RESOURCES

European Union Regulatory Updates

This is a compilation of the recent regulatory updates for the European Union. Every week, we post an update of what's new, which you can **view here**.

As of January 1, 2021, EU FMD no longer applies to the United Kingdom. Due to traditional supply routes through Great Britain to other countries where EU FMD still applies, notably Cyprus, Malta, Ireland, and Northern Ireland, the European Commission and the MHRA have provided relative guidance.

2023

- **October 16:** Reports of counterfeit medicines entering the supply chain in Austria have been confirmed. The counterfeit drugs hospitalized many residents across the country.
- **October 9:** The Clementine release of the European Alert Management System (EAMS) is scheduled for PRD launch on November 17, 2023.
- **October 9:** Finland is set to switchover from the NMVS to the SolidSoft system on November 18, 2023.
- **October 9:** Belgium is set to transition to “full FMD” in 2024 pending a circular by the NCA. The exact date is still to be determined.
- **October 9:** Switzerland is expected to deliver a mandatory safety feature legislation/plan within the next two years.
- **October 2:** EMVO held an informational session on September 27 to

showcase the capabilities of the Clementine release of the European Alert Management System (EAMS). Meeting materials were distributed on October 2.

- **October 2:** The Federal Parliament of Switzerland adopted a motion to make medicinal pack safety features mandatory within two years.
- **June 19:** The European Directorate for Food and Health Safety (DG SANTE) is pushing for Member States to end their stabilization periods, which were implemented to help ease the FMD transition and prevent medicine shortages.
- **June 19:** EMVO is calling on Member States to participate in a pilot that would create a "non-FMD" list of products to reduce overall alert rates.
- **June 19:** In the United Kingdom, the MHRA has published guidance on medicines packaging and the ending of EU FMD in Northern Ireland on January 1, 2025. This follows the Windsor Framework and legislation promulgated by the European Commission.
- **April 17:** Post-deadline stabilization periods, which were implemented to help ease the FMD transition and prevent medicine shortages, are being wound down. Only four remain active across the region.
- **April 3:** EMVO announced its slate of governance directors in place for 2023-2025. The European Commission also completed its first reading of a proposal for medicines for Northern Ireland.

2022

- **October 10:** European Medicines Verification Organization (EMVO) published several notices throughout September regarding the release of its latest version of its Alert Management System (AMS), codenamed Lilith. EMVO also answered several questions about Lilith, addressing common user questions on the AMS, platform access, and country connectivity.
- **October 10:** EMVO published its fee model presentation and consolidated fee table for 2023.
- **September 26:** European Medicines Verification Organization (EMVO) has

launched a self-service portal that's designed to streamline user support.

- **July 11:** The European Commission Directorate General for Health and Food Safety has updated its **questions and answers document**. The document now answers an additional question regarding rules for verifying products that are not in the physical possession of the verifier.
- **July 11:** The European Medicines Verification Organization (EMVO) announced that the next FMD Implementation Workshop will be held in Brussels on September 8, 2022. Attendees can join in person and online.
- **June 27:** The European Medicines Verification Organization (EMVO) will publish another update for the EU Hub and alert endpoint certificate renewal procedure on June 27, 2022.
- **June 13:** The European Medicines Verification Organisation (EMVO) published an update to its certificate renewal announcement, reporting that users can expect Arvato blueprint system downtimes June 27-28, 2022.
- **June 13:** EMVO successfully deployed EU Hub Release 1.11 to the production environment on June 11, 2022.
- **June 5:** EMVO - EU Hub Certificates: The European Medicines Verification Organization (EVMO) continues to publish updated information and progress on the installation of new certificates. These certificates are required to maintain connection to the EU Hub and to receive potential falsification alerts.
- **June 5:** Finland NMVO - Training Events: The Finnish Medicines Verification Organization has set up numerous "refresher course" training events in English for MAHs in September and October. Registration is required.
- **June 5:** Germany, Poland - Ukraine Donations: Germany and Poland have published rules for donating medical supplies to Ukraine. Each country differs in how to treat EU FMD obligations.
- **June 5:** Ireland - Stabilization Period: The Irish Medicines Verification Organization announced the end of its "Use and Learn" period as of May 30, 2022. This means that medicine packs that generate alerts may not be dispensed to patients until the root cause of the alert is resolved.

- **June 5:** UK, Romania - New National Medicines Verification System (NVMS) Feature: SecureMed and OSMR published information on a new NMVS feature that could prevent double-decommissioning attempts from generating an L5 alert.
- **May 22:** EMVO deployed its AMS (Alert Management System) “Bud” release into Production. The AMS Team is planning a National Competent Authority (NCA) workshop on June 15
- **May 15:** EMVO updated instructions for the renewal of EU Hub and alert endpoints certificates.
- **May 15:** EMVO held a highly interactive six-hour FMD Implementation Workshop in Brussels on May 12. About 70 OBPs attended the live meeting, with another 100 attending online. Highlights included a panel discussion of several country NCAs and NMVOs on stabilization periods and pack quarantining, as well as discussions on the new EMVS alerts imposed by Brexit.
- **May 1:** EMVO will be holding a six-hour FMD Implementation Workshop in Brussels on May 12, 2022.
- **April 24:** EMVO published a detailed timeline for renewal of certificates for connecting to the EU Hub and for alert endpoints.
- **April 24:** As of the end of February 2022, the overall EMVS alert rate was 0.18%. In 2021, EMVO revised its calculation methods, so this number is not directly comparable to earlier data.
- **April 17:** The EMVO Alert Management System team published its second newsletter, which highlights recent and upcoming releases to the system in preparation for the End-to-End piloting phase in May 2022.
- **April 17:** EMVO published the agenda for its 6-hour workshop in Brussels on May 12. Topics include EMVS operational updates, the Alert Management System, Brexit updates, Stabilization Periods, and Alert Reduction.
- **April 10:** EMVO sent out confirmations to attendees for their live, 6-hour, implementation workshop in Brussels on May 12. Attendance is limited to one

person per company. Live streaming will be available.

