DMVO

Dansk
Medicin
Verifikation
Organisation
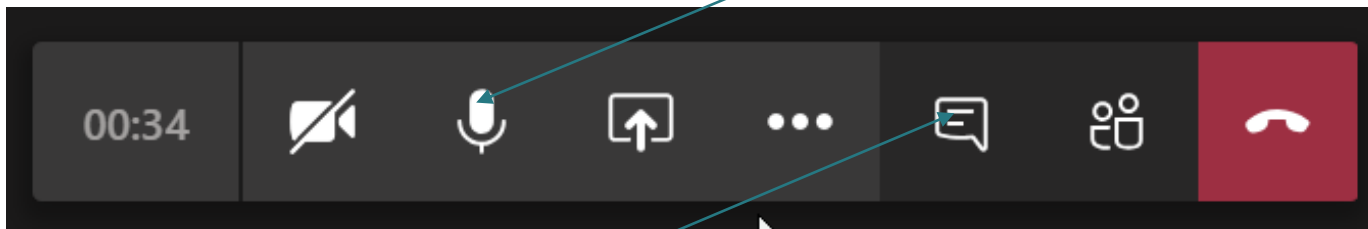
Danish Medicine Verification Organisation

Virtual Meeting 24.09.2020

Alert statistics Denmark

THE HOUSE RULES of DMVO during virtual meeting

- All participants are on mute by default to reduce noise

- Unmute yourself by clicking on the microphone icon

- Feel free to ask questions during the meeting

- Chat comments are always welcome

- The meeting will be recorded and made available for download and later review

DMVO

Danish Medicines Verification Organisation

Tina Hou Marer
Program Director

Lars Martinussen
IT Project Manager

Katja Ploug
Project Coordinator

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Project Administrator & QA

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Alerts in Denmark and alert statistics

Walk through of the agenda of today´s meeting:

