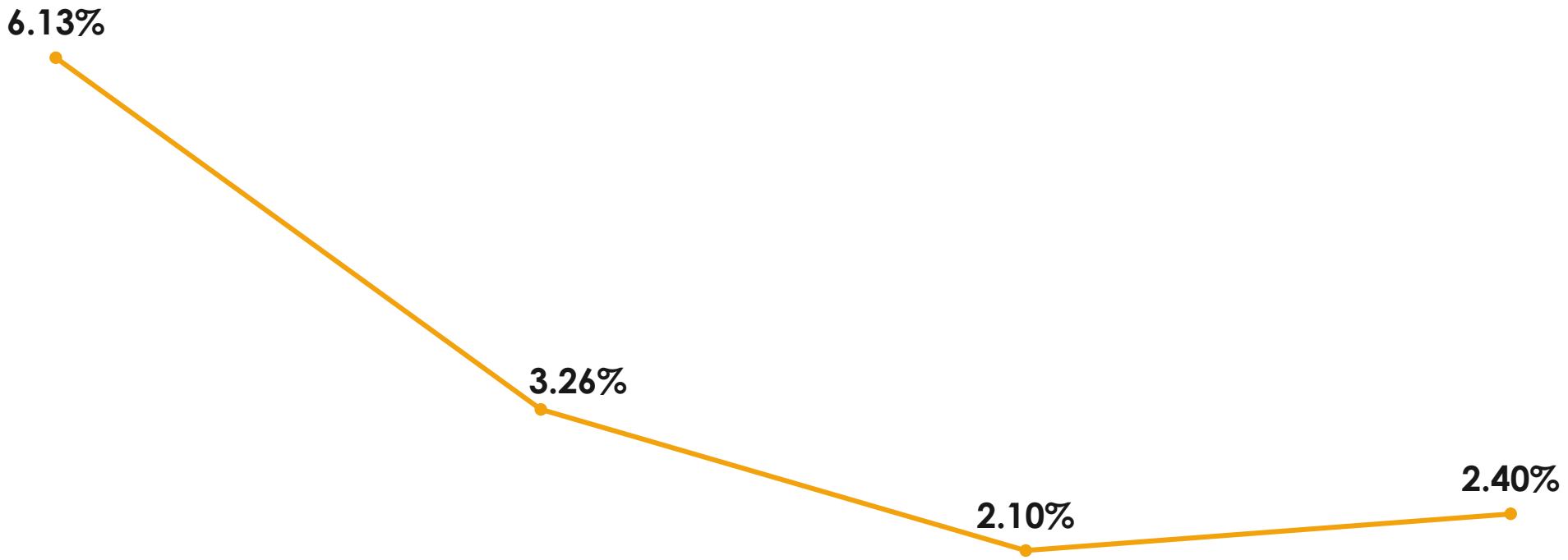
(**) NMVO is currently working closely with the NCA to identify the relevant baseline of wholesalers that have to be connected.

(*) In The Netherlands (NL) healthcare institutions are connected as pharmacies. Therefore, the On-boarding of healthcare institutions in NL is reflected in the overview on pharmacies connection.

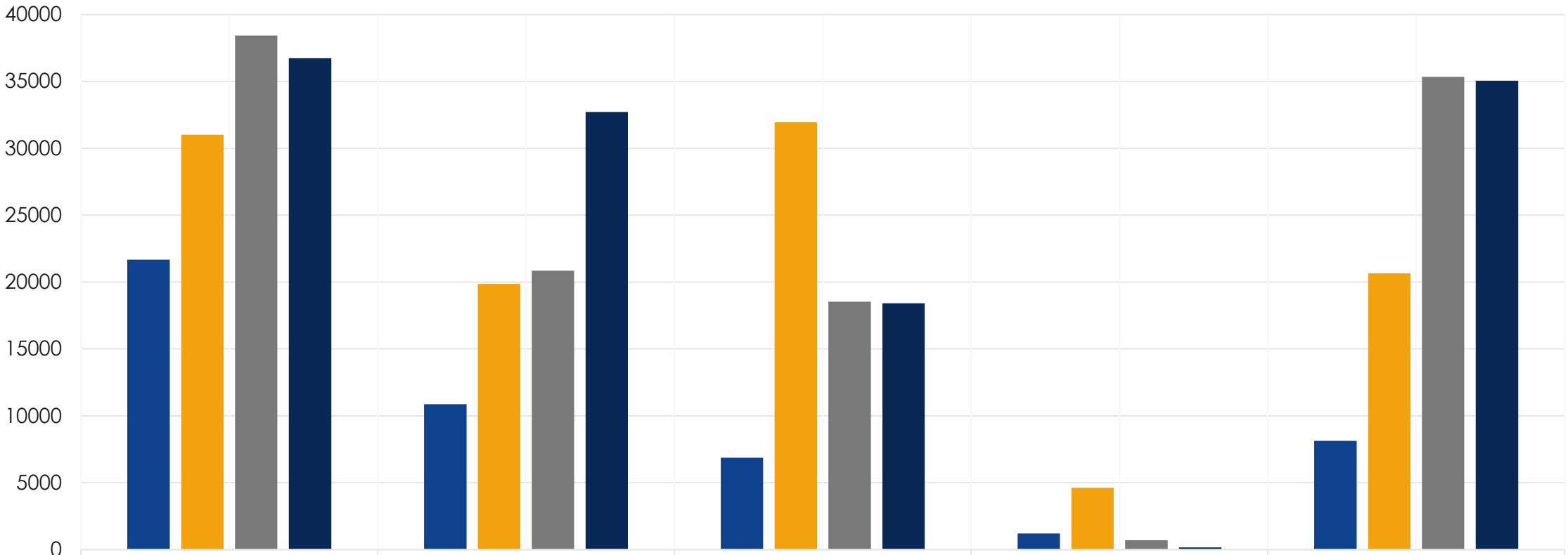
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	21669	10874	6866	1207	8126
2019 Week 42	31021	19856	31947	4607	20653
2020 Week 10	38432	20841	18527	701	35343
2020 Week 11	36723	32710	18408	167	35045

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

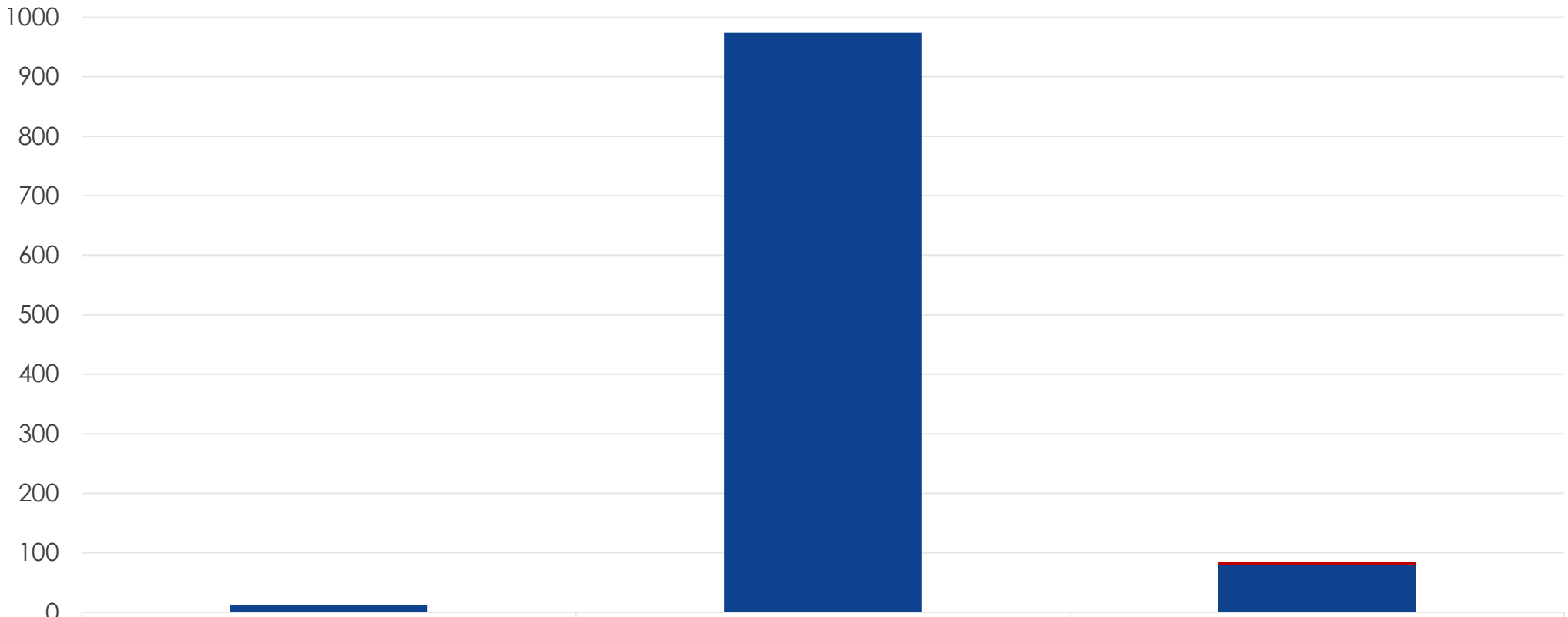
The Dutch NMVO has provided no particular insight for the past 4 weeks.

HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

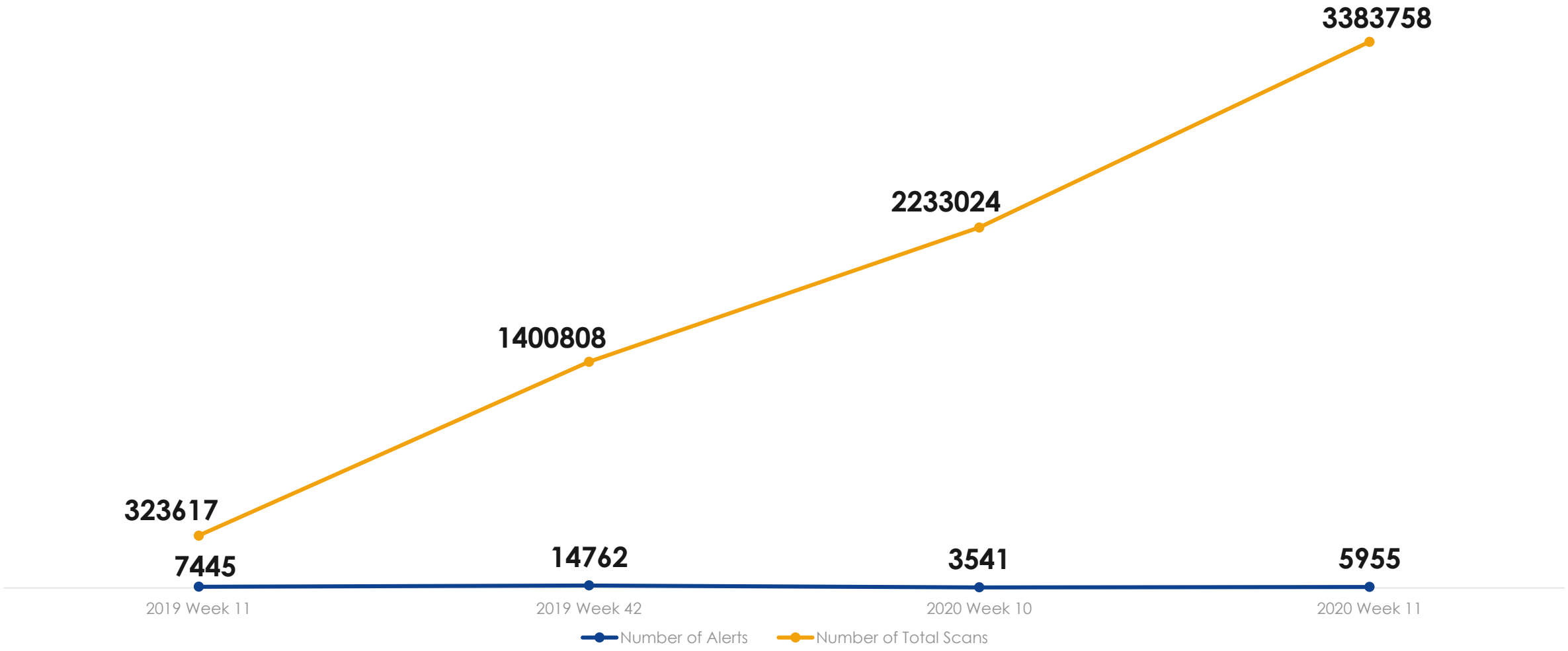
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

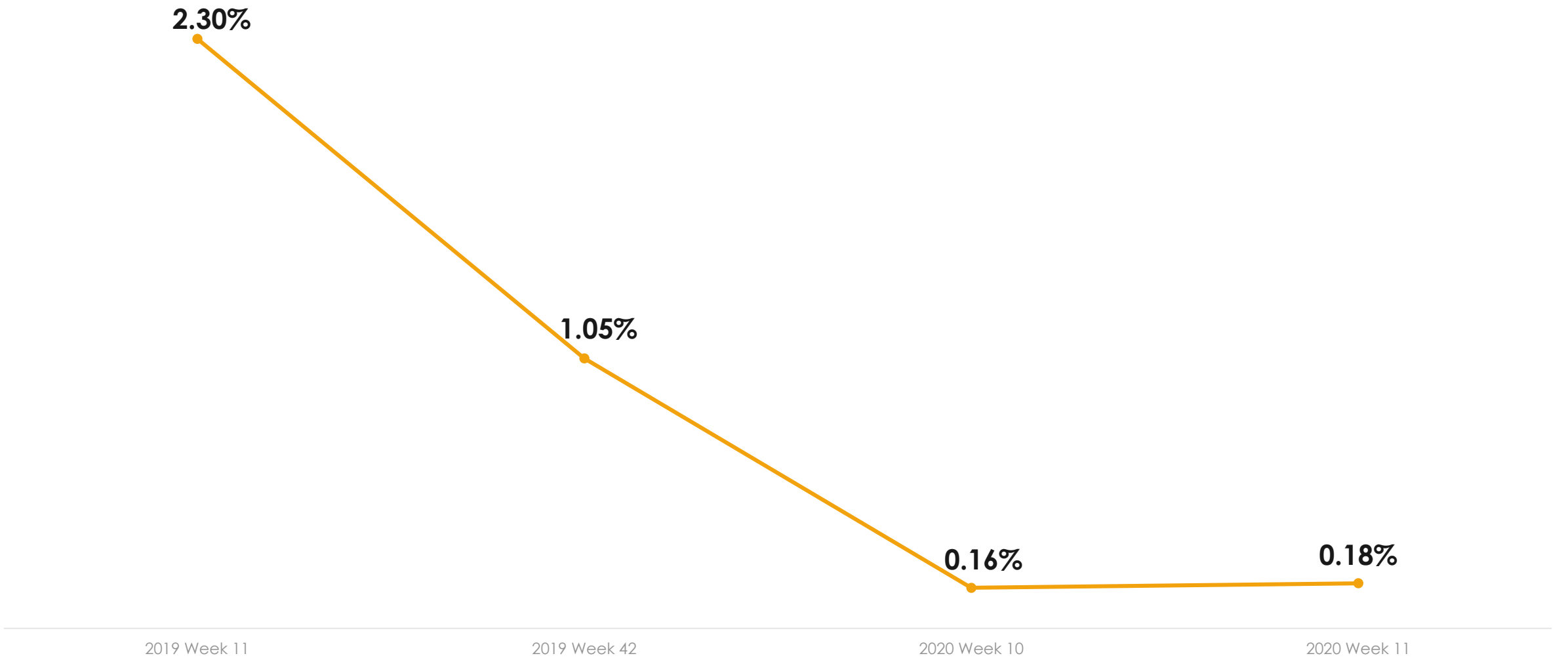


	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	0	0	4
Connected	12	974	81
Percentage remaining	0.00%	0.00%	4.71%

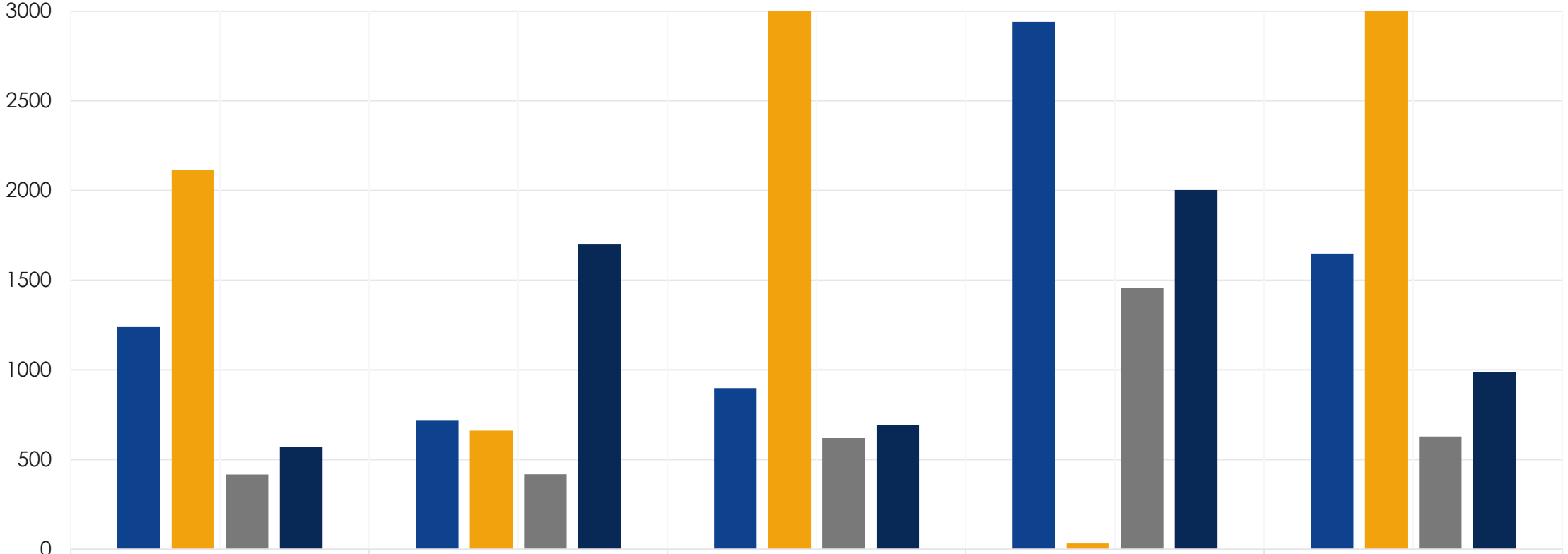
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE : ALERTS PER CATEGORY PER WEEK CAP 3.000