- **April 3:** EMVO is urging technical teams and solution providers to attend an upcoming Q&A session, scheduled between April 20 and May 18, for guidance on renewing EU Hub certificates.
- **April 3:** EMVO distributed the first issue of its Alert Management System email newsletter, which contains project progress and key upcoming milestones.
- **April 3:** The German NMVO, securPharm, published its 22-page annual Status Report, which covers legislative changes, progress in reducing alerts, and a review of several EU FMD principles.
- **March 27:** EMVO is holding a live, 4-hour, implementation workshop on May 12 in Brussels. Attendance is limited to one person per company and registration closes on April 8.
- **March 20:** EMVO and the NMVOs published the latest edition of their Community Newsletter, which covers national progress on alerts and Alert Management System status.
- **March 20:** Alert Management. EMVO held an Alert Management System (AMS) Informational Session on Monday, March 7. The first countries to pilot the AMS will be Germany, Poland, Romania (TBC), Cyprus, France, and Slovenia.
- **March 20:** The Czech NMVO (NOOL) reminded users that re-validating an alert-generating pack that is quarantined will generate additional alerts until the investigation has been closed.
- **March 20:** The Czech NMVO (NOOL) and the Czech Republic Ministry of Health published instructions for decommissioning medicine packs donated to Ukraine, as well as considerations for companies organizing such donations.
- **March 20:** The Finnish NMVO (FiMVO) published its March 15, 2022 webinar presentation for end-users on managing FMD packs.
- **March 20:** The Hungarian NMVO (HUMVO) provided instructions for managing packs destined for Ukraine and possible scenarios where

decommissioning would be required.

- **March 20:** The Irish NMVO “use and learn” period ends May 30, 2022. Alert-generating packs may be supplied to patients until that time unless there is an overriding concern that the pack is falsified.
- **March 20:** The Polish NMVO (KOWAL) created a knowledge base on EU FMD and use of the PLMVS. The compendium is intended for all end users.
- **March 20:** The latest Romanian NMVO (OSMR) newsletter noted the extended deadline, up until as late as Feb 9, 2025, for Italy and Greece to implement FMD. OSMR expressed their willingness to support those countries with best practices learned over the past three years of FMD.
- **March 6:** MVO held an Alert Management System Informational Session on March 7. The first countries to pilot the AMS will be Germany, Poland, Cyprus, France, Slovenia, and possibly Romania.
- **February 27:** The European Commission has published Delegated Regulation 2022/315, which amends DR 2016/161 (EU FMD):
    - DR 2022/315 was published in the Official Journal on February 28, 2022.
    - The amendments apply retroactively to January 1, 2022.
    - Details on the amendments, which are mostly Brexit-related, were discussed in late December and in the March 3 session of the EU SIG Community.
- **February 27:** EMVO will hold an Alert Management System Informational Session on Monday, March 7. Registration is required.
- **February 6:** Happy Birthday! EMVO and several NMVOs recognized the EMVS’ third anniversary of its System Go-Live through press releases reiterating the system’s mission and progress in preventing counterfeit medicines.
- **February 6:** The UK Medicines and Healthcare products Regulatory Agency (MHRA) has not yet circulated the February 2 and February 3 session recordings, but announced its intent to do so soon.
- **January 30:** EMVO announced four one-hour Alert Management System

Summit sessions to be held in March 2022. Capacity is limited to 250 participants for each session.

- **January 30:** Registration has closed for the February 9 FMD Implementation Workshop and EMVO has published the topics, which include:
  - Three Years of FMD: New EMVO Structure, Achievements, Upcoming Projects
  - Operations: EMVS Update for 2022
  - Brexit Updates
  - Alert Management System Updates
- **January 30:** At its February 2 and February 3 webinars on Northern Ireland, The UK Medicines and Healthcare products Regulatory Agency (MHRA) explained the pathways for product licensing and validity in the post-Brexit transition period.
- **January 30:** Sweden's NMVO (eVis) published an announcement that the Swedish Medical Product Agency now requires that wholesale distributors and outpatient pharmacies comply with NMVS certification prerequisites when applying for operating licenses.
- **January 30:** Ireland's NMVO (IMVO) updated its phased ending of relaxed FMD requirements. The "Use and Learn" FMD Stabilisation Period will formally end on May 30, 2022.
- **January 23:** The Medicines and Healthcare products Regulatory Agency (MHRA) will be holding webinars on February 2 and February 3 on medicines supply for Northern Ireland. Registration is required.
- **January 16:** Registration for the next EMVO FMD Implementation Workshop is due by February 2, with limited capacity. Topics have yet to be published for the 3-hour workshop. Past topics have included EU Hub releases, "product unknown" processes, the EMVO Alert Management System, and Brexit.
- **January 16:** The Italian Ministry of Health indicated that it had not started its FMD implementation yet in response to a TraceLink information request on the status of the project.