- Alert codes
- Alert highlights of August in DK
- Example of monitoring an alert code
- The monitoring report and an example + highlights
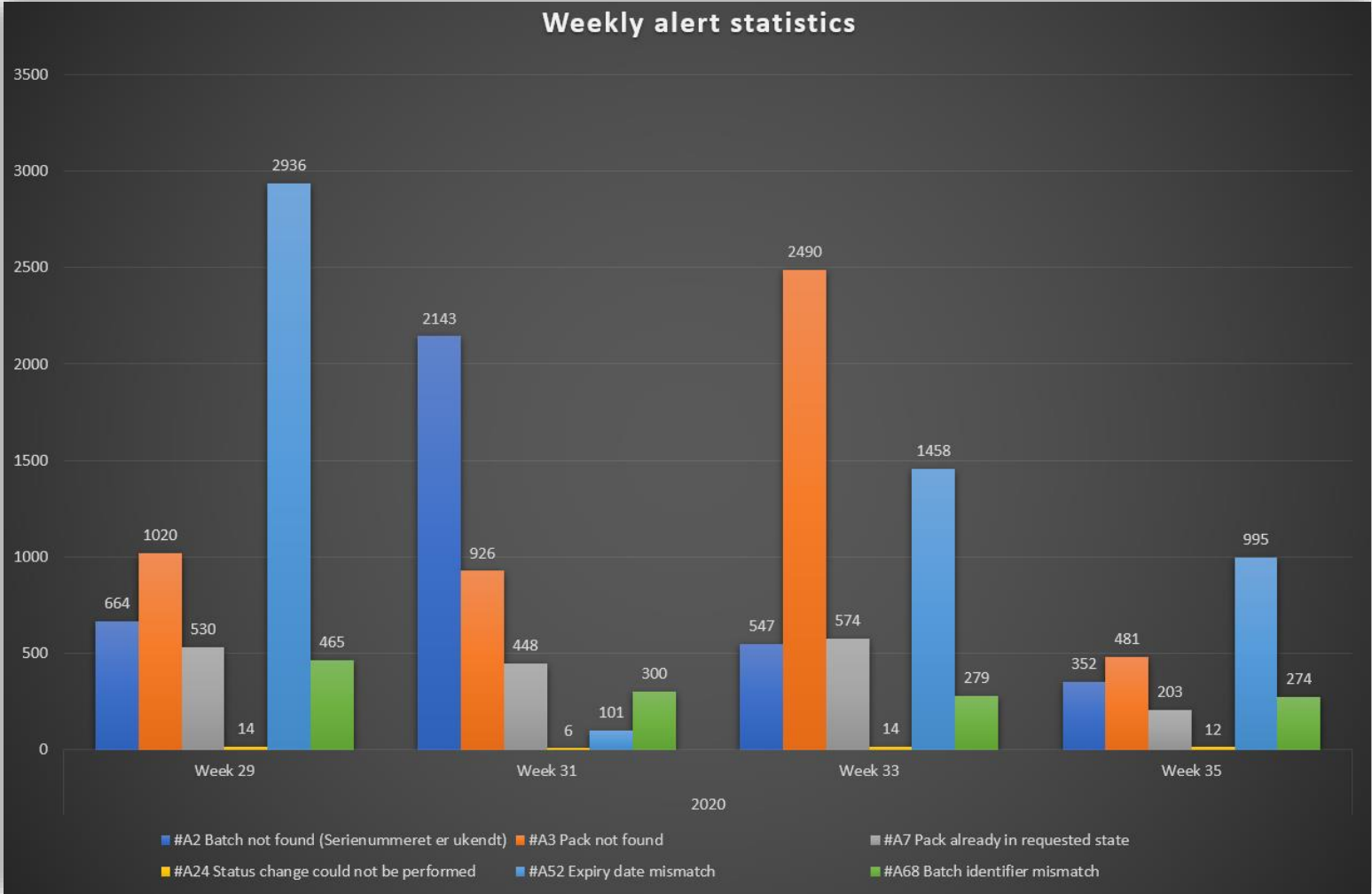- Where does DMVO handle the alerts?
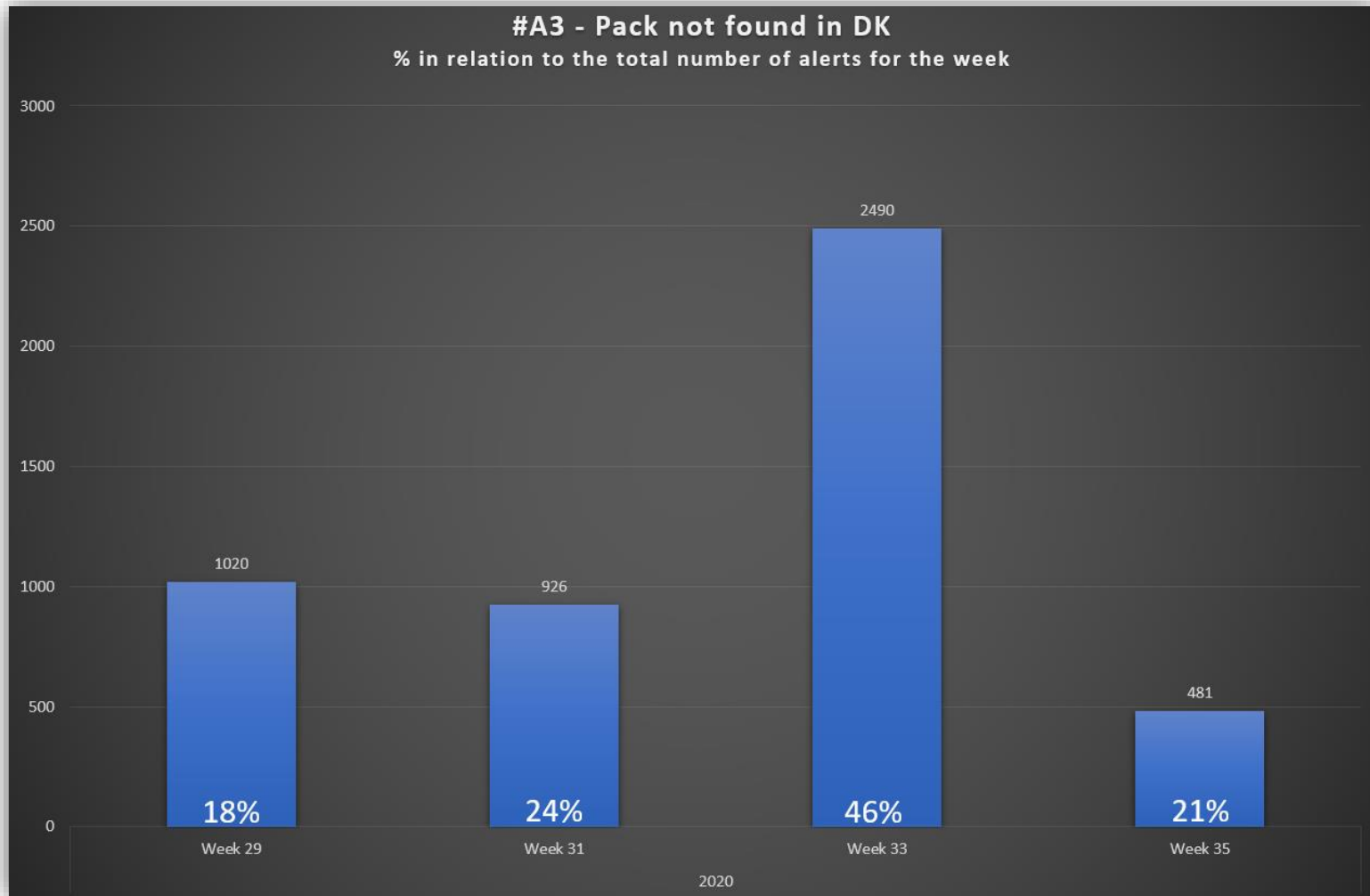
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Alert codes