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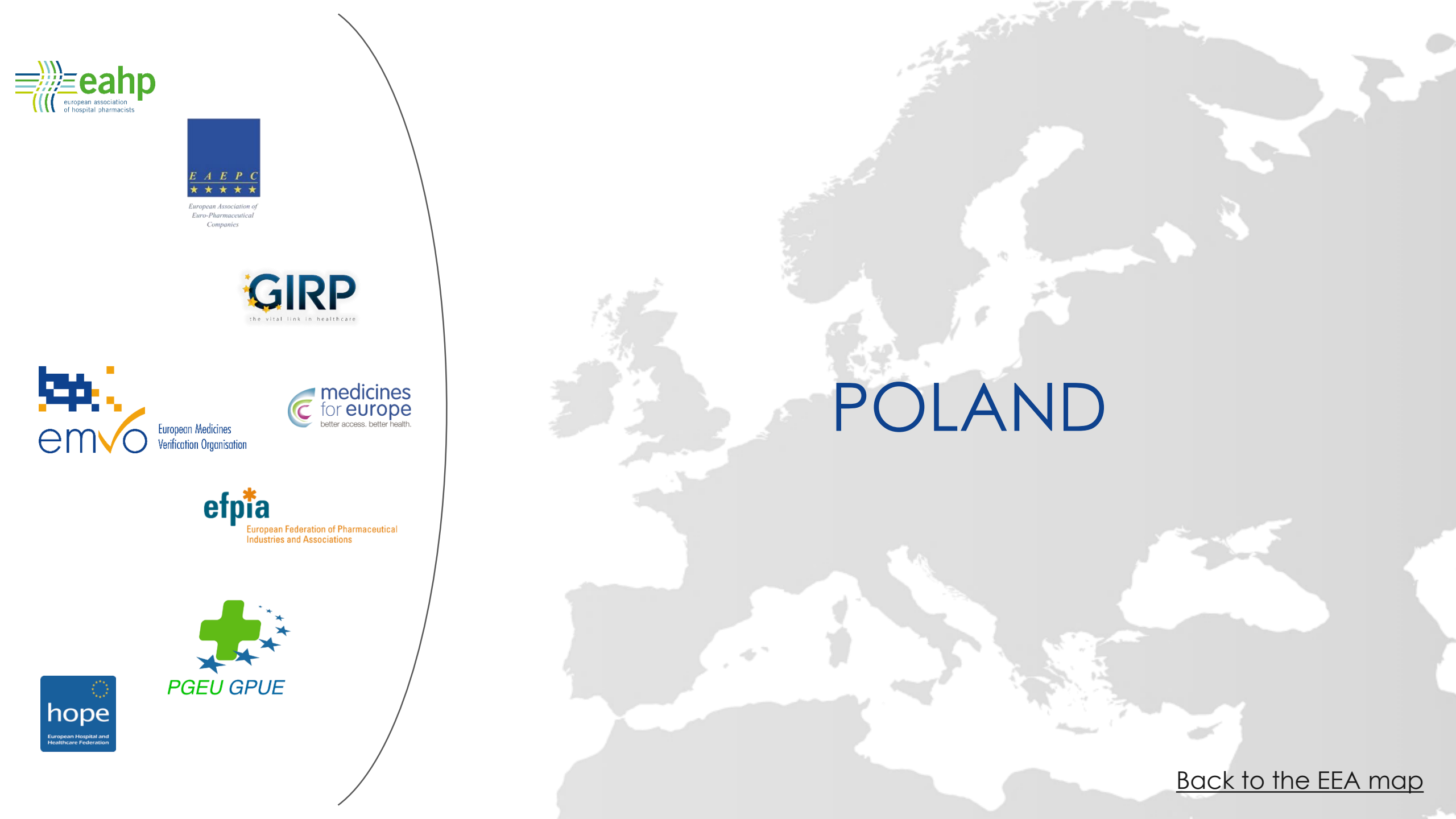
2019 Week 11	1239	717	899	2941	1649
2019 Week 42	2113	661	3740	32	8216
2020 Week 10	417	418	620	1457	629
2020 Week 11	571	1699	693	2003	989

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

The Norwegian NMVO has provided no particular insight for the past 4 weeks.

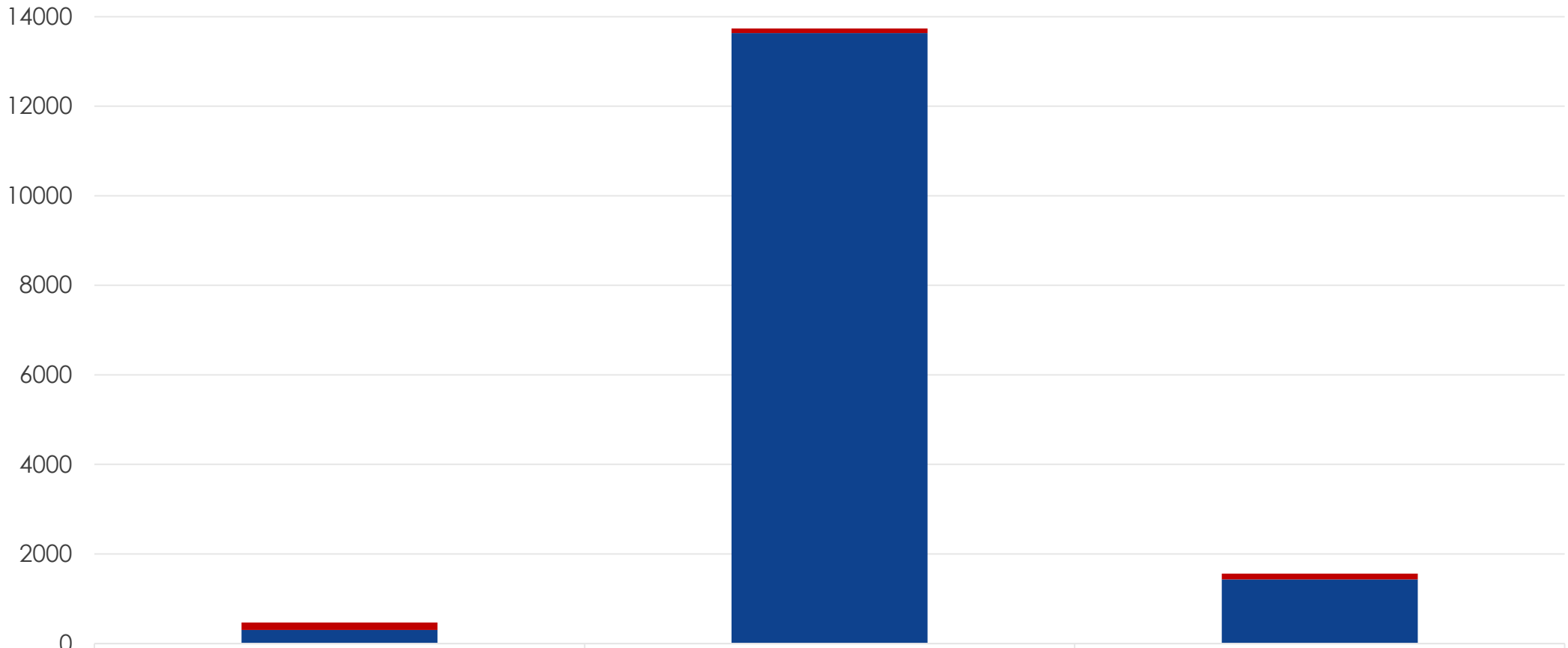
HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February



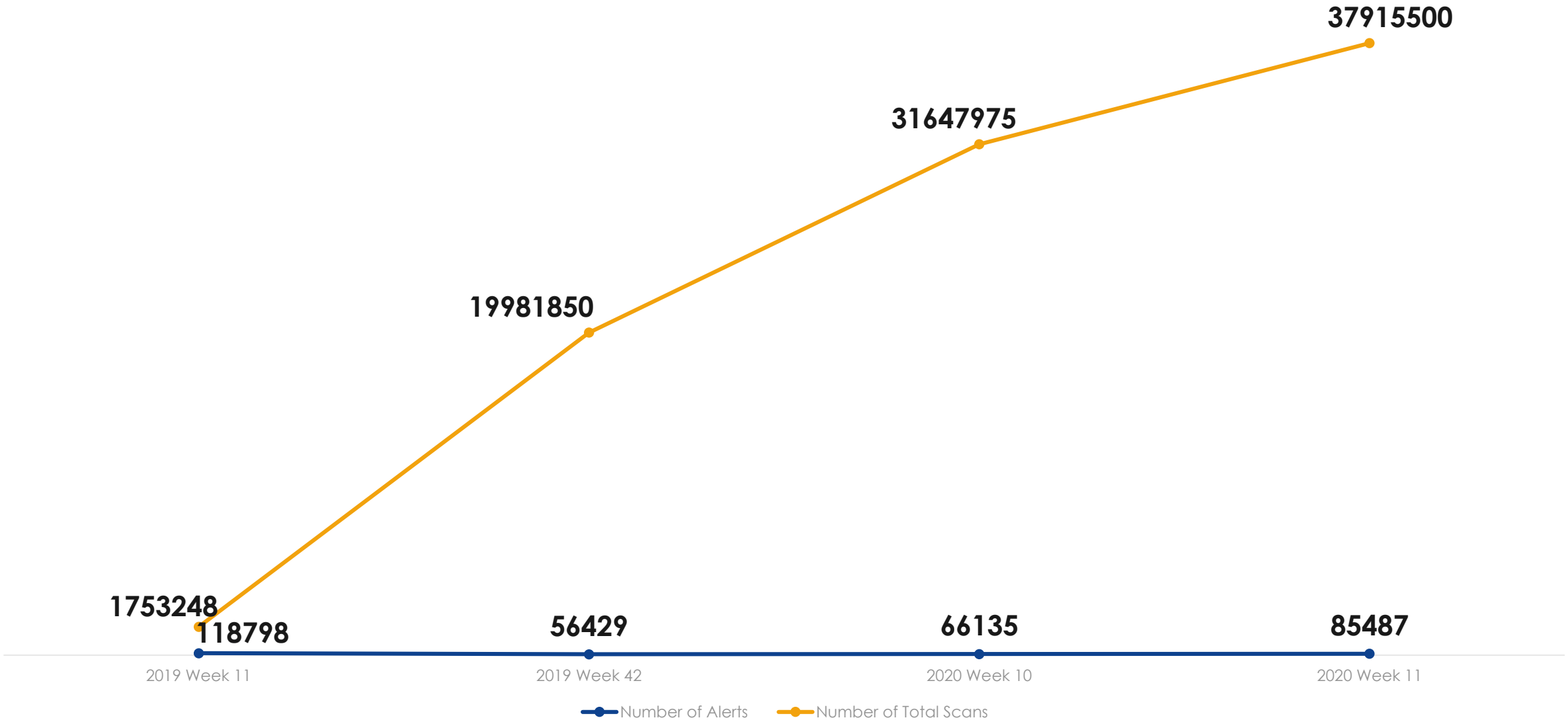
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

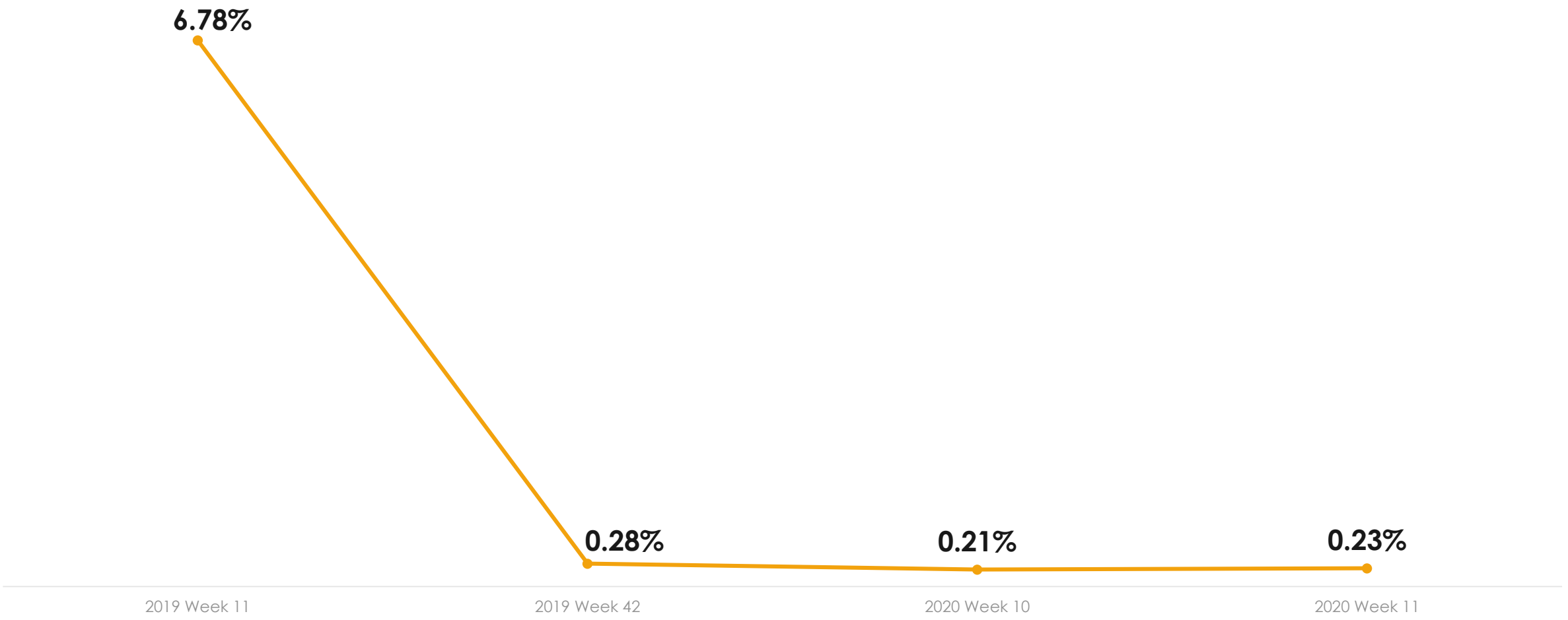


	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	168	103	125
Connected	302	13633	1435
Percentage remaining	35.74%	0.75%	8.01%

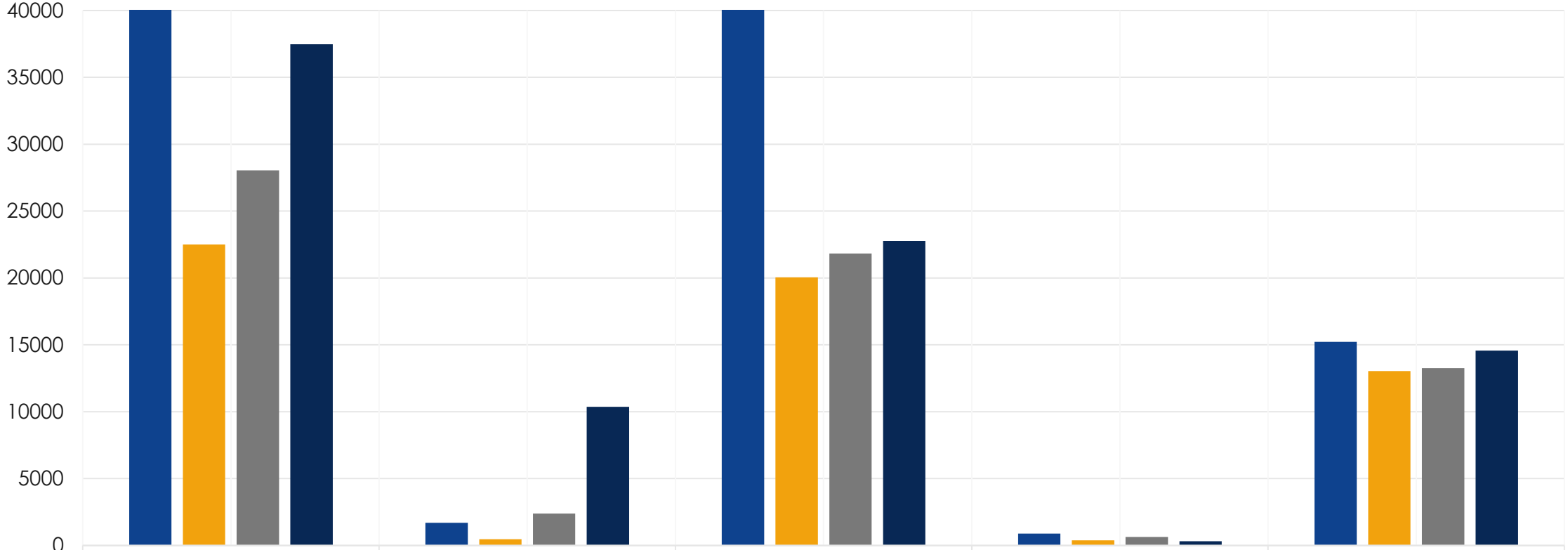
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 40.000



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	50342	1694	50661	886	15215
2019 Week 42	22500	461	20047	385	13036
2020 Week 10	28050	2378	21823	627	13257
2020 Week 11	37478	10362	22769	306	14572

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

- During week 9, there was an increase of A3 Alerts due to one OBP who bulk verified circa 5000 items via the EU HUB (packs were not uploaded). Moreover there is one major IT supplier whose clients overuse CapsLock (Pharmacies below/SNs with letters), but this supplier just migrated over 6000 of his users to a new version of the software that corrects the user mistake. The differences from week 9 to 8 (on the total number of alerts) have been detailed in the table below.

Week 8		Week 9			
User group	***% of alerts***	***User group***	***% of alerts***	***Difference CW9-CW8***	***Reason***
Pharmacies	65%	Pharmacies	62%	+4 935	Analysis in progress (large number of multiple resons)
Wholesalers	15%	Wholesalers	18%	+3 724	One wholesaler acccidentally bulk duspensed twice two Batches of two products (over 10K items)
OBPs	7%	OBPs	10%	+3 444	One OBP with two MAHs bulk verified not uploaded SNs (ca 5000 items)
Hospitals	13%	Hospitals	10%	-883	Decrease
				+11 220	

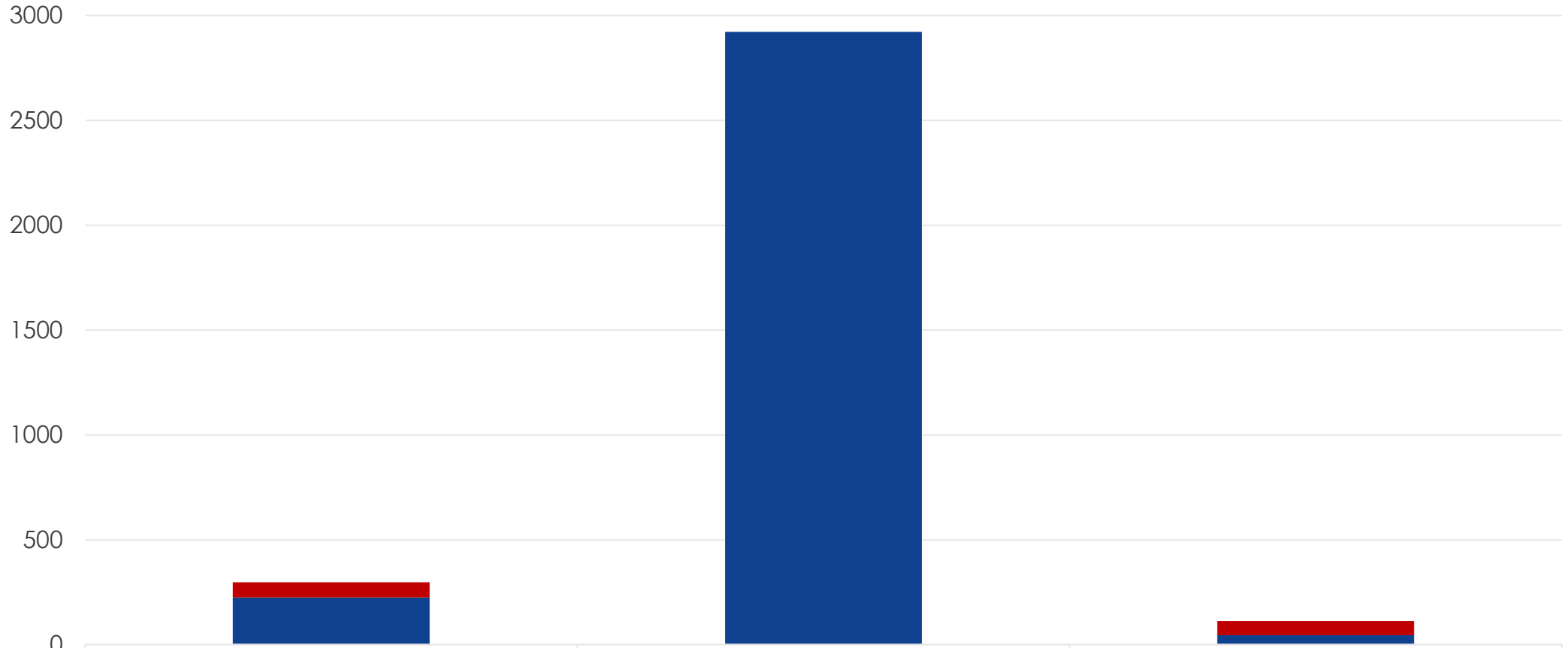
- During this period, the system has known an increase of almost 1,7 mio in activity (6% growth of scans) and a 650K growth of successfully dispensed packs (7% growth).

HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

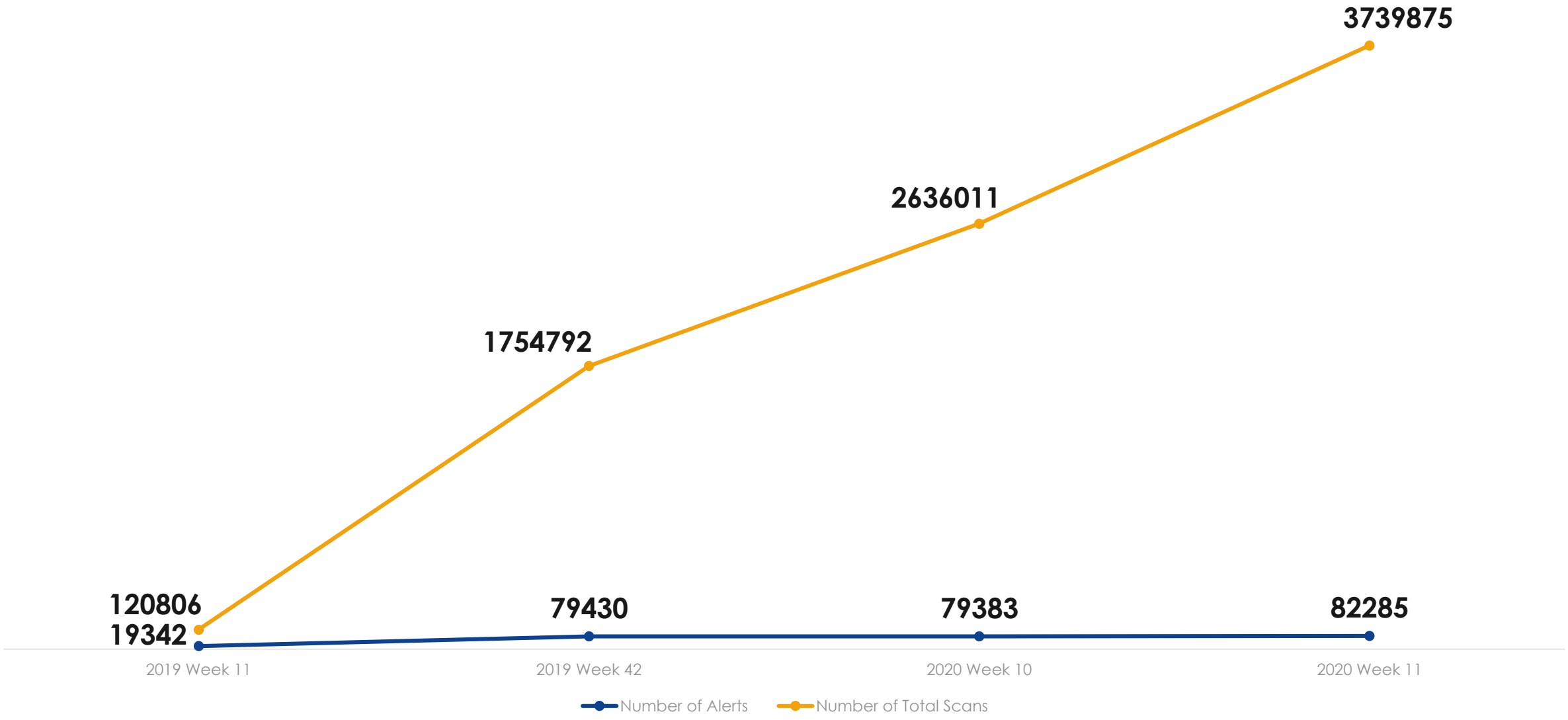
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

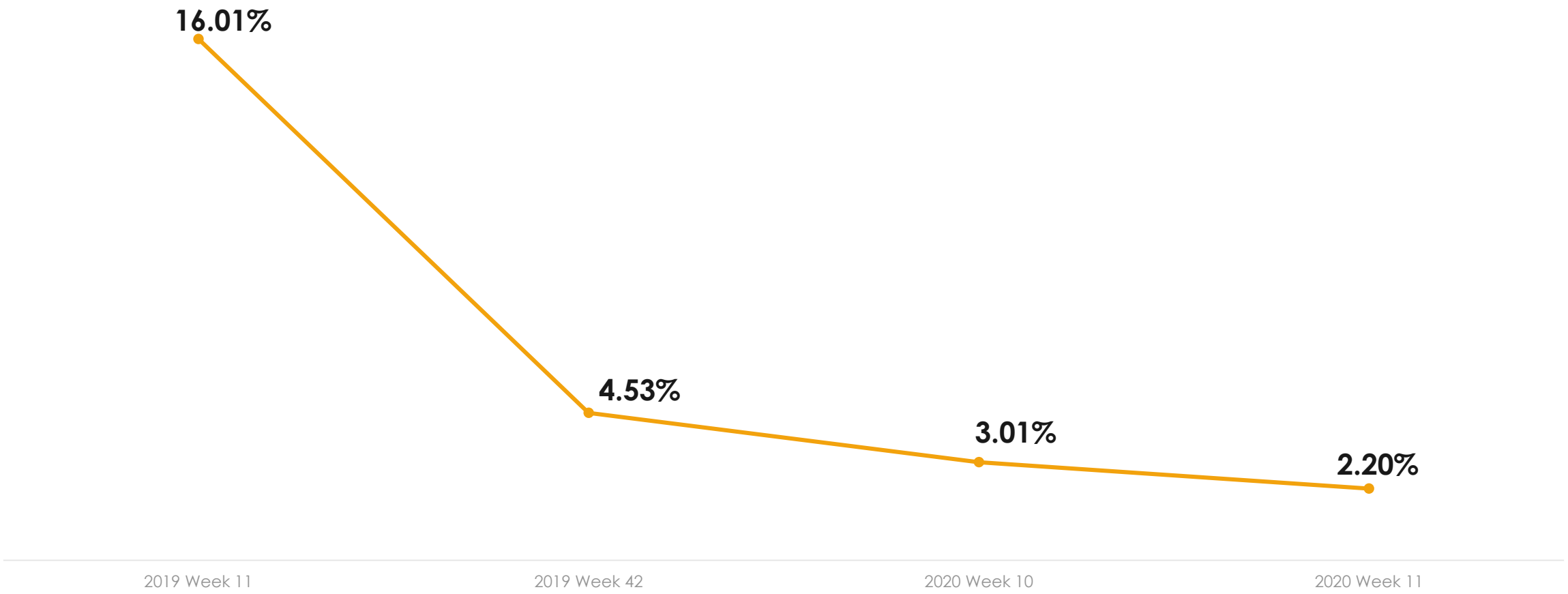


	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	72	0	67
Connected	225	2922	45
Percentage remaining	24.24%	0.00%	59.82%

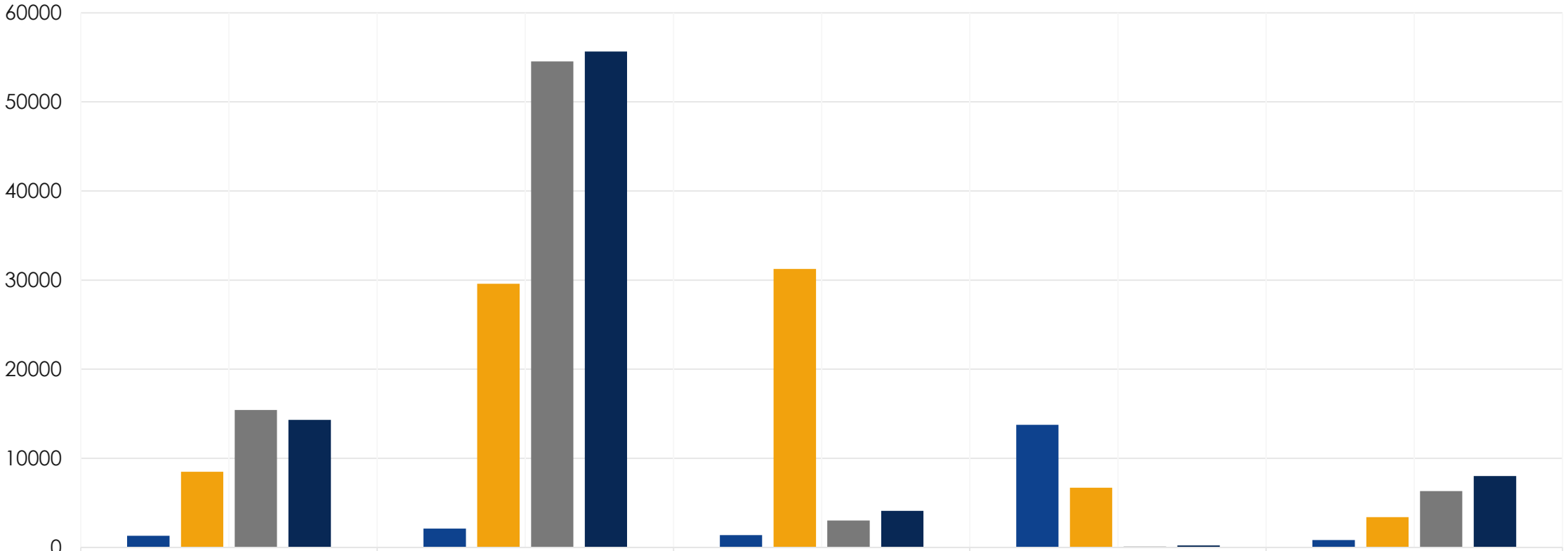
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	1291	2106	1370	13764	811
2019 Week 42	8479	29589	31254	6705	3403
2020 Week 10	15414	54556	3008	93	6312
2020 Week 11	14299	55650	4108	221	8007

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

The total number of alerts in Portugal was significantly higher in week 9, due to a software deployment at end-user side that has caused loops, generating multiple alerts for the same serial number at fixed time intervals.

HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
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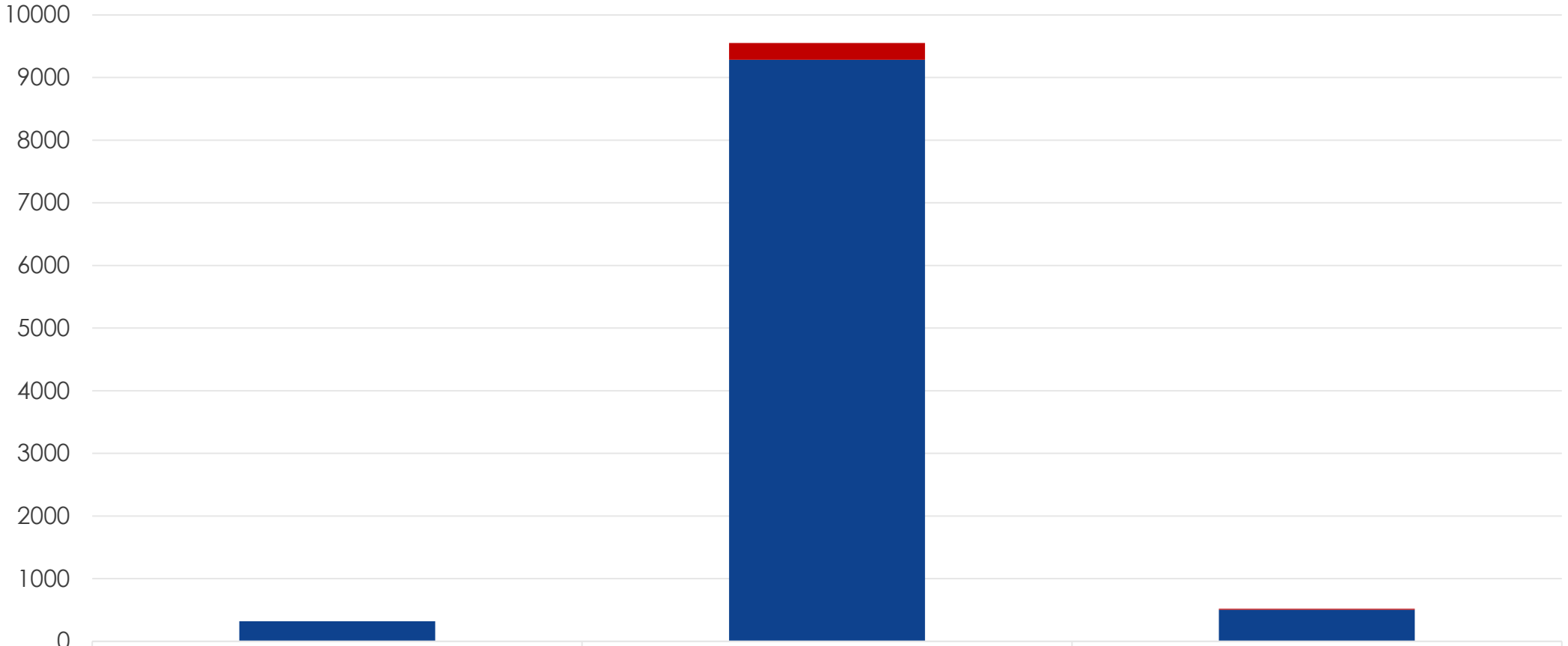
- Highlights of February

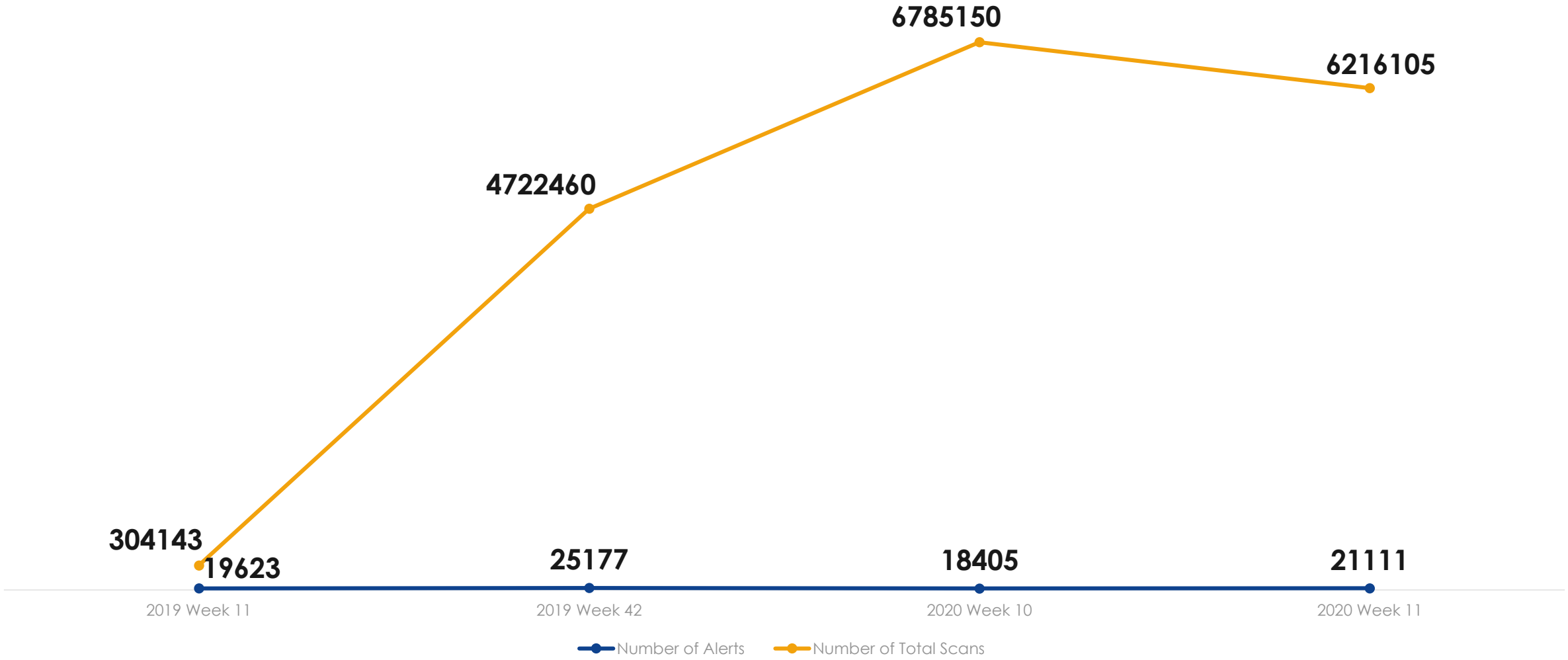
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