- **January 16:** The Medicines and Healthcare products Regulatory Agency (MHRA) published further updates to its post-Brexit guidance documents for Medicines and Medical Devices, including supply and FMD requirements for Northern Ireland. The MHRA will be holding webinars on February 2 and 3 on medicines supply for Northern Ireland. Registration is required.
- **January 9:** The Czech NMVO (NOOL) announced that MAHs can close out alerts after 14 days if an end-user fails to provide additional investigatory information.
- **January 9:** SecurMed, the UK medicines verification system provider, reiterated its commitment—and that of the Medicines and Healthcare products Regulatory Agency (MHRA)—to supporting EU FMD in Northern Ireland.
- **January 2:** EMVO invited stakeholders to its FMD Implementation Workshop on February 9. Registration and approval to attend is mandatory and completion is recommended by February 2.
- **January 2:** The European Commission and Pharmaceutical Acquis Consultation are conducting a “Have Your Say” consultation on changes to EU pharmaceutical legislation to ensure continuity of medicines supply to Northern Ireland, Ireland, Cyprus, and Malta. The consultation ends on March 2 and focuses on marketing and manufacturing authorizations in Great Britain and in wholesaler/import authorizations for the aforementioned countries.
- **January 2:** United Kingdom – The Medicines and Healthcare products Regulatory Agency (MHRA) updated its guidance on FMD requirements in line with various UK Marketing Authorization types.
- **January 2:** United Kingdom – The MHRA stated that the government is committed to exploring all options, including consultation, for a national system.
- **January 2:** The Czech NMVO (NOOL) announced that beginning in Spring 2022, end users will be able to reconcile alerts generated because of technical errors such as keyboard layout mismatches and incorrect CapsLock

settings on scanners. Currently, OBPs are responsible for alert resolution.

- **January 2:** The Ireland NMVO (IMVO) delayed implementation of Phase 3 and Phase 4 of its “Use and Learn” period due to COVID priorities.
- **January 2:** The Romania NMVO (OSMR) announced that it would take part in the Alert Management System (AMS) pilot beginning in March 2022.

2021

- **December 19:** The Member State FMD Working Group issued version 19 of the Safety Feature Q&A, with one new question and three revisions to previous questions. Of particular note is the change in Q7.19, which now “strongly discourages” data upload from outside the European Economic Area, but does not strictly require data upload from the EEA.
- **December 19:** On December 17, the European Commission announced additional legislative amendments to facilitate the implementation of the Northern Ireland (N.IE) Protocol.
- **December 19:** The European Commission is amending six articles in the 2016/161 Delegated Regulation. Among the amendments are a 3-year extension of the derogation for EU/UK export decommissioning, as well as changes to alerts and wholesaler verifications in some countries.
- **December 12:** The Member State expert FMD Working Group issued version 19 of the Safety Feature Q&A, with one new question and three revisions to previous questions.
- **December 12:** EMVO announced issues related to Alert messages which do not contain the Source parameter.
- **December 5:** EMVO announced the successful deployment of EU Hub Release 1.10 to the Production environment on December 5.
- **December 5:** EMVO shared results of a survey of NMVOs that provides an overview of alert resolution times determined by each country.
- **December 5:** EMVO has postulated three scenarios for the continuation or discontinuation of EU FMD in Northern Ireland, but urges stakeholders to continue with “business as usual” in serializing and uploading UK pack data.

- **December 5:** The Finnish MVO (FiMVO) has communicated a “three scan” threshold at a given location before a double-decommissioning alert is generated.
- **November 28:** Indications are that the European Commission will not be limiting data upload to the EU Hub from the European Economic Area only. This proposal was previously in play as a potential amendment to the Delegated Regulation.
- **November 28:** The European Commission is developing amendments to the Delegated Regulation to ensure uninterrupted medicines supply in Northern Ireland.
- **November 28:** EMVO announced the departure of long-time EMVO leader and COO Tobias Beer as of December 31.
- **November 14:** EMVO published a Q&A document from the September 16 workshop related to Designated Wholesalers.
- **November 7:** There is no news on the European Commission’s intentions to amend the Delegated Regulation:
    - An extension of derogation of export decommissioning from the European Economic Area (EEA) to Great Britain until the end of 2024.
    - Additional alerts on medicines intended for Northern Ireland which are then detected in other EU markets.
- **October 31:** Depending on the outcome of EU/UK negotiations, the following amendments may be applied to the Delegated Regulation:
    - An extension of derogation of export decommissioning from the European Economic Area (EEA) to Great Britain until the end of 2024.
    - Additional alerts on medicines intended for Northern Ireland which are then detected in other EU markets.
- **October 31:** EMVO presented an Alert Management System (AMS) Information Session, including a project overview and AMS demo on managing alerts, as well as a timetable for 2022 pilots and implementation.
- **October 31:** EMVO announced that EU Hub Release 1.10 would go into

production in December. It has successfully been deployed into the integrated test environment (ITE).

- **October 24:** Several NMVOs have announced downtimes in October for NMVS upgrades and releases. Maintenance windows generally take place late in the evening.
- **October 17:** France has submitted a notice to the European Commission (EC) to change its product coding scheme. The industry is concerned that the new scheme will be incompatible with EU FMD standards. The EC will be assessing industry feedback until December 29, 2021.
- **October 17:** No further news at this time on the European Commission's proposal to restrict data upload to the EMVS only through hardware/software infrastructure physically located in the European Economic Area and Northern Ireland.
- **October 17:** EMVO will be conducting four Alert Management System (AMS) awareness workshops between late October and mid-November. Registration is required and space is limited.
- **October 10:** No further news at this time on the European Commission's proposal to restrict data upload to the EMVS only through hardware/software infrastructure physically located in the European Economic Area and Northern Ireland.
- **October 10:** EMVO announced its next FMD Implementation Workshop for November 18.
- **October 10:** The Czech NMVO (NOOL) updated its "Important Information / Q&A" aimed at end-users.
- **October 10:** The Danish NMVO (DMVO) continues to receive requests on reactivating packs that have been decommissioned, and reminds users that there is a 10-day window for doing so. Reactivation must be done from the same location and some statuses, such as "exported", cannot be reversed.
- **October 10:** The Latvian NMVO (LZVO) announced the pilot phase of the Alert Management System (AMS) Hub, effectively launching the pilot in the

production environment as of October 4.