List of alerts:

- #A2 –Batch not found
- #A3 –Pack not found
- #A7 –Pack already in requested state
- #A24 –Status change could not be performed
- #A52 –Expiry date mismatch
- #A68 –Batch identifier mismatch

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Alert overview DMVS

Weekly alert statistics

Danish alert code example

#A3 - Pack not found in DK
% in relation to the total number of alerts for the week

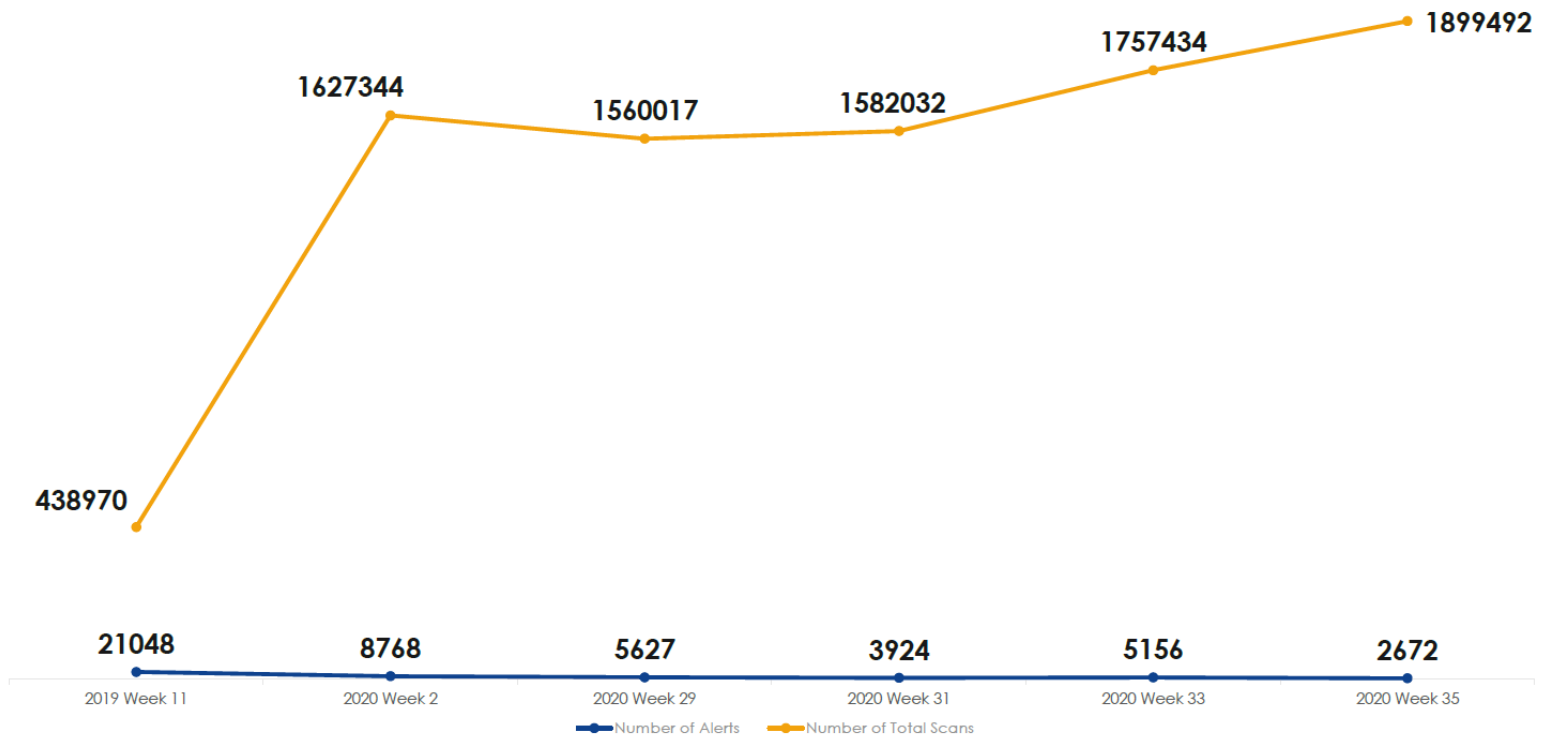| Week	Value	%
Week 29	1020	18%
Week 31	926	24%
Week 33	2490	46%
Week 35	481	21%