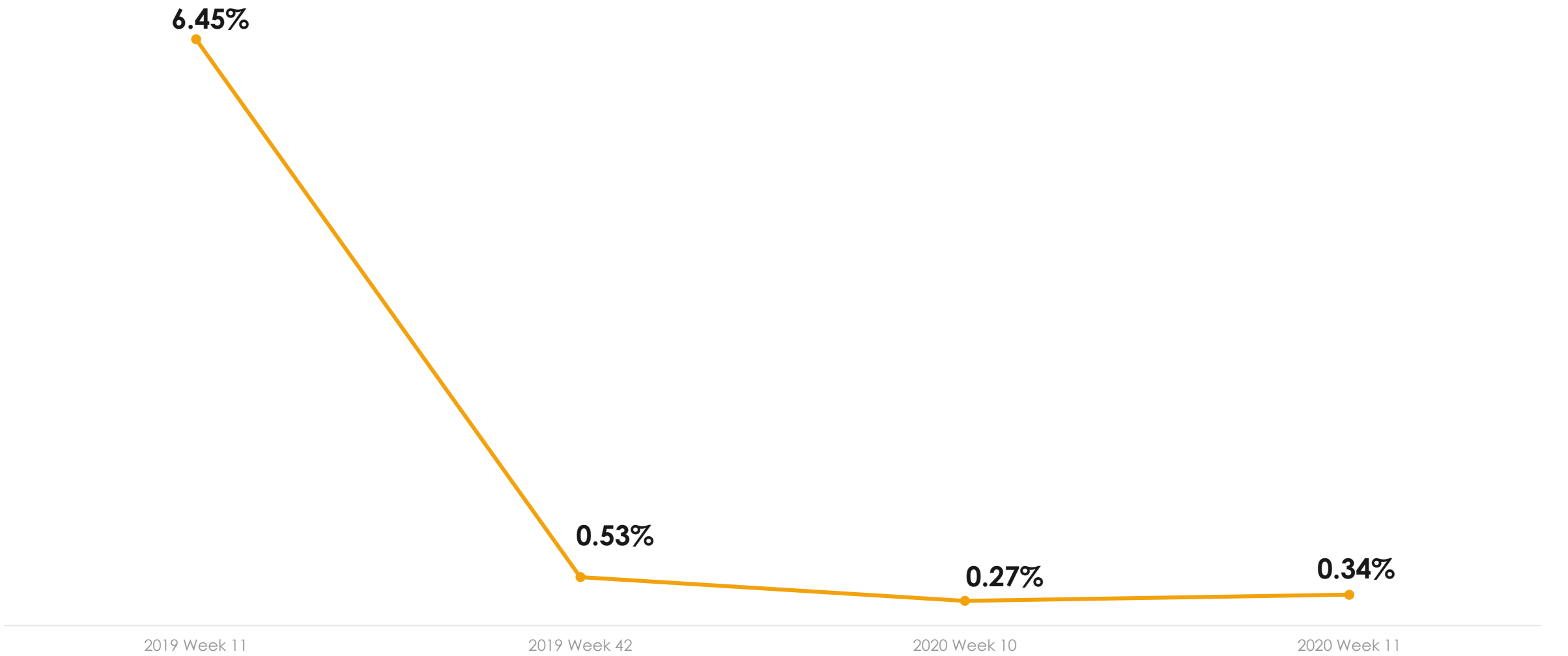


	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	0	267	17
Connected	320	9284	503
Percentage remaining	0.00%	2.80%	3.27%

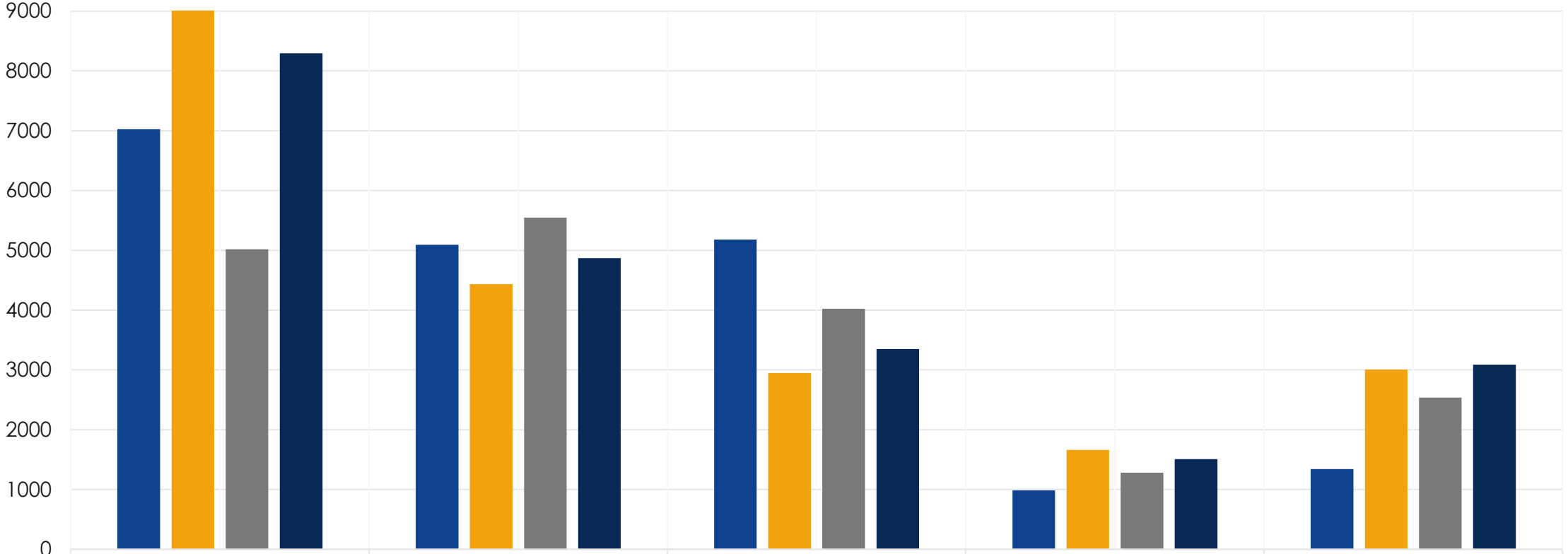
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION WITH THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 9.000



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	7025	5092	5178	987	1341
2019 Week 42	13123	4436	2949	1662	3007
2020 Week 10	5017	5546	4024	1282	2536
2020 Week 11	8296	4871	3349	1507	3088

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

Analysis of A7&A24 in Week 8

Hospital NoOfAlerts		
2	NMVS_NC_PCK_19	Property is already set on pack.
402	NMVS_NC_PCK_22	Pack is already inactive.
PHARMACY NoOfAlerts		
776	NMVS_NC_PCK_22	Pack is already inactive.
WHOLESALER NoOfAlerts		
4	NMVS_NC_PCK_19	Property is already set on pack.
125	NMVS_NC_PCK_22	Pack is already inactive.
NoOfAlerts-EMVO-OBP		
530	NMVS_NC_PCK_22	Pack is already inactive.
NoOfAlerts-EMVO-IMT		
84	NMVS_NC_PCK_19	Property is already set on pack.

Analysis of A7&A24 in Week 9

Hospital NoOfAlerts		
1	NMVS_NC_PCK_19	Property is already set on pack.
485	NMVS_NC_PCK_22	Pack is already inactive.
PHARMACY NoOfAlerts		
691	NMVS_NC_PCK_22	Pack is already inactive.
1	NMVS_NC_PCK_19	Property is already set on pack.
WHOLESALER NoOfAlerts		
931	NMVS_NC_PCK_22	Pack is already inactive.
NoOfAlerts-EMVO-OBP		
4236	NMVS_NC_PCK_22	Pack is already inactive.
NoOfAlerts-EMVO-IMT		
194	NMVS_NC_PCK_19	Property is already set on pack.

ROOT CAUSE FOR BOTH WEEKS

- Root cause for Hospitals and Pharmacy is the fractional sale.
- Root cause for WHOLESALER is IMT prepare.
- Root cause for EMVO/OBP is the OBP transactions.
- End Users from Hospitals, Pharmacy and WHOLESALER were contacted.

HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
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- Highlights weeks 29 and 30
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SLOVAKIA

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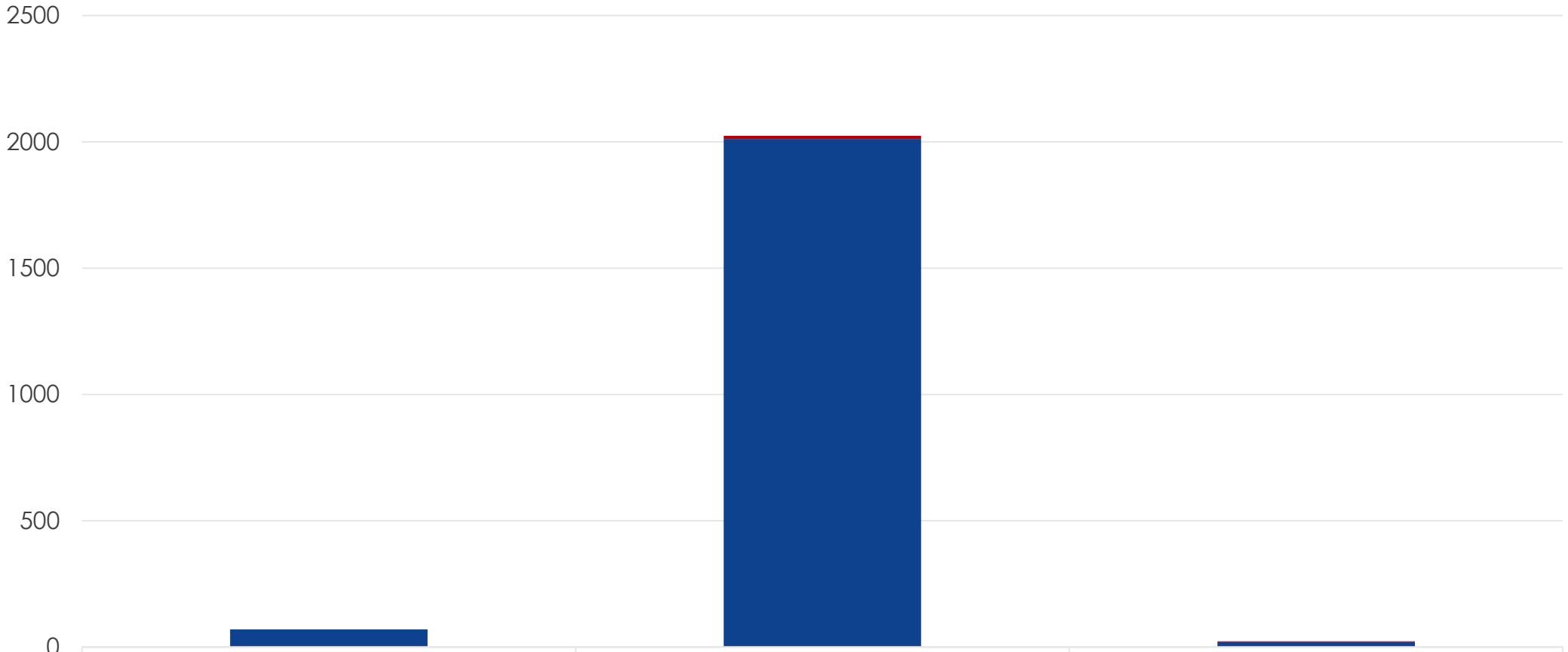
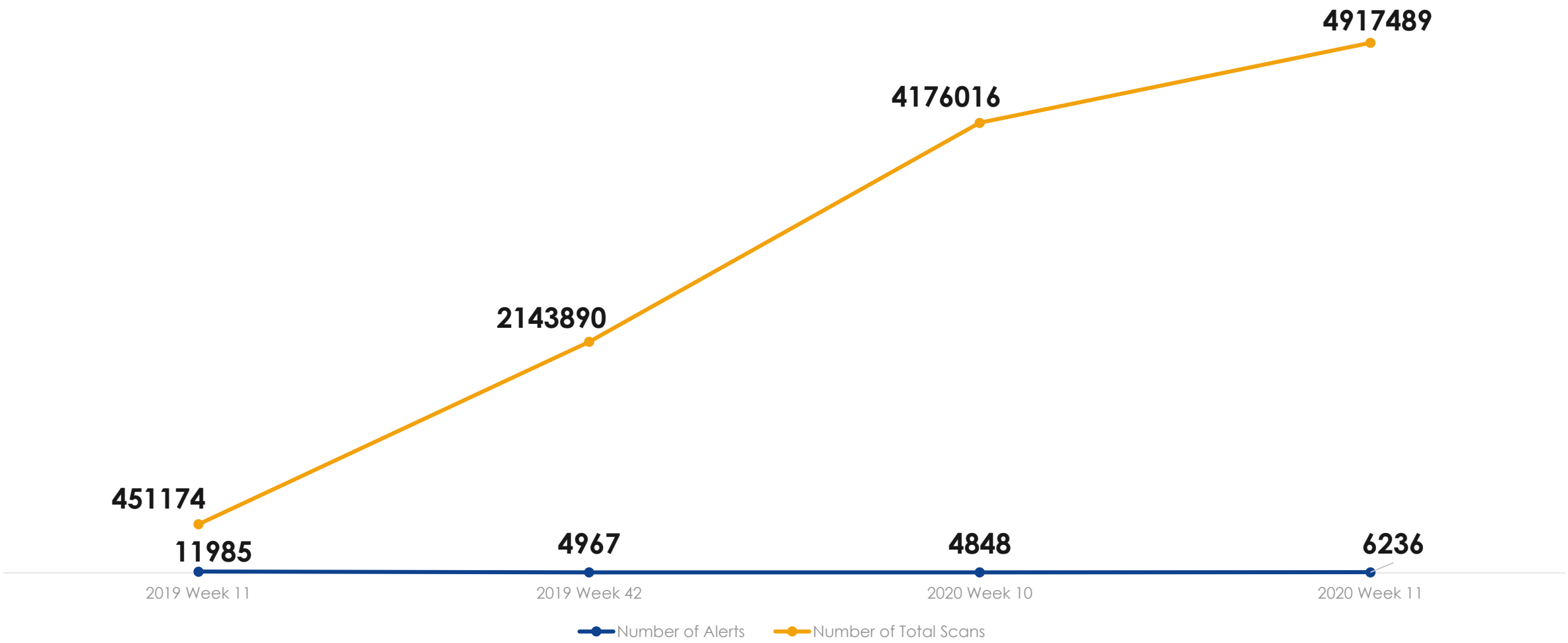
OVERVIEW OF END-USERS CONNECTION

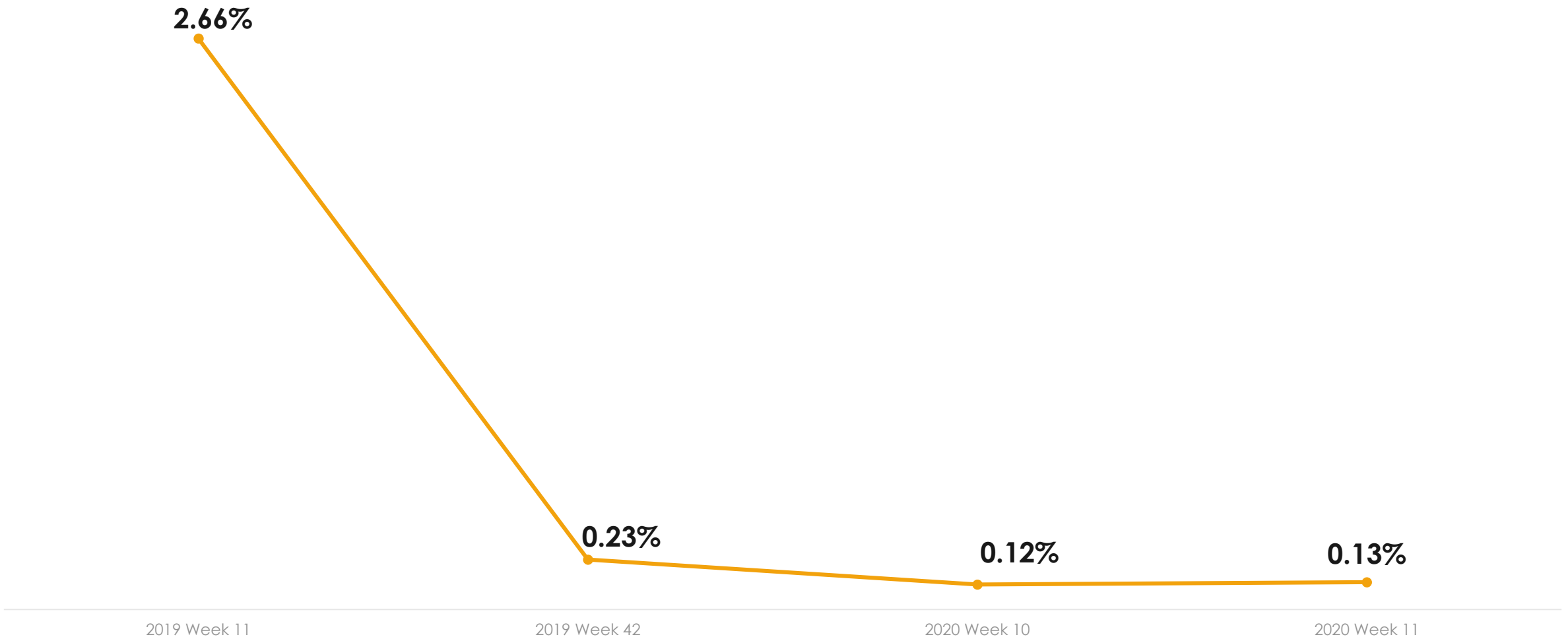


	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	0	12	3
Connected	70	2012	20
Percentage remaining	0.00%	0.59%	13.04%

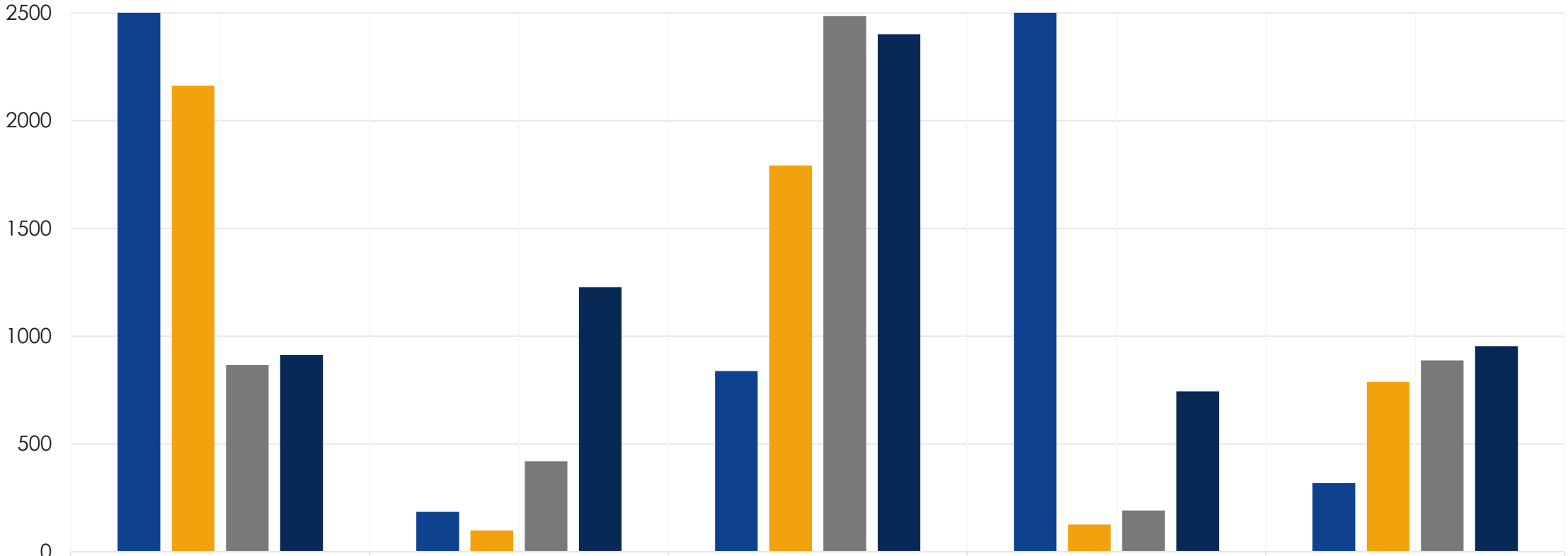
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 2.500



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2019 Week 11	6474	185	838	4170	318
2019 Week 42	2163	98	1792	126	788
2020 Week 10	866	419	2485	191	887
2020 Week 11	912	1227	2401	743	953

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

In Slovakia, one MAH caused an increase in alerts A24&A7 during week 9 by repeatedly using the G135 process - Bulk destroy packs - for the same set of packs (7975 pcs x 4 attempts= 31900 alerts). The MAH has been contacted to provide an explanation.