- **October 10:** The Maltese NMVO (MaMVO) will hold an explanatory session of NMVS Release 9 on October 14. The event is aimed at end-users and requires registration.
- **October 10:** The Icelandic NMVO (ICEMVO) published its findings on reducing alert rates, with “double decommissioning” the primary culprit, and announced plans to connect to the Alert Management System (AMS) Hub in 2022.
- **October 3:** The industry is reacting urgently to the European Commission’s proposal to restrict data upload to the EMVS only through infrastructure/hardware/software physically located in the European Economic Area and Northern Ireland. The European Federation of Pharmaceutical Industries and Associations (EFPIA), Medicines for Europe, and EMVO are urging MAHs to voice their concerns on the impact of the amendment directly through their industry associations.
- **October 3:** EMVO issued a reminder that verifications can only be carried out for product packs under physical possession of an on-boarding partner (OBP).
- **September 26:** EMVO published an announcement that Product Withdrawal, Batch Recalls and Decommissioning to certain pack statuses cannot be undone, and that EMVO does not have the functionality to rectify OBP mistakes in this regard.
- **September 26:** The Czech NMVO (NOOL) presented the English version of its IT workshop webinar, which led to questions on how alert-generating packs would be quarantined and possibly returned to wholesalers and manufacturers.
- **September 26:** The Icelandic NMVO (ICEMVO) published instructions for using the NMVS-Alerts service (nmvs-alerts.com) used by many SolidSoft Blueprint countries.
- **September 26:** The Latvian NMVO (LZVO) published a reminder that only medicinal packs in a user’s physical possession may be

verified/decommissioned.

- **September 26:** The Swedish NMVO, e-Vis, announced that National System fees for 2022 would be reduced by 10% with respect to the 2021 fees.
- **September 26:** The Swiss Medicines Verification Organization (SMVO) published the Federal Health Office (BAG) timeline for implementing the government's localized version of FMD into Swiss Law, projected to be in force by mid-2023 following incorporation of consultation feedback. It remains unclear whether the final law in Switzerland will impose mandatory adoption of localized FMD measures. Currently FMD remains voluntary.
- **September 19:** Approximately 200 people attended EMVO's September 16 FMD Implementation Workshop. The 3-hour meeting covered EU Hub enhancements and various aspects of Alert Management.
- **September 19:** EMVO will be issuing an announcement on the permanency of reporting batches as "recalled" or "withdrawn" because neither operation can be undone.
- **September 19:** EMVO continues to ramp up its training and implementation plans for the overall Alert Management System (AMS). The user access and architecture will mirror that of the EU Hub.
- **September 5:** EMVO announced that testing activities for the Alert Management System Hub and Portal will be conducted throughout September and will be deployed in production in October.
- **September 5:** EMVO will hold its next FMD Implementation Workshop on September 16. Registration is required by September 9. The agenda is expected to cover EMVS enhancements, Alert Management System (AMS), and Northern Ireland Pack Management in 2022.
- **August 29:** EMVO will hold its next FMD Implementation Workshop on September 16. Registration is required by September 9. The agenda is expected to cover EMVS enhancements, Alert Management System (AMS), and Northern Ireland Pack Management in 2022.
- **August 29:** The Czech NMVO (NOOL) will be holding webinars in both Czech

and in English on their Alert Management System and on new processes.

- **August 29:** The Finnish NMVO (FiMVO) will hold a webinar in Finnish for pharmacies and wholesalers to manage alerts generated by returns processes.
- **August 29:** The United Kingdom/Northern Ireland Medicines Verification Organization (SecurMed) published a reminder of the requirements/restrictions for uploading packs intended for supply in Northern Ireland into the European Medicines Verification System (EMVS).
- **August 15:** EMVO will hold its next FMD Implementation Workshop on September 16. The registration deadline is September 9.
- **August 8:** The European Medicines Verification Organization (EMVO) announced its next FMD Implementation Workshop for September 16. Registration is required by September 9. No topics have been announced, but it is expected that the Alert Management System will be discussed.
- **August 1:** For the first time, the European Commission has rejected an application to include a medicine (Zinc-D-Gluconate) onto the FMD white list, which contains prescription medicines exempted from EU FMD requirements.
- **August 1:** The German NMVO (ACS PharmaProtect/securPharm) will be holding a webinar on September 15 (in German) on plans for the local and EMVO Alert Management Systems.
- **August 1:** The Czech NMVO (NOOL) has launched its alert management tool for end users, notifying them that, like MAHs, they will have a certain number of days to resolve or respond to L5 alerts.
- **July 25:** EMVO published an announcement reminding onboarding partners (OBPs) to confirm the correct entries for Designated Wholesalers in their product master data for each product.
- **July 11:** The Irish NMVO (IMVO) has announced a 7-phase approach to ending its “use and learn” stabilization period by Q1 2022.
- **July 4:** The European Medicines Verification Organization (EMVO) released v2.0 of its Alert Management Guideline, which promotes harmonization of

processes and tools for resolving L5 alerts through the learnings of the past two years. The guideline is not prescriptive as alert management follows national policies and practices.