2020

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Highlights & analysis

- The alert frequency has decreased. In week 35; 0,12% of the scanned products generated alerts whereas 0,30% generated alerts in week 33.

- The number of scanned sold products has increased. 374 MAH´s have uploaded 186 mio. packs. Product Pack Data = 9.835 (PPD), this is 76% of all Product Master Data (PMD). The number of uploaded packs is continuesly increasing.

- A large number of #A3 –Pack not found in week 33 due to missing software update at some end users. The scanners have now been re configueret.

- Both in week 33 and 35 a considarable number of #52 – ”expiry data mismatch” was generated due to the well known scanner error where ”00” in the date is read incorrectly.

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DK: Increasing number of scans
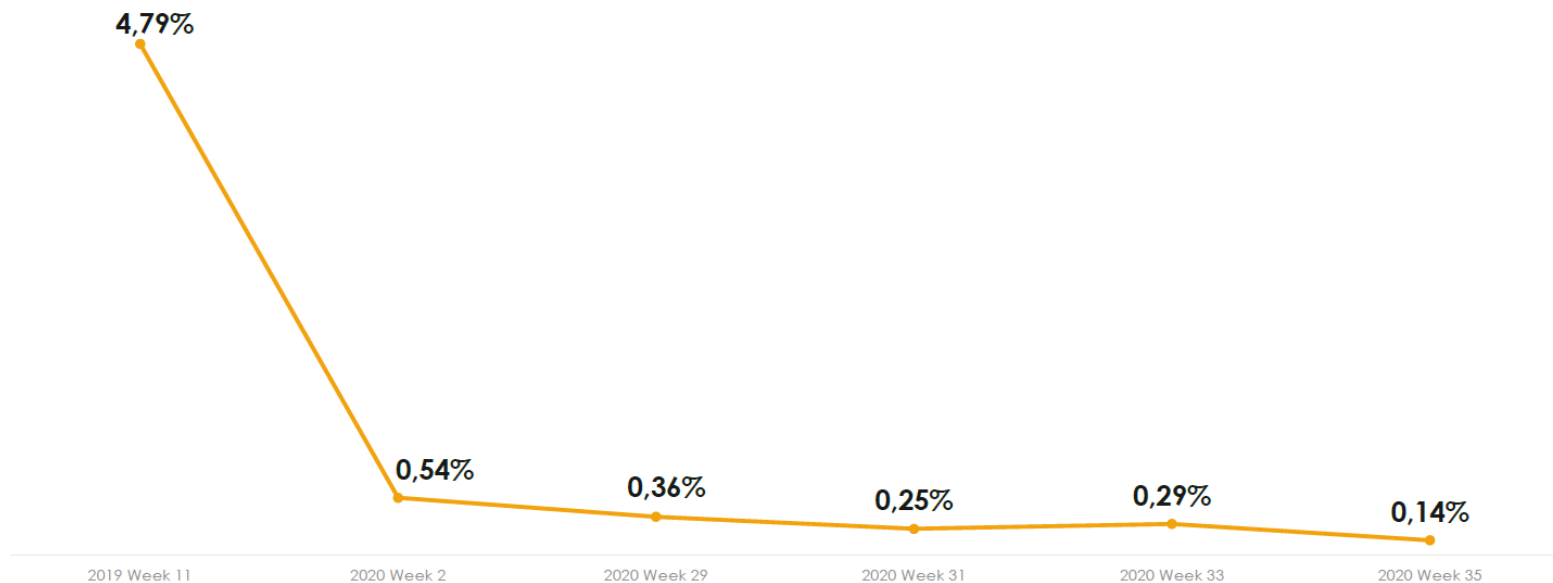