Transaction Time Descending	Process Id	Process Name	Batch Id	Exp Date	Return Code	Return Code Description	Process State	New Status	Interface
28.02.2020 09:48:50.19	G135	Submit bulk pack status change from EU Hub	86924800	220430	NMVS_NC_PCK_22	Pack is already inactive.	n/a	n/a	EUWEBSERVICE
28.02.2020 09:48:50.19	G135	Submit bulk pack status change from EU Hub	-	220430	NMVS_NC_PCK_22	Pack is already inactive.	n/a	n/a	EUWEBSERVICE
28.02.2020 09:47:19.27	G135	Submit bulk pack status change from EU Hub	-	220430	NMVS_NC_PCK_22	Pack is already inactive.	n/a	n/a	EUWEBSERVICE
28.02.2020 09:47:19.27	G135	Submit bulk pack status change from EU Hub	86924800	220430	NMVS_NC_PCK_22	Pack is already inactive.	n/a	n/a	EUWEBSERVICE
28.02.2020 09:47:15.79	G135	Submit bulk pack status change from EU Hub	86924800	220430	NMVS_SUCCESS	Successfully processed.	n/a	n/a	EUWEBSERVIC

HISTORY OF HIGHLIGHTS COMMUNICATED

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- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
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SLOVENIA

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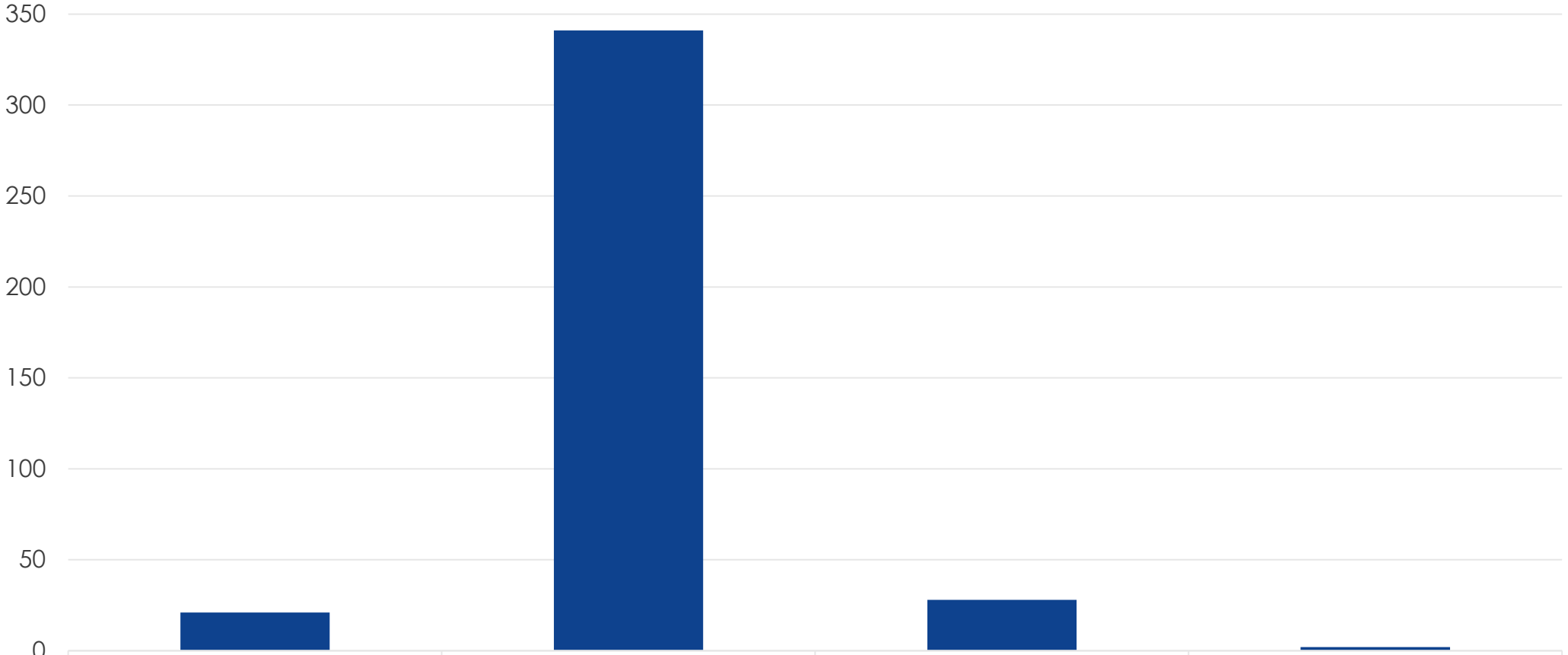
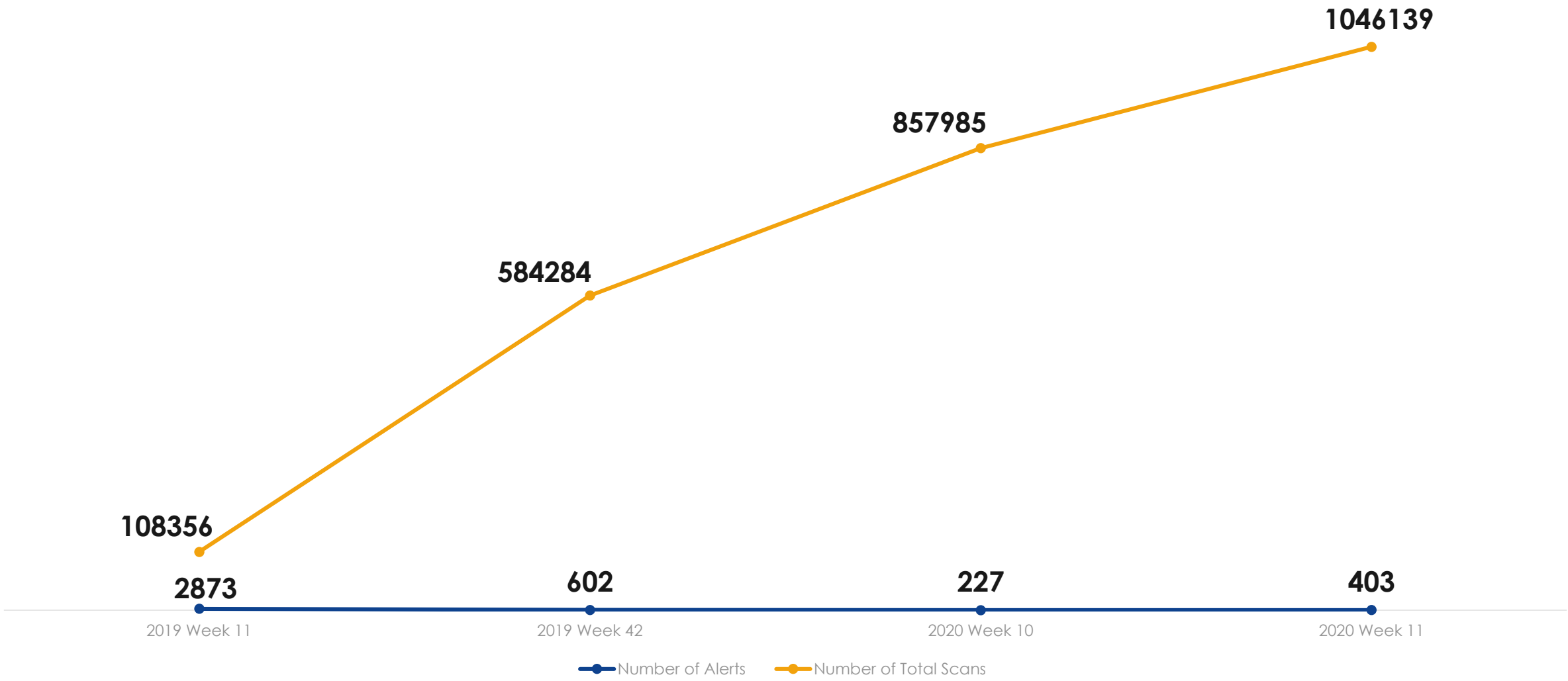
OVERVIEW OF END-USERS CONNECTION



	Wholesalers	Pharmacies	Healthcare Institutions	Other Decommissioning Channels
Not connected	0	0	0	0
Connected	21	341	28	2
Percentage remaining	0.00%	0.00%	0.00%	0.00%

OVERVIEW OF TOTAL OF ALERTS AND SCANS



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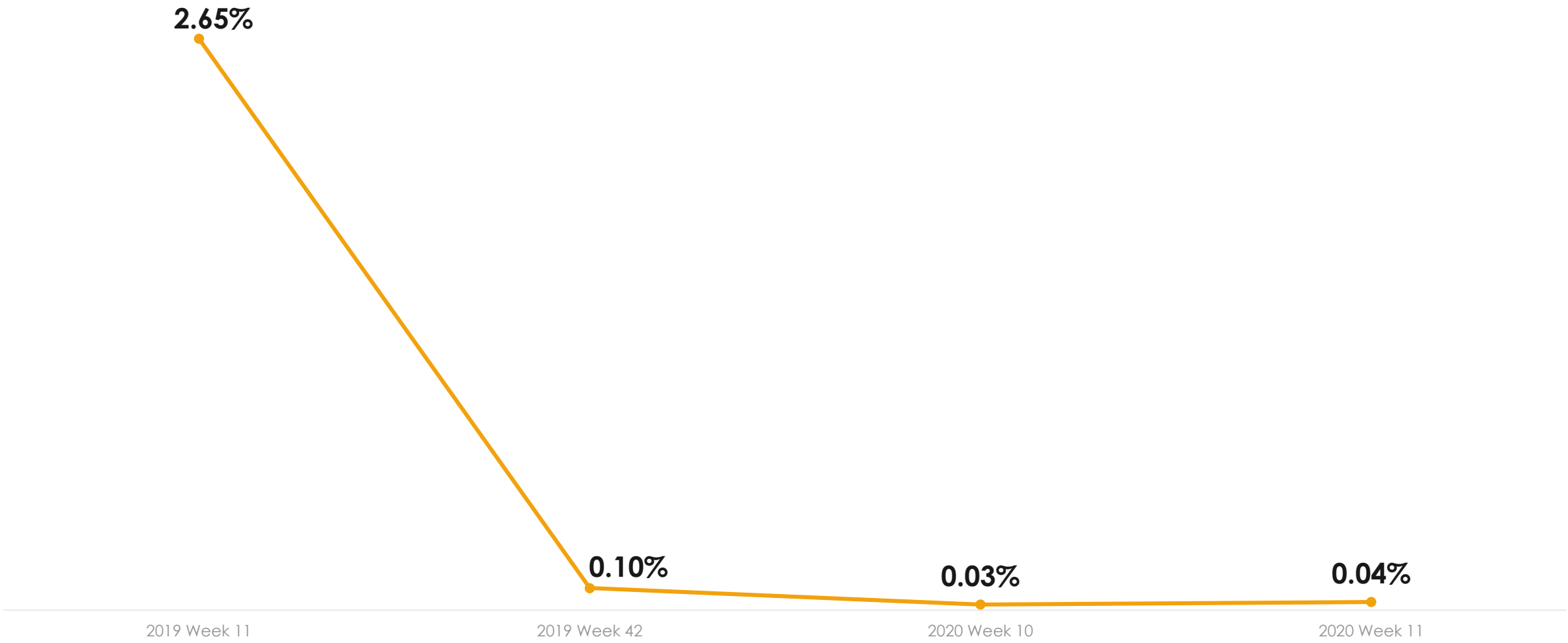
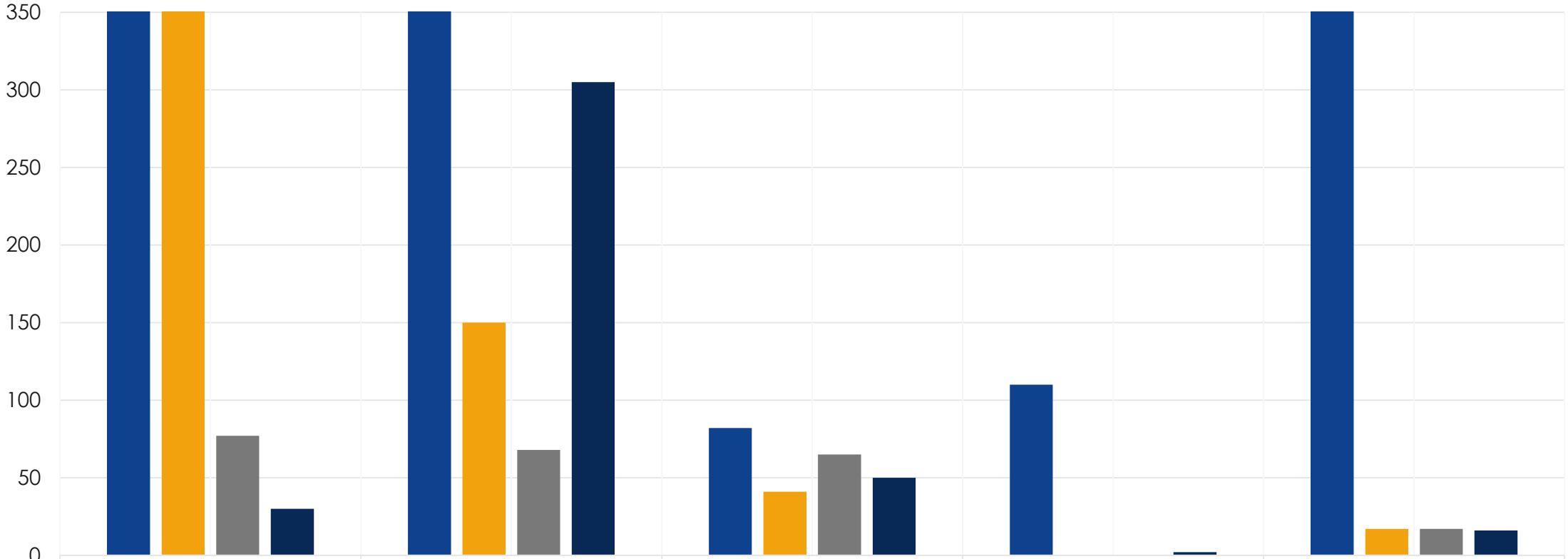


ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 350



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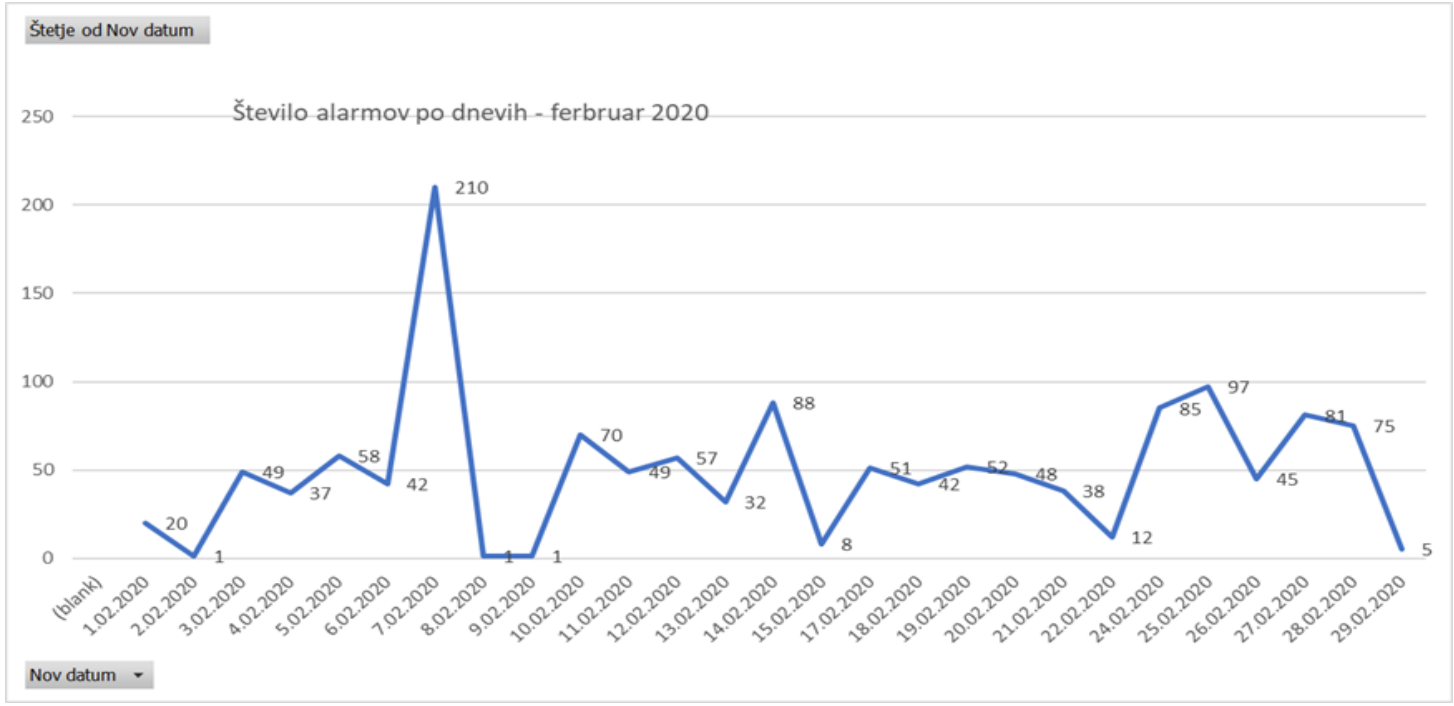
2019 Week 11	1062	660	82	110	959
2019 Week 42	394	150	41	0	17
2020 Week 10	77	68	65	0	17
2020 Week 11	30	305	50	2	16

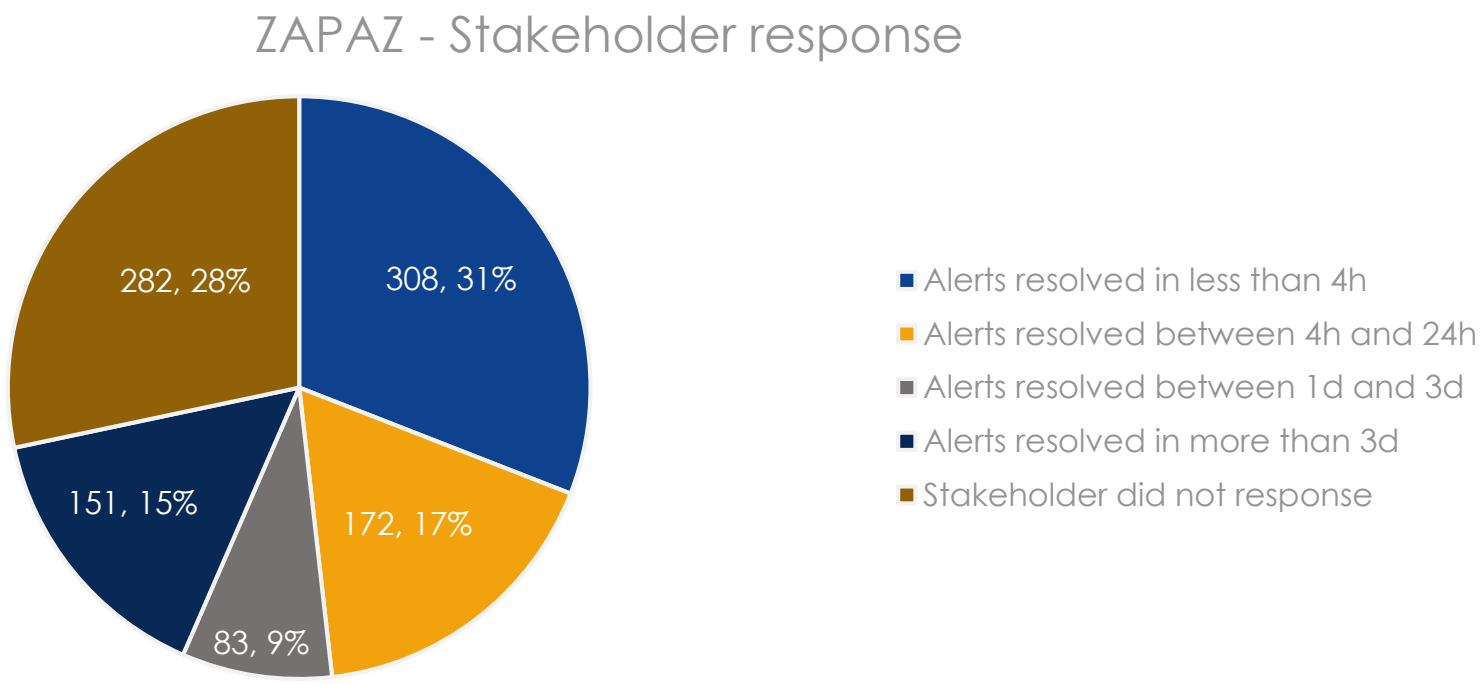
HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

In Slovenia, week 9 showed a slight increase in the total number of alerts, due to a medicine from a manufacturer which was not uploaded in EMVS; causing 106 alerts. There was also a significant peak last month on 7th February because of a MAH activity. However, there was no impact on distribution of medicines in Slovenia.



HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

In Slovenia, the response times for Alert investigation inquiries that ZAPAZ initiates with the stakeholders are tracked. A list of unresponsive cases is sent to the Slovenian NCA each week, ZAPAZ encourages their stakeholders to be actively involved in the alert investigation communication.



HISTORY OF HIGHLIGHTS COMMUNICATED

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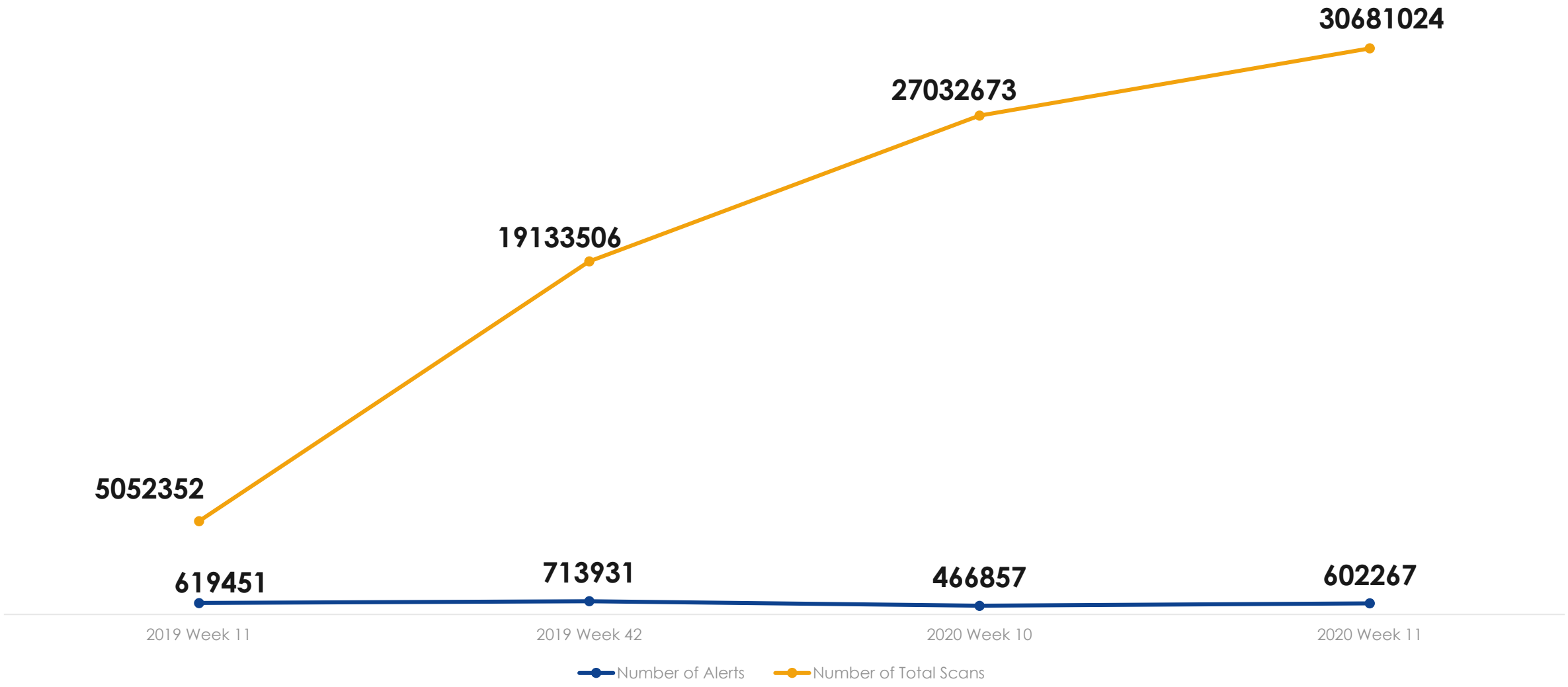
OVERVIEW OF END-USERS CONNECTION

	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	16	0	415
Connected	309	22100	185
Percentage remaining	4.92%	0.00%	69.17%

OVERVIEW OF TOTAL OF ALERTS AND SCANS



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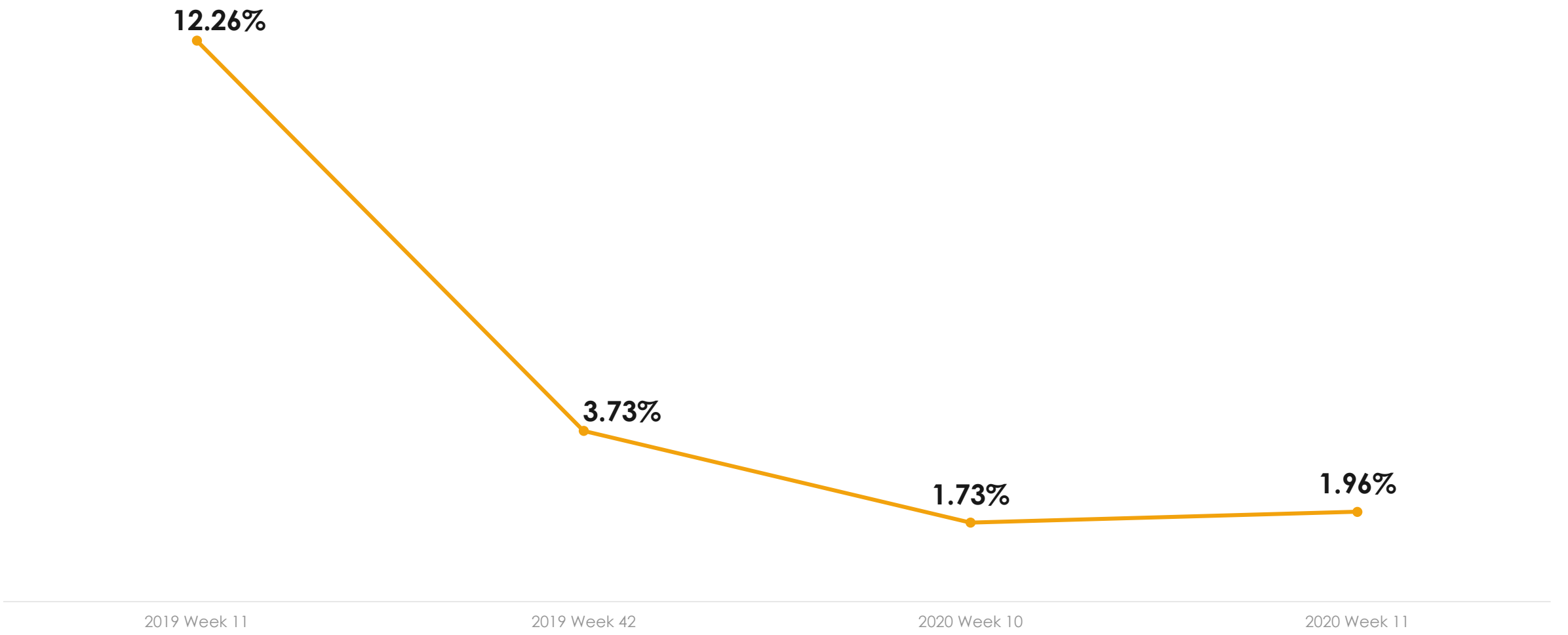
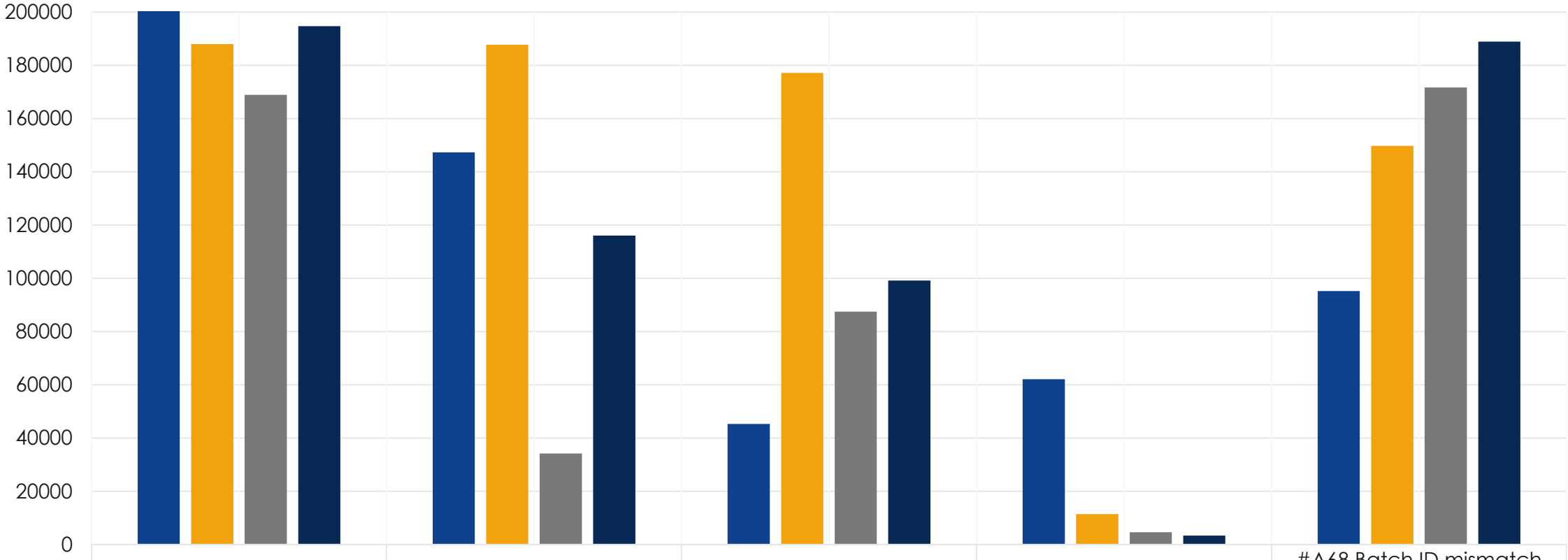


ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 200.000



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2019 Week 11	269550	147338	45253	62101	95209
2019 Week 42	187939	187722	177104	11419	149747
2020 Week 10	168866	34178	87453	4644	171716
2020 Week 11	194714	116060	99168	3392	188933

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

During week 9 there was an increase of 500.000 alerts due to a problem in the communication network of several pharmacies of the same region. Some of these pharmacies could not manage correctly their contingency situation, generating these false alerts.

HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
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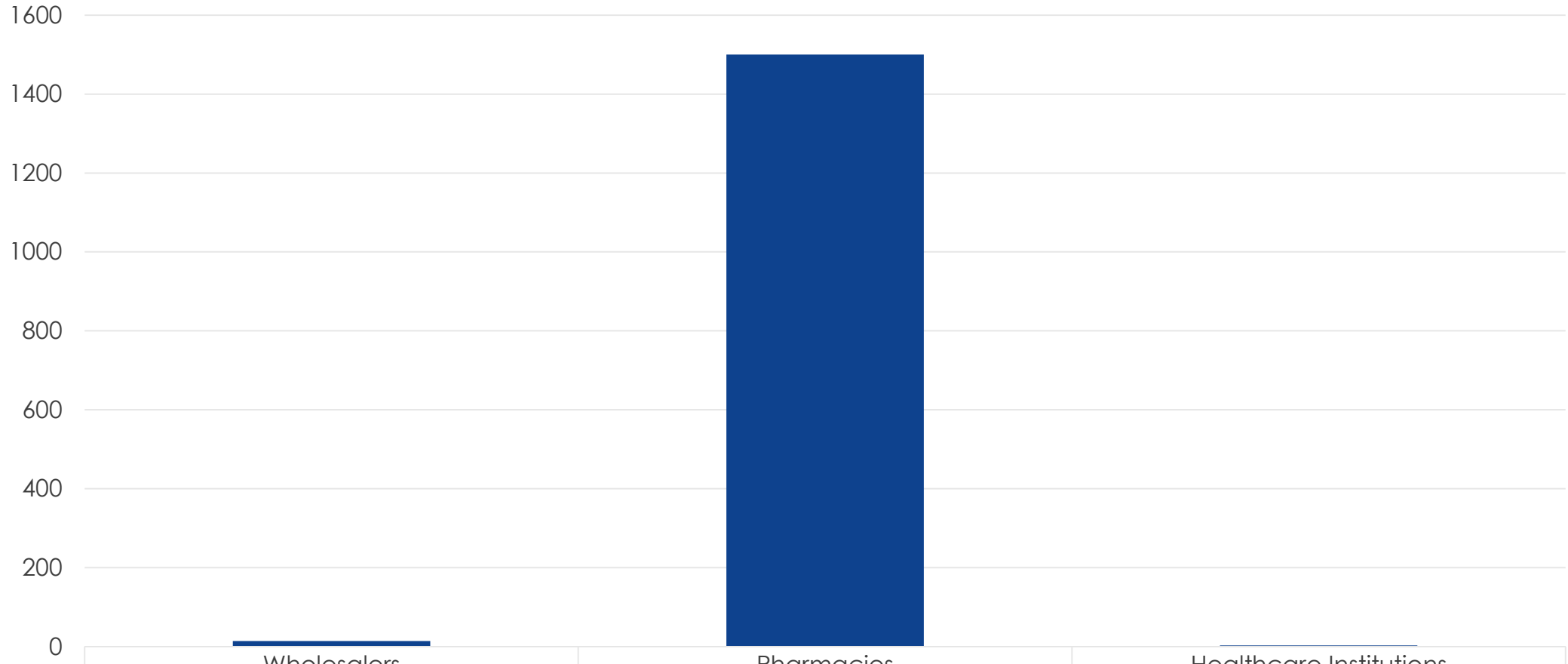
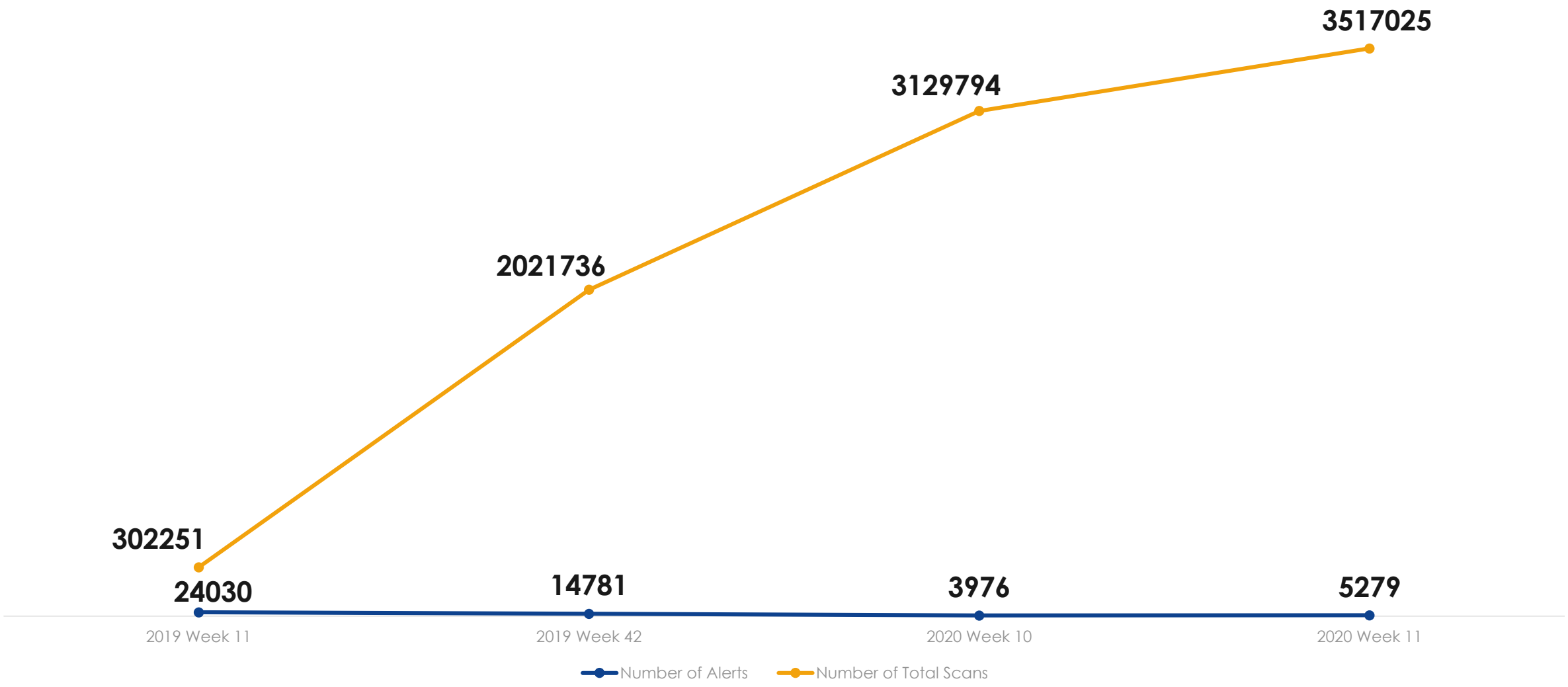
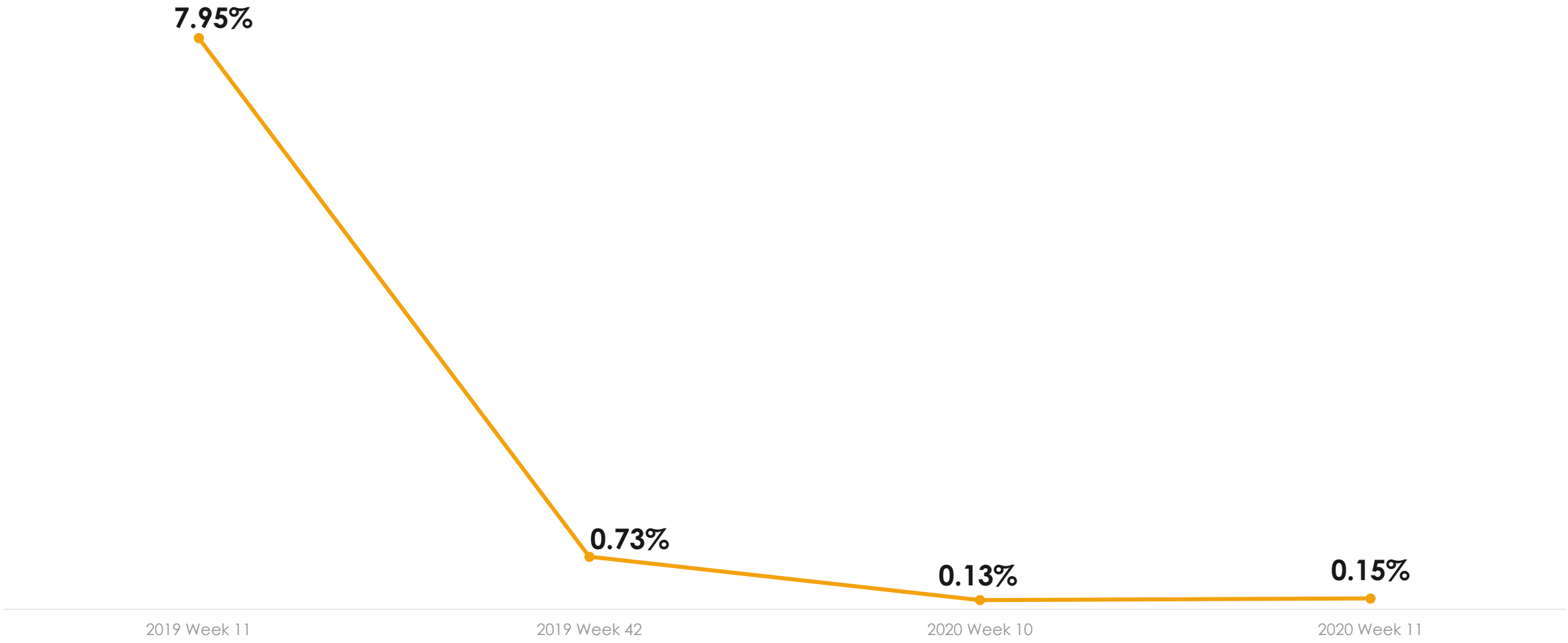