- **June 27:** The Austrian NMVO (AMVO) held a two-hour informational webinar for marketing authorization holders (MAHs), emphasizing changes in alert management upon the end of its "start phase." An exact date has not been given, but is anticipated to be in Autumn 2021.
- **June 20:** The Belgian NMVO (BeMVO) has updated the FAQ on its website, with practical information for stakeholders to manage operational tasks.
- **June 20:** The Czech Republic NMVO (NOOL) is preparing to release v4.0 of its alert management system, which will go live in the first half of August 2021.
- **June 20:** In its summer newsletter, the Finnish NMVO (FiMVO) provided subscribers with information on its latest system release (primarily for end-users such as wholesalers and pharmacies), as well as a short FAQ on resolving "Product Not Found" alerts.
- **June 20:** Poland's medicines regulator, Główny Inspektorat Farmaceutyczny (GIF) has published a guide for medicines verification, describing and clarifying processes on EU FMD rules and alert management.
- **June 13:** The European Medicines Verification Organization (EMVO) published an announcement stating that packs ("Approved Packs") with EU-wide marketing authorizations should only be uploaded to those target markets where the packs are intended to be marketed and sold.
- **June 13:** The deployment of EU Hub Release 1.9 was successfully performed on June 5, 2021.
- **June 13:** The Expert Working Group of the European Commission made a minor change in the response to its Safety Feature Q&A (Question 1.14) on the reference standard for anti-tamper devices. The version is now "18B."
- **June 13:** The Austrian NMVO (AMVO) held a comprehensive webinar on a range of topics, including alert management. AMVO presented a 3-day time window for MAHs to determine whether an alert was generated as a process

error, posing challenges in the case of end-user generated alerts such as A7, A24, and A68.

- **June 6:** The deployment of Release 1.9 to the EU Hub production environment is planned for June 5, 2021.
- **June 6:** EMVO, via the Danish NMVO (DMVO), published a color-coded Alert Rate map per country (red >1%, orange >0.1%, and green <0.1%).
- **June 6:** The Polish NMVO (KOWAL) expanded its FAQs to include a perspective from supervisory authorities.
- **May 30:** The deployment of Release 1.9 to the EU Hub production environment is planned for June 2021. An exact date has not yet been communicated.
- **May 30:** EU FMD: An expanded FAQ from securPharm/ABDA (Federal Union of German Associations of Pharmacists) has been published to help pharmacies avoid generating “false positive” alerts and to engage in the alert resolution process.
- **May 23:** The Finnish NMVO (FiMVO) delivered an information session for MAHs on the EMVS Change Control Board and Alert Management status and causes (Finland is at 0.04%, below the target threshold). The materials are available in English.
- **May 23:** The Latvian NMVO (LZVO) reported a 15% year-over-year increase of packs scanned by end users in Q1 2021, signifying a steady increase in adoption of EU FMD in Latvian pharmacies.
- **May 23:** The Maltese NMVO (MaMVO) has announced an Orphan Drug Fee Exemption scheme for centrally authorized products, such as those at the EU-level. Some conditions apply and the exemption must be re-applied for annually.
- **May 23:** The Polish NMVO (KOWAL) expanded its FAQ on Alert Management in response to recent enquiries from stakeholders. The additional content focuses mostly on the wholesaler segment.
- **May 23:** The Romanian NMVO (OSMR) has published a perspective on EU

FMD by a representative of the Romanian College of Pharmacists. The article suggests that perceptions regarding the “inconvenience” of EU FMD are slowly changing.

- **May 23:** The Slovenian NMVO (ZAPAZ) has published a list of medicines whose packaging contains so-called “inactive codes.” The similar appearance to the 2D Data Matrix required by FMD has created confusion and system errors upon scanning.
- **May 16:** EMVO held a three-hour online event on May 12 for EMVS stakeholders. Approximately 170 people participated in discussions on:
    - EMVS ecosystem updates
    - Alert management (including the alert management system)
    - FMD application to COVID-19 vaccines
    - Change Control Board processes
- **May 16:** The Danish NMVO published an interview with the director of the Spanish NMVO (SEVeM) regarding Spain’s onboarding challenges for public hospitals to the NMVS. Part of Spain’s plan (about to be piloted) includes providing aggregated data to hospitals for verification/decommissioning.
- **May 9:** The European Medicines Verification Organization (EMVO) published its first issue of the EMVS Community Newsletter, a joint communication effort amongst EMVO and the NMVOs.
- **May 9:** The Irish NMVO (IMVO) published a survey on how community pharmacies have been benefiting from Falsified Medicines Directive (FMD) software through the additional data acquired. One example cited was expiry date tracking.
- **May 9:** The Swedish NMVO (e-Vis) published an article on how the recent SolidSoft Blueprint Release 8 facilitates alert investigations with functionalities designed to provide better information to end-users and facilitate resolution for on-boarding partners (OBPs).
- **May 2:** The European Medicines Verification Organisation (EMVO) reports that the overall EMVS alert rate is declining, with a 0.26% rate being recorded in

Week 13.