OVERVIEW OF TOTAL OF ALERTS AND SCANS

DENMARK
Back to the EEA map

	2019 Week 11	2020 Week 2	2020 Week 29	2020 Week 31	2020 Week 33	2020 Week 35
Number of Total Scans	438970	1627344	1560017	1582032	1757434	1899492
Number of Alerts	21048	8768	5627	3924	5156	2672

Number of Alerts   Number of Total Scans

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DK: Decreasing number of alerts

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

DENMARK
Back to the EEA map

2019 Week 11	2020 Week 2	2020 Week 29	2020 Week 31	2020 Week 33	2020 Week 35
4,79%	0,54%	0,36%	0,25%	0,29%	0,14%

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DK: Distribution of alert codes

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)
2020 Week 29	664	542	1020	2936	465
2020 Week 31	2143	454	926	101	300
2020 Week 33	547	382	2490	1458	279
2020 Week 35	407	245	540	1165	315

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What is DMVO doing to lower the number of alerts?

- Development of a national <u>alert handling guideline</u>

- Direct contact to MAH/OBP

- Direct contact to end user

- Monitoring of development(s)

- Continues dialouge with the Danish Medicines Agency

- Knowledge exchange with the other NMVO´s – what has been initiated to lower the alert number etc.

- Underlining the recommendation to verify 1 pack per batch before release

- The alert management system NMVS Alerts is monitored daily

- Participation in a cross country work group in order to standardize the alert handling process

- Development of a general <u>overview of root causes and tips to investigate</u>

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The alert page list

- "NMVS Alerts" is an automated tool for displaying alert information and performing investigations