	Wholesalers	Pharmacies	Healthcare Institutions
Not connected	0	0	0
Connected	14	1500	3
Percentage remaining	0.00%	0.00%	0.00%

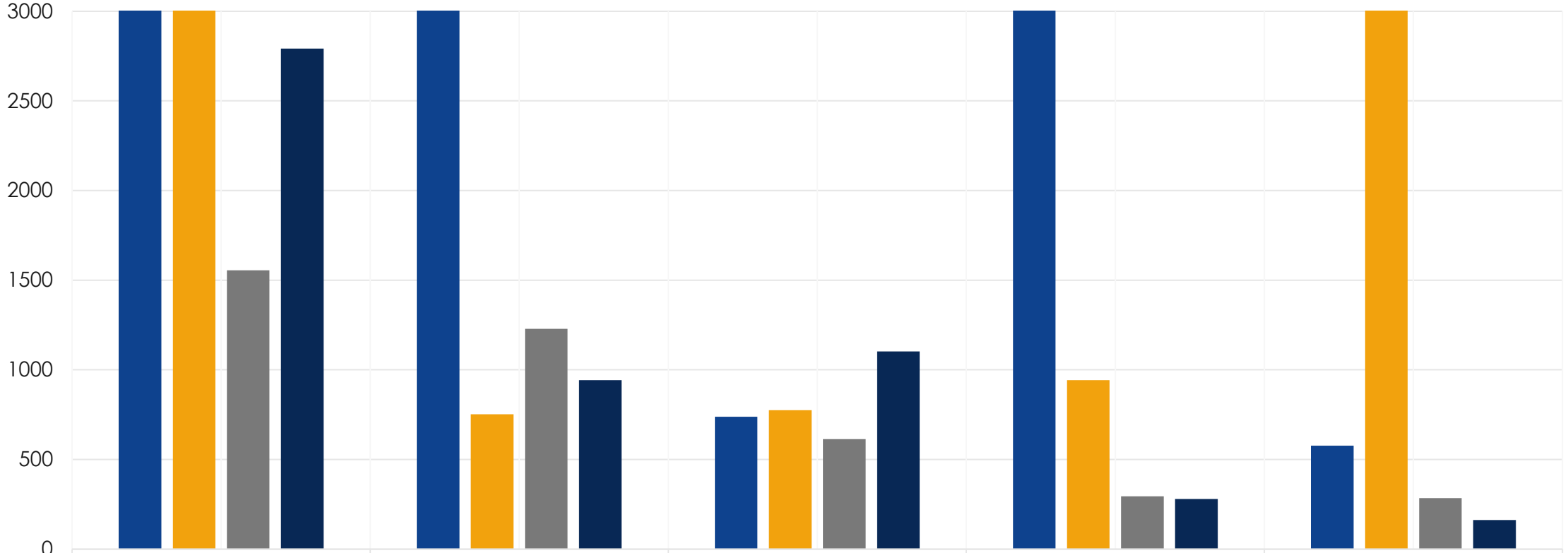
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 3.000



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	15673	3606	738	3436	577
2019 Week 42	4784	752	775	942	7528
2020 Week 10	1555	1229	613	294	285
2020 Week 11	2791	943	1103	280	162

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

There is an increase of A3 alerts during week 9 due to an OBP trying to destroy packs that could not be found in the Swedish system and therefore creating approximately 5900 false alerts.

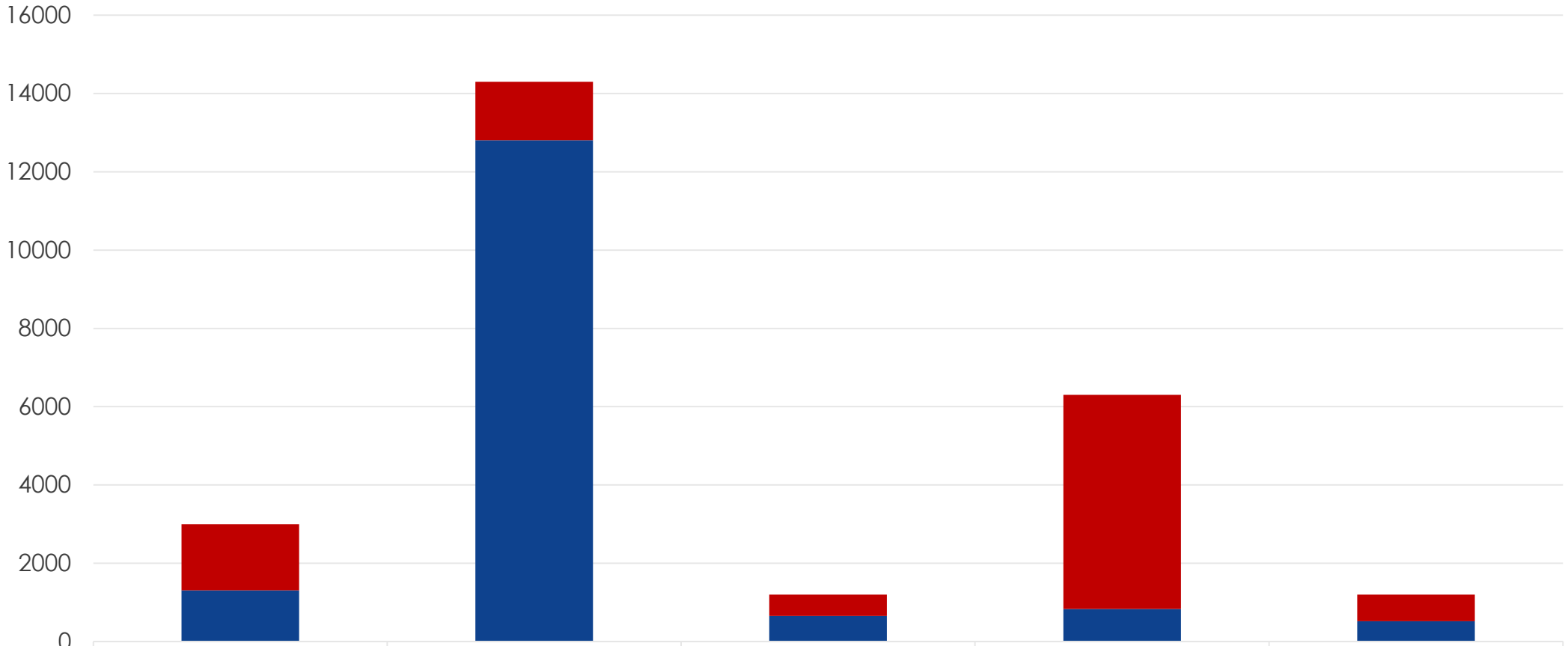
HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

UNITED KINGDOM

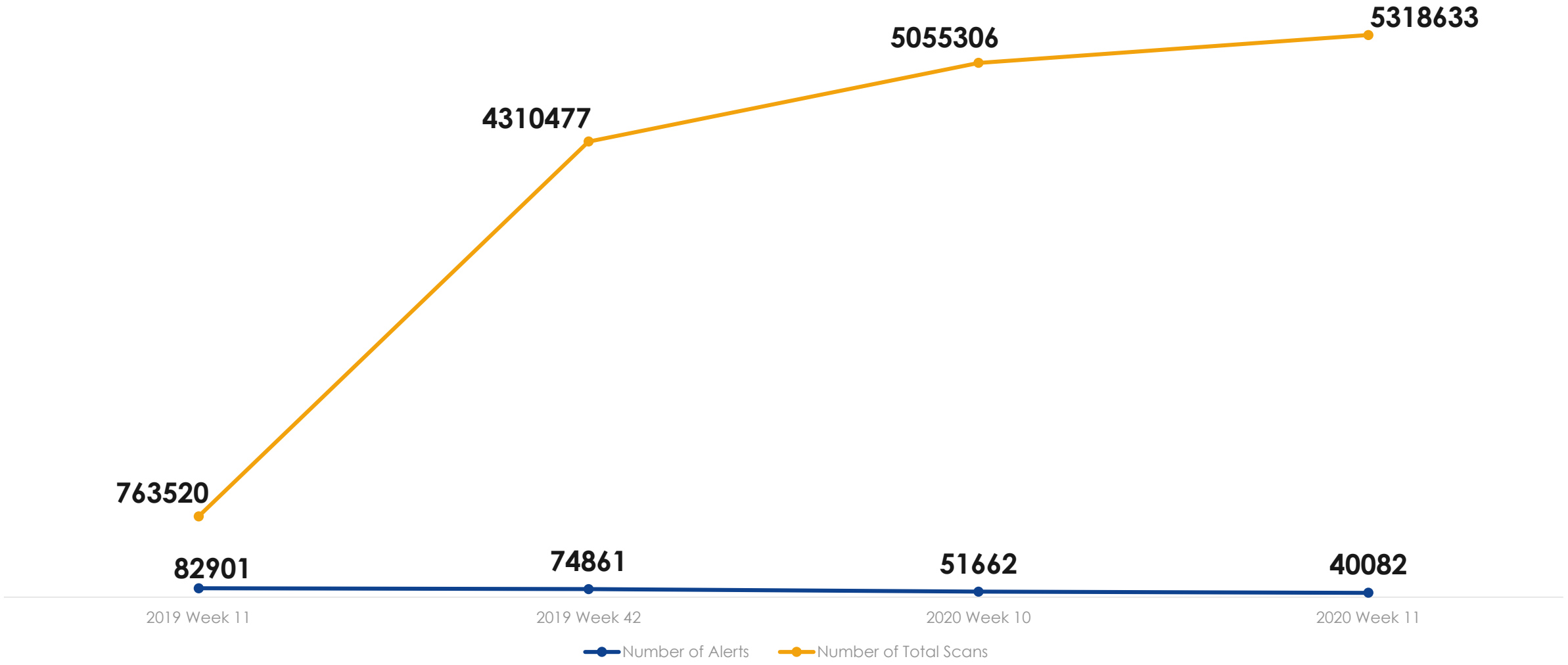
Back to the EEA map

OVERVIEW OF END-USERS CONNECTION

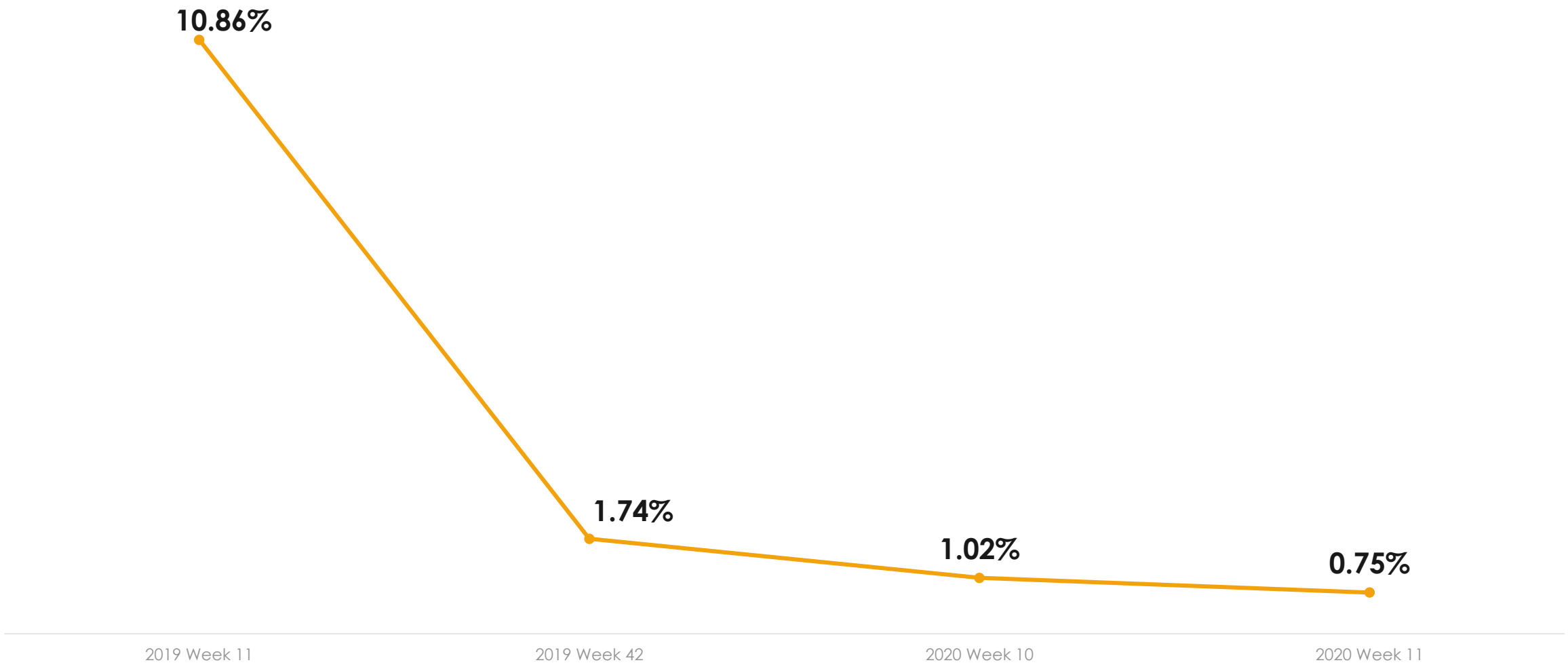


	Wholesalers	Pharmacies	Healthcare Institutions	Other Decommissioning Channels	Dispensing Doctors
Not connected	1689	1495	547	5471	679
Connected	1311	12805	653	829	521
Percentage remaining	56.30%	10.45%	45.58%	86.84%	56.58%

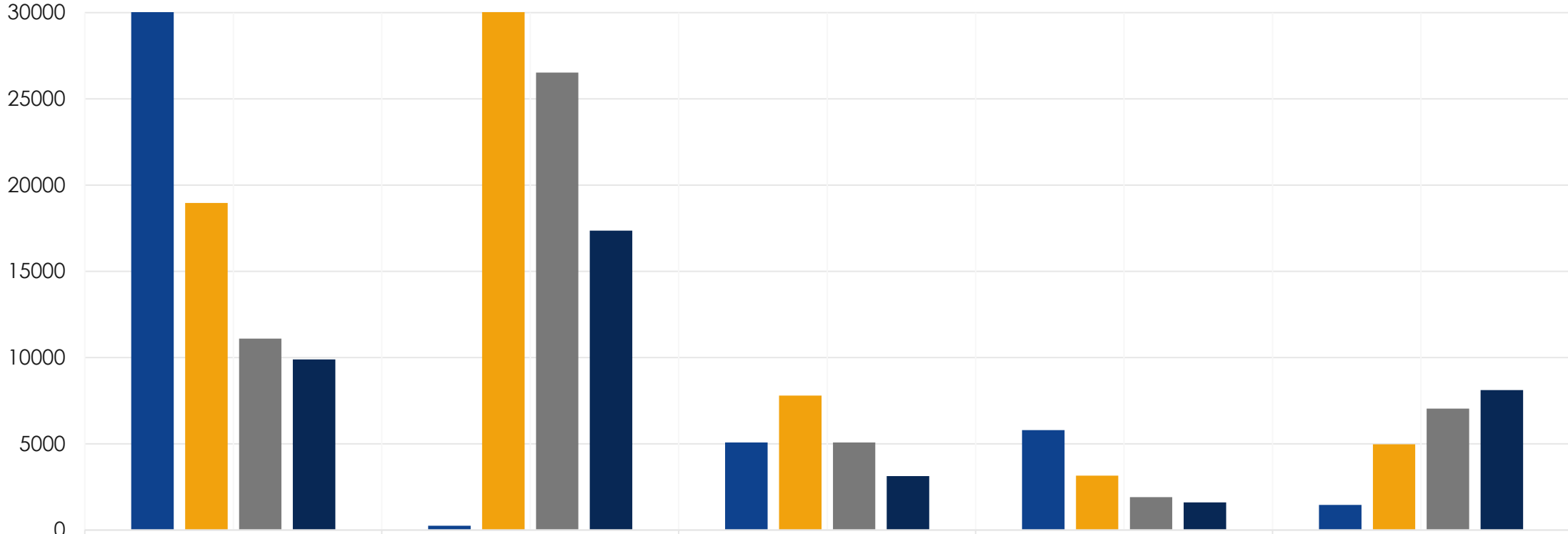
OVERVIEW OF TOTAL OF ALERTS AND SCANS



TOTAL NUMBER OF ALERTS IN RELATION TO THE TOTAL NUMBER OF SCANS



ABSOLUTE: ALERTS PER CATEGORY PER WEEK CAP 30.000



	#A2 Batch ID unknown (Product Code - correct, Batch ID unknown)	#A24 & #A7 Attempt to decommission an already decommissioned pack	#A3 Unknown serial number	#A52 Expiry date mismatch	#A68 Batch ID mismatch (Product Code - correct, Serial Number - correct, Batch ID - wrong)
2019 Week 11	70315	252	5085	5790	1459
2019 Week 42	18966	39963	7801	3162	4969
2020 Week 10	11105	26518	5084	1910	7045
2020 Week 11	9890	17353	3124	1600	8115

HIGHLIGHTS & ALERT EXPLANATION FOR THE PAST 4 WEEKS

The British NMVO has provided no particular insight for the past 4 weeks.