- **April 25:** The European Medicines Verification Organization (EMVO) announced EU Hub Release 1.9, which will be deployed to production in early June and focus primarily on alert management, including integration with the Alert Management System (AMS).
- **April 25:** The European Medicines Verification Organization (EMVO) carried out maintenance on the portal for on-boarding partners (OBPs) early last week and continues to encourage OBPs to subscribe to the **European Medicines Verification System Information (EVI) notifications**, which provide news and updates on scheduled and unscheduled downtimes for the various national verification systems.
- **April 25:** The securPharm FAQ is now available in **English**. It includes detailed information on IFA registration numbers and a description of the process for de-escalating alerts. Note that alerts that go unaddressed for more than 7 calendar days will be escalated by securPharm to the Federal Institute for Drugs and Medical Devices.
- **April 25:** Several national systems (NMVOs) relayed the warning to consumers not to acquire vaccines online and referenced the Wall Street Journal article on fake doses seized in Poland and Mexico.
- **April 25:** Several national systems (NMVOs) running the SolidSoft blueprint are upgrading their national system software this week, with downtimes expected in the late evening hours.
- **April 18:** An issue with the EU Hub in mid-March resulted in an unknown number of alerts being irretrievably lost. Members of TraceLink's EU SIG also experienced this system failure when "unresolved" alerts were communicated to them by the NMVOs.
- **April 18:** Alert Management Updates
    - Finland's NMVO (FiMVO) updated its alert management and resolution process (v2.0) and will go into effect on May 3.
    - Poland's NMVO (KOWAL) published FAQs on its website for dispensers to

manage common alert causes. A government website links to the Alert Management Guide and reporting templates.
    - Slovakia's NMVO (SOOL) has created three portals for alert management, each for a different stakeholder group: MAH, Pharmacy, and Distributor.
    - The United Kingdom/Northern Ireland NMVO, SecurMed, stated that they encourage MAHs to upload alert root causes analyses overnight. This presents a challenge for many OBPs.
- **April 18:** The securPharm FAQs for pharmaceutical companies have been updated. Version 4 replaces version 3 from September 2, 2020 and features one new question and changes to 14 others. **An English translation is now available.**
- **April 11:** The Icelandic NMVO (ICEMVO) announced R8.0 for SolidSoft blueprint NMVS's. Most of the changes are back-end enhancements related to APIs for pharmacies and wholesalers. Although it has yet to be implemented, one notable enhancement is a "Repeat check-out alert for the same user" that is intended to reduce L5 alerts where a warning will be issued in lieu of an alert. The threshold number of retries is being negotiated within the EU.
- **April 4:** Several NMVOs have published brief news items linking to the European Commission Amendment of Article 22 regarding the derogation of export decommissioning from the European Economic Area (EEA) to the UK for 2021.
- **March 28:** The European Commission Amendment of Article 22, which provides a derogation for the requirement to decommission packs exported from the European Economic Area (EEA) to the United Kingdom for the entirety of 2021, has now been published in the Official Journal of the EU. DR 2021/457 amends DR 2016/161 to provide a temporary derogation from January 1, 2021 to December 31, 2021 for the requirement of wholesalers to decommission packs exported from the EEA to Great Britain.
- **March 28:** Some NMVOs announced a recent update of their NMVS transactional and reporting systems, which are expected to be rolled out to all

Arvato-blueprint NMVS as well. NMVS Core Release 1.08.008 provided performance improvements while NMVS Reporting Release 1.05.010 enhanced report delivery to National Competent Authorities.

- **March 28:** The Norwegian NMVO (NOMVEC) launched a website aimed at the general public regarding the prevalence of counterfeit medications and how the pharmaceutical industry has reacted to safeguarding supply.
- **March 21:** The European Commission Amendment of Article 22, which provides a derogation for the requirement to decommission packs exported from the European Economic Are (EEA) to Great Britain for the entirety of 2021, has still not yet gone into force because of the procedural 60-day "objection period" within the EU.
- **March 21:** The Bulgarian NMVO (BgMVO) published its first version of Bulgaria's Alert Management guideline.
- **March 14:** The European Commission Amendment of Article 22, which provides a derogation for the requirement to decommission packs exported from the EEA to Great Britain for the entirety of 2021, has still not yet gone into force because of the procedural 60-day "objection period" within the EU.
- **March 14:** EMVO published the collective decision of EMVS stakeholders to not propagate 2020 alerts that had been stuck in a queue to Onboarding Partners (OPBs), citing that such alert forwarding would constitute an excessive and unnecessary investigational burden for OBPs and NMVOs.
- **March 14:** The Finnish NMVO (FiMVO) published guidance on the treatment of expired packs in the EMVS. The EMVS automatically marks a pack as "Inactive" after its expiry date. After this date, the pack status can no longer be changed, so attempts to do so generate error messages.
- **March 14:** The German NMVO, securPharm, published its 2021 Status Report on the German NMVS within the context of the entire EMVS. The report includes details on 2020 operations, adoption; system progress and development; challenges related alert management; and an overall outlook. The report is available in both German and English.

- **March 14:** The Latvian Ministry of Health and the Latvian NMVO (LZVO) published a consumer-directed statement on the risk of counterfeit COVID-19 medications being sold online. COVID vaccines are not authorized to be sold online in Europe.
- **March 14:** The Romanian NMVO (OSMR) published its March 2021 newsletter which contains national alert statistics and illustrates the hot topic of alert investigations related to intermarket transactions (IMTs), both from a system perspective and a compliance/contractual perspective.
- **March 14:** The Swedish NMVO (e-Vis) issued a press release on the European COVID vaccine distribution model and anti-counterfeiting measures in place, including the strategy of using selected National Systems as a data repository. The article also echoes the elevated risk of counterfeiting due to the high demand and limited supply.
- **March 7:** The European Commission Amendment of Article 22, which provides a derogation for the requirement to decommission packs exported from the EEA to Great Britain for the entirety of 2021, has still not yet gone into force because of the procedural 60-day "objection period" within the EU. The amendment could go into force as early as March 14, 2021 and will be retroactive to January 1, 2021.
- **March 7:** The UK Healthcare Distribution Association (HDA) is asking that pharma companies supply to their wholesalers SKU-level information needed to complete paperwork for distribution of medicines to Northern Ireland; these include Commodity Code, COO (country of origin), and Article description. This appears to be a customs requirement.
- **February 28:** The EU Change Control Board (CCB) published its latest newsletter, outlining its role in the COVID-19 Task Force, Brexit, and the 2021 EMVS Roadmap. This governance body is composed of representatives from EMVO, several NMVOs, and two industry associations.
- **February 28:** Brexit/Northern Ireland Updates
    - The European Commission Amendment of Article 22, which provides a