Statistics from NMVS alert

Reports

Apply Filter

| 1.9.2020 | 10.9.2020 | Resolution Times ⌄ | Request |

Report

10.5%
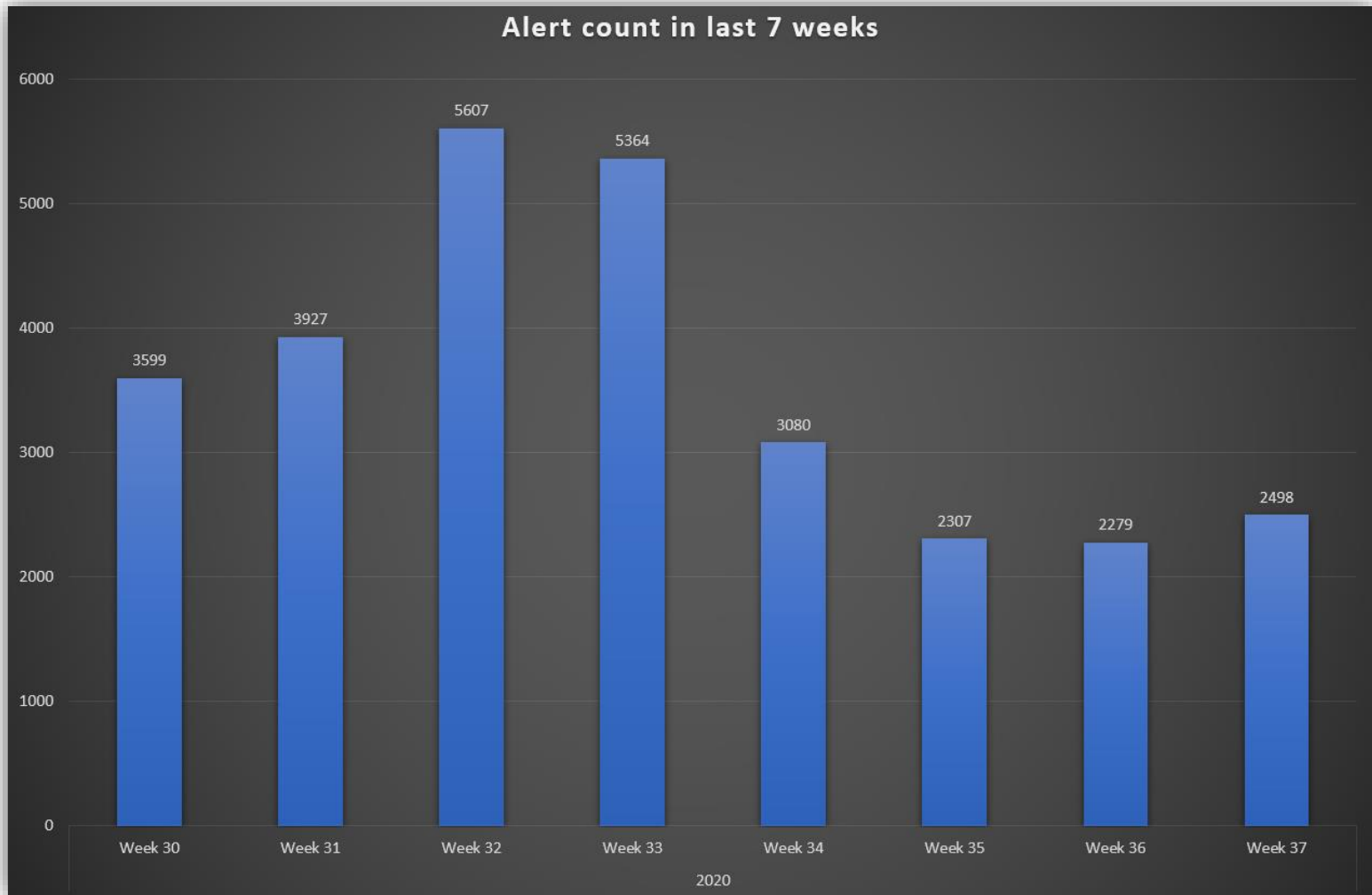6.6%
29%
53.8%
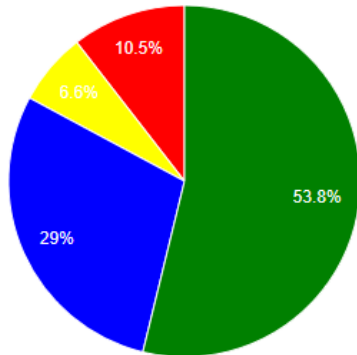
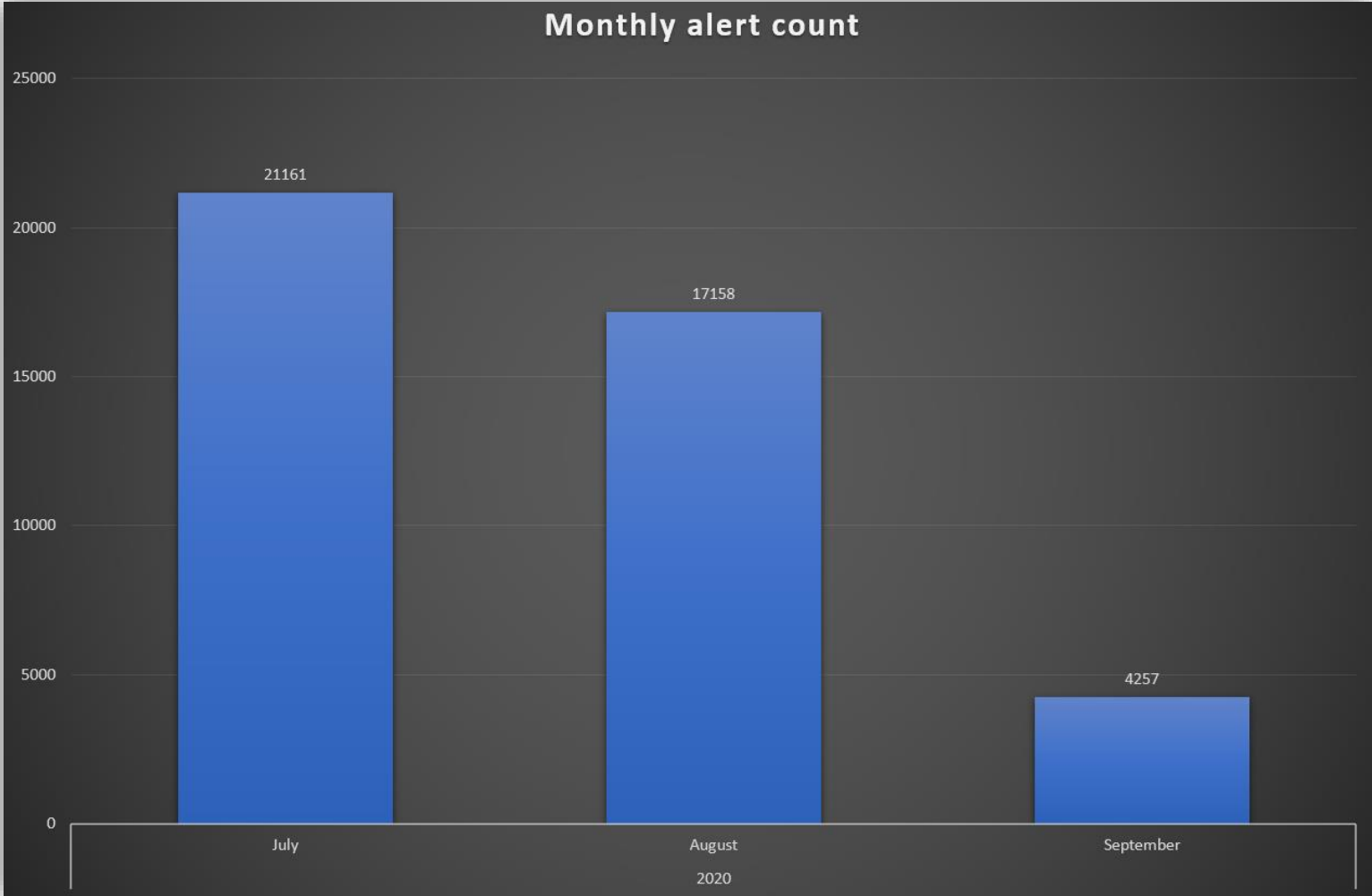|	Resolution times	Count
1	Sum 1: Alerts resolved in less than 4h	502
2	Sum 2: Alerts resolved between 4h and 24h	271
3	Sum 3: Alerts resolved between 1d and 3d	62
4	Sum 4: Alerts resolved in more than 3d	98

Total sum: 933

Export

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General overview of alerts from NMVS Alerts

Alert count in last 7 weeks

Week	Count
Week 30	3599
Week 31	3927
Week 32	5607
Week 33	5364
Week 34	3080
Week 35	2307
Week 36	2279
Week 37	2498

2020

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Monthly alert overview

Signing up for NMVS Alerts

SIGN UP

Kindly send name and email to info@dmvo.dk

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DMVO´s information needs when investigating alerts

Kindly provide following <u>mandatory information</u> to <u>info@dmvo.dk</u>:

- ☐ Alert Id
- ☐ Batch number (LOT/Batch)
- ☐ Product code (PC/GTIN)
- ☐ Expiry date (EXP)
- ☐ Contact person

Additional highly recommendable information:

1) Serial Number (SN)
2) Picture of the 2D Data matrix code from identical same batch

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Question time!

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Thank you for your participation!