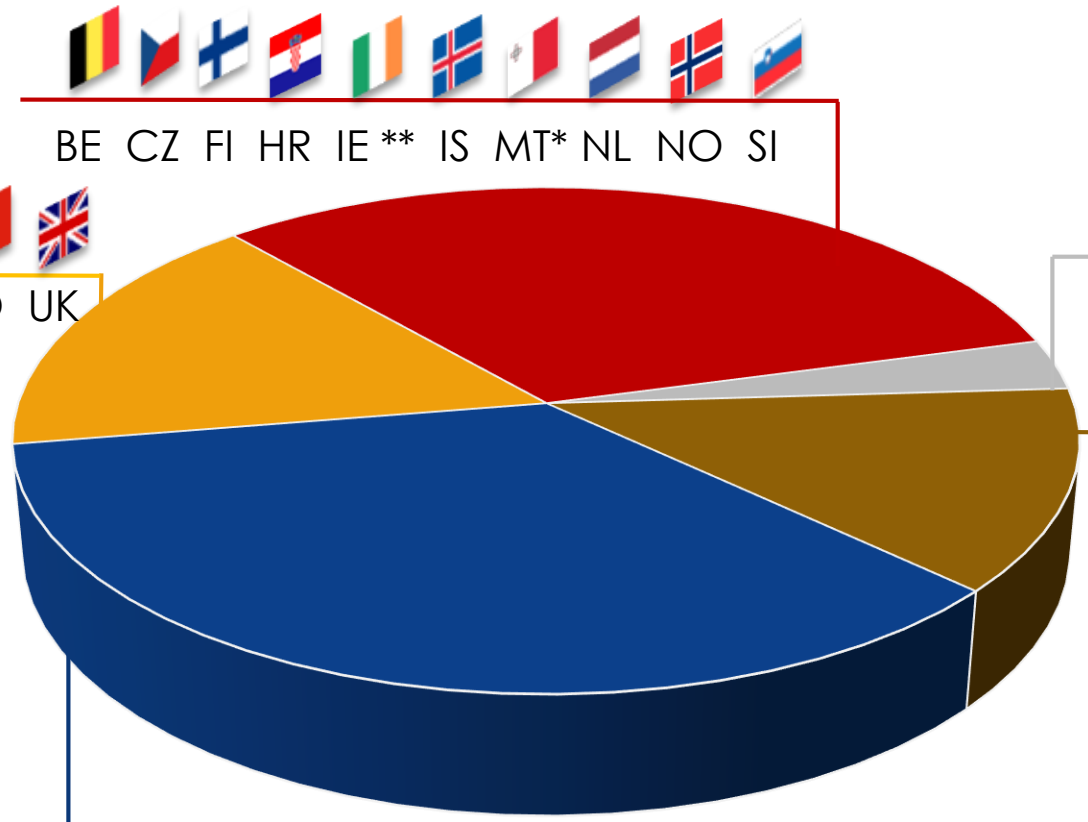
HISTORY OF HIGHLIGHTS COMMUNICATED

- Highlights weeks 23 and 24
- Highlights weeks 25 and 26
- Highlights weeks 27 and 28
- Highlights weeks 29 and 30
- Highlights weeks 35 and 36
- Highlights of September
- Highlights of October
- Highlights of November
- Highlights of January
- Highlights of February

AGENDA

- Status OBP/MAH connection
- Status End-Users connection
- Development of alerts
- Country Overview
- Fines & Stabilisation Periods Overview

STABILISATION PERIODS OVERVIEW



Stabilisation period has ended
10 Countries

BE CZ FI HR IE ** IS MT* NL NO SI

No stabilisation period has been decided
5 Countries

LU LV PL RO UK

N/A
1 Country

LI

Phased approach to end stabilisation period
4 Countries

AT HU SE SK

Stabilisation period confirmed
11 Countries

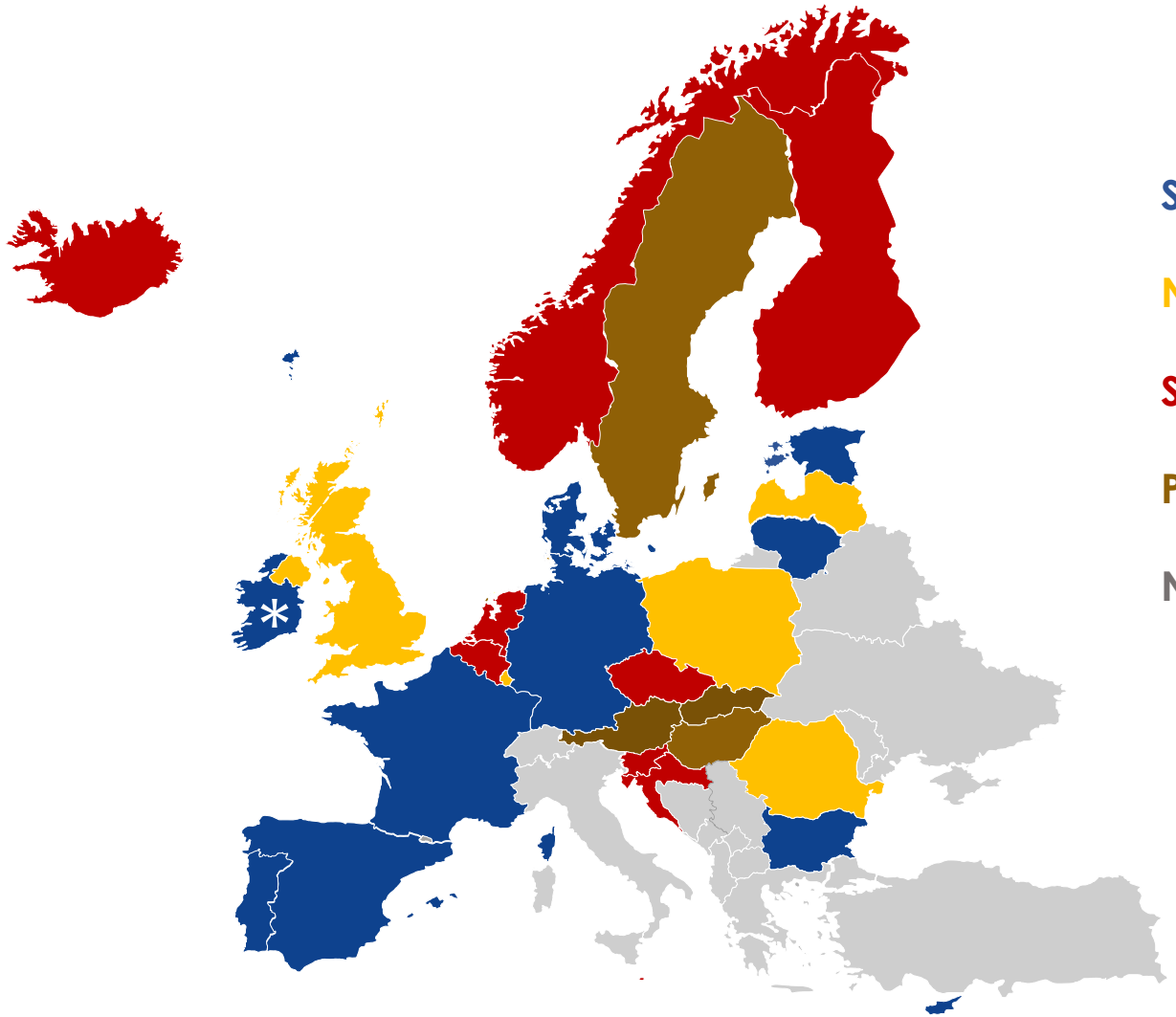
BG CY DE DK EE ES FR IE ** LT MT* PT

Note : stabilisation period only applies to packs released before 9th February 2019 for DK, FI, DE, and PL

* In Malta the stabilisation period has ended for wholesalers (9th August 2019) but has been extended for pharmacies
** In Ireland, stabilisation has ended for products that are parallel imported and parallel distributed and products handled by primary wholesalers (certain activities only)

STABILISATION PERIODS OVERVIEW

Note : stabilisation period only applies to packs released before 9th February 2019 for DK, FI, DE, and PL



Stabilisation period confirmed

No stabilistion period has been decided

Stabilisation period has ended

Phased approach to end stabilisation period

N/A

*In Ireland, stabilisation has ended for products that are parallel imported and parallel distributed as well as for products handled by primary wholesalers (certain activities only)

DURATION OF THE STABILISATION PERIOD
IDENTIFIED TIMEFRAMES

Country	Duration	Expectations
MT (only for wholesalers)	Until 8th August 2019	**Stabilisation period has ended for wholesalers** but has been extended for pharmacists
BE	Until 1st September 2019	**Stabilisation period has ended**
SE IS	Until 30th September 2019	**SE Stabilisation period is ending in a phased approach** **IS Stabilisation period has ended**
NL	Until 1st October 2019	**Stabilisation Period has ended**
SI	Until 1st December 2019	**Stabilisation Period has ended**
HR CZ	Until 31st December 2019	**Stabilisation Periods have ended**

DURATION OF THE STABILISATION PERIOD
IDENTIFIED TIMEFRAMES

Country	Duration	Expectations
NO	Until 20th January 2020	**Stabilisation Period has ended**
FI	Until 31st January 2020	**Stabilisation Periods has ended**
AT SK	Until 8th February 2020	**AT Stabilisation period is ending in a phased approach** **SK Stabilisation period is ending in a phased approach**
IE	Until 2nd March 2020	**Stabilisation has ended** for products that are parallel imported and parallel distributed as well as for products handled by primary wholesalers (certain activities only)
LT	Until 21st April 2020	Stabilisation period had initially ended on January 31st but has been now reinstituted due to COVID-19
IE	Until May 2020 (date to be notified)	Stabilisation period ends for all wholesalers
MT (only for pharmacists)	Until 8th May 2020	Stabilisation Period has been recently extended
EE IE	Until September 2020	IE Stabilisation Period ends for pharmacies & hospitals (date to be notified)
CY	Until 30th September 2020	Date is fixed

DURATION OF THE STABILISATION PERIOD
UNIDENTIFIED TIMEFRAMES

Country	Duration
BG ES FR HU PT DE	Under discussion by National Competent Authorities (NCA)
DK	Until Packs expiry date for products released prior to 9th Feb. 2019
LV PL RO	No stabilisation period has been decided

The overview communicated about the Stabilisation Periods in the EEA reflects the information available to the NMVOs, to the best of their knowledge at the time of the report. This information reflects the latest update

FINES FOR END-USERS FOR NON-COMPLIANCE

In stabilisation period - fines are applicable

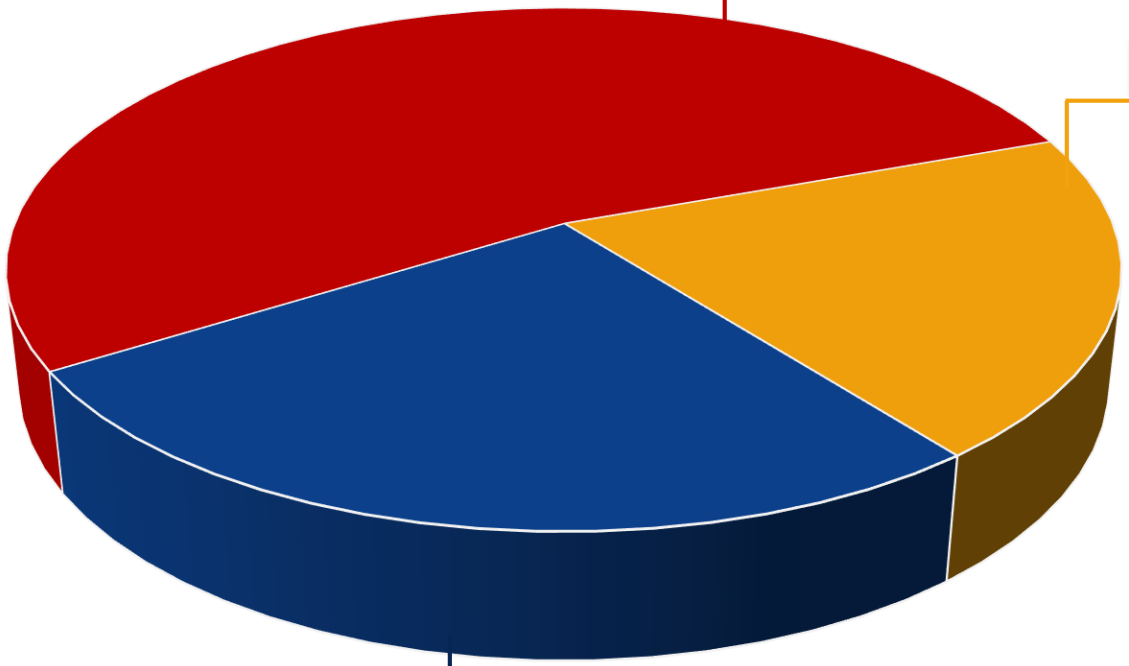
7 Countries

AT BE CZ FI HR IE** IS LU LV MT* NL NO RO PL SI UK

CY DK FR HU MT* SE SK

Stabilisation period ended / No stabilisation period – fines are in place under applicable law

16 Countries



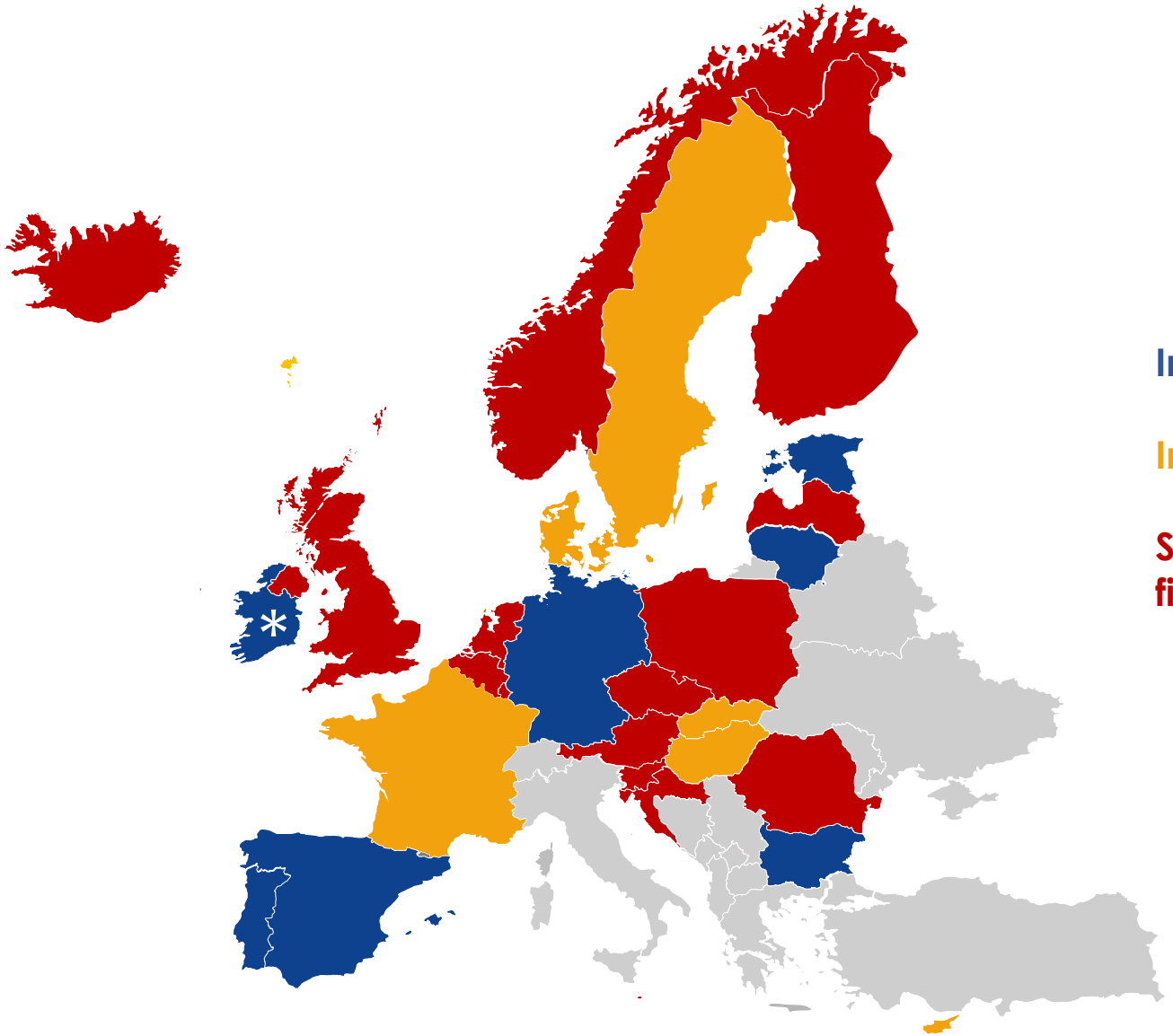
BG DE EE ES IE** LI LT PT

In stabilisation period – no fines applicable

8 Countries

* In Malta the stabilisation period has ended for wholesalers (9th August 2019) but has been extended for pharmacies
** In Ireland, stabilisation has ended for products that are parallel imported and parallel distributed as well as for products handled by primary wholesalers (certain activities only)

FINES FOR END-USERS FOR NON-COMPLIANCE



In stabilisation period - no fines applicable

In stabilisation period - fines applicable

Stabilisation period has ended/no stabilisation period - fines are in place under applicable law

*In Ireland, stabilisation has ended for products that are parallel imported and parallel distributed as well as for products handled by primary wholesalers (certain activities only)