derogation for the requirement to decommission packs exported from the European Economic Area (EEA) to Great Britain for the entirety of 2021, has still not yet gone into force because of the procedural 60-day "objection period" within the EU. The amendment could go into force as early as March 14, 2021 and will be retroactive to January 1, 2021.
    - EMVO published a clarification on uploading requirements for packs intended for Northern Ireland, stating that MAHs must consider the marketing authorization's validity in that region to determine the obligation to apply EU FMD safety features and upload data to the EMVS.
- **February 28:** Alert Management Updates
    - EMVO published the collective decision of EMVS stakeholders to not propagate to OBPs 2020 alerts that had been stuck in a queue, citing that such alert forwarding would constitute an excessive and unnecessary investigational burden for OBPs and NMVOs.
    - The Czech NMVO (NOOL) has updated its extensive alert management guidance and now includes several detailed process flowcharts for determining investigative courses of action.
    - The Danish NMVO (DMVO) has updated its reference list of basic alert root causes and investigation requirements for MAHs; most importantly, it references conditions under which MAHs are expected to investigate A7 alerts.
    - The Maltese NMVO (MaMVO) held an evening training session for end-users to manage EU FMD alerts and asked that users attend that training (on demand) before submitting alert-related questions to the NMVO.
- **February 28:** The Swedish NMVO (eVis) will be holding a meeting on March 18 for all EU FMD stakeholders to discuss stabilisation periods, alert management, new system releases, COVID, and other relevant topics. The "Nordic Outlook" section will be held in English.
- **February 21:** The European Commission Amendment of Article 22, which provides a derogation for the requirement to decommission packs exported

from the EEA to Great Britain for the entirety of 2021, has not yet gone into force because of the procedural 60-day “objection period” within the EU. The amendment could go into force as early as March 14, 2021 and will be retroactive to January 1, 2021.

- **February 14:** The European Commission has still not officially published the Amendment of Article 22, which provides for a derogation of the export decommissioning requirement for packs entering the UK from the European Economic Area (EEA). Once published, it will apply from January 1, 2021 to December 31, 2021. The delay in publication is due to the right of the European Parliament and the Council to express objections. The amendment received positive assessment from the EU FMD Expert Working Group composed of representatives from National Competent Authorities throughout the EU.
- **February 14:** EMVO and several NMVOs are celebrating the two-year mark of the “go-live” of EU FMD across Europe, highlighting in particular the success of the stakeholder-driven model which sees participation and governance from across the pharmaceutical supply chain.
- **February 7:** There is still no official publication of the Amendment of Article 22, which provides for a derogation of the export decommissioning requirement for packs entering the UK from the european Economic Area (EEA). Once published, it will apply from January 1, 2021 to December 31, 2021. The delay in publication is due to the right of the European Parliament and the Council to express objections. The amendment received positive assessment from the EU FMD Expert Working Group composed of representatives from National Competent Authorities throughout the EU.
- **February 7:** EMVO updated its “preliminary account” of Brexit, now in its third version as of February 2. With respect to the previous version, it clarifies criteria for uploading packs into the United Kingdom/Northern Ireland Medicines Verification System (UKNI MVS) and outlines the verification steps based on EC Notice C (2020) 9264 that outlines steps to ensure the medicine

supply to nations dependent on Great Britain.

- **February 7:** The French NMVO is renewing its efforts to onboard the nation's more than 20,000 pharmacies to the NMVS, offering a simplified procedure for connection via a centralized connector.
- **February 7:** Malta will end its stabilization period on February 9, 2021.
- **February 7:** The Swedish NMVO, e-Vis, announced the planned deployment of the SMVS Release 8.0 (SolidSoft) at the end of April 2021 to facilitate end-users in investigating alerts. There are no major functional changes.
- **January 31:** The European Commission's amendment of Article 22, which provides for a derogation of the export decommissioning requirement for packs entering the UK from the European Economic Area (EEA), has not yet been published in the EU Official Journal, despite its apparent adoption on January 13, 2021. The amendment will go into effect once published, and will apply retroactively to January 1, 2021 and be in force until December 31, 2021.
- **January 31:** The European Medicines Verification Organization (EMVO) acknowledged the increase in A7 alerts being propagated to on-boarding partners (OBPs) as a result of configuration changes, backlogs/retries, and timestamp format changes. OBPs and National Medicines Verification Organizations (NMVOs) have been instructed to ignore A7 alerts older than 2021. A follow-on announcement is expected as EMVO investigates further.
- **January 31:** EMVO published instructions for manufacturers on uploading pan-European GTINs for COVID-19 vaccines: the data is to be uploaded to 11 target markets only to avoid overload of smaller National Medicines Verification Systems (NMVSs). EMVO also requests OBPs to provide a single point-of-contact for alerts generated by COVID-19 vaccines to ensure speedy resolution.
- **January 31:** The Greek government published in its Official Gazette the establishment of the Hellenic Medicines Verification Organization (HMVO) and associated legal constructs for the application of EU FMD in Greece. No

timelines for implementation have been communicated.

- **January 31:** The German NMVO operated by ACS/securPharm has launched an anonymous questionnaire for customers to evaluate ACS services and system functionalities such as alert management and reports. The questionnaire can be filled out in English or German.
- **January 24:** The European Commission (EC) has provided further information on its derogation of Article 22 of the Commission Delegated Regulation (DR) that governs export decommissioning of packs from the European Economic Area (EEA) to a "third country" such as the United Kingdom (UK). This amendment of Article 22 has not yet been published in the EU official journal, but appears to have been adopted on January 13, 2021 and would apply retroactively from January 1, 2021. It would allow a derogation of the requirement to decommission packs exported from the EEA to the UK from January 1, 2021 to December 31, 2021. The Amendment is a less restrictive approach with respect to that communicated in the EC Notice C (2020) 9264, which provided for such a derogation only when packs transit through Great Britain en route to Ireland (IE), Malta (MT), Cypress (CY), or Northern Ireland.
- **January 24:** At least two NMVOs (Latvia and Germany) have aligned with the original EC Notice C (2020) 9264 (not the less restrictive Amendment as described above) on export decommissioning of products being shipped to the UK. It is expected that this guidance will change when the Amendment to Article 22 (DR) is officially published. In the meantime, the Latvian NMVO has stated that:
    - Medicines exported from Latvia to Northern Ireland will continue to follow EU FMD regulations.
    - Medicines exported from Latvia to Great Britain must be decommissioned as "export".
    - Medicines exported from Latvia and passing through Great Britain en route to CY, IE, MT, or Northern Ireland, are not to be decommissioned, but export wholesalers must perform pack verification before shipment

and the importing wholesaler (in one of the aforementioned countries) must perform verification at receipt.

- **January 17:** Key differences in intent and operational guidance between the United Kingdom regulatory authority (MHRA) and the European Commission continue to challenge the industry in converging on a single interpretation regarding the need for export decommissioning for products originating from the European Economic Area (EEA) to the UK. Both agree that EU FMD serialization and reporting requirements apply to products destined for Northern Ireland. The key differences regard the final destination of the pack when transiting from the UK to an EU country and the timing of derogations. As of January 17, there have been no further updates or guidance from the primary authorities:
  - MHRA states that in 2021 it will not require products supplied from the EEA into the UK to be decommissioned upon export if the pack has a marketing authorization valid in Northern Ireland.
  - The European Commission has stated their intent to amend DR Article 22 to not require export decommissioning of products transiting via Great Britain and onward to Ireland, Cyprus, Malta, and Northern Ireland. No time limit is specified for this derogation.
  - EMVO guidance on export decommissioning is aligned with that of the EC. Its draft Brexit FAQ remains at v2 from December 9, 2020.
- **January 17:** Národní organizace pro ověřování pravosti léčiv (NOOL), the non-profit organization responsible for managing the Czech national medicines verification system (CZMVS) announced that end-users such as pharmacies can now participate in their Alert Management System, a tool for alert investigation and bi-directional anonymous communication between end-users and MAHs.
- **January 17:** The Norwegian NMVO reports multiple warnings from health authorities and INTERPOL in Europe about a significant risk of counterfeiting of COVID-19 vaccines. Europe does not currently allow the sale of these vaccines

over the internet, but rather through national immunization programs run by public health departments. The first wave of vaccine batches may be in non-country specific packaging and new vaccines will have the EU FMD safety features applied.

- **January 17:** SecurMed published technical instructions for end-users to connect to the the UK National Medicines Verification System (UKNI), now covering only pharmacies, wholesalers, and hospitals in Northern Ireland, and involves downloading a TAN code to be used with username and password.
- **January 10:** SecurMed, the not-for-profit company set up to establish the UK Medicines Verification System under EU FMD, announced that as of January 1, 2021, the UK National Medicines Verification System has become the UK NI (Northern Ireland) National Medicines Verification System and serves pharmacies, hospitals, wholesalers, and other end-users located in Northern Ireland.
- **January 10:** The United Kingdom regulatory authority (MHRA) provided yet more updated guidance on the pharmaceutical landscape in Northern Ireland and its relation to Great Britain. It states that throughout 2021 it will take a pragmatic approach in applying rules for supplying medicines to NI. It also recommends manufacturers and distributors retool their supply chains in preparation for 2022 with options that will not require importation controls when supplying medicines to NI.
- **January 10:** There have been no further updates or guidance since December's announcement on the European Commission's intent to amend DR Article 22 to not require export decommissioning of products transiting via Great Britain and onward to IE, CY, MT, and Northern Ireland.
- **January 10:** Pharmaceutical products intended for Bulgaria will be matched to the GTIN using a National Code, but this national number will not require encoding in the FMD 2D Data Matrix.
- **January 3:** The end of the Brexit Transition Period was December 31, 2020. The UK and EU have negotiated and passed a trade deal that went into effect

on January 1, 2021, after which EU FMD no longer applies to Great Britain but continues to apply to Northern Ireland. The UK National Medicines Verification System becomes the UK NI (Northern Ireland) National Medicines Verification System and serves pharmacies, hospitals, wholesalers, and other end-users located in Northern Ireland.

- **January 3:** The European Commission published a notice outlining further details of its recent Unilateral Declaration in relation to supply of medicines to Northern Ireland and other small markets after the end of the Transition Period (Medicines Supply in UK-dependent Markets). The document offers flexibility to certain EU pharmaceutical regulations because of the reliance of Cyprus, Ireland, Malta, and Northern Ireland on products from Great Britain. It states the EC's intent to amend DR Article 22 so that products exported from the Europe Economic Area (EEA) to Great Britain and then imported into Cyprus, Ireland, Malta, or Northern Ireland would not be subject to export decommissioning in 2021.

2020

- **December 27:** The EU/UK Joint Committee issued a draft unilateral declaration expressing the application of EU pharmaceutical regulations in Northern Ireland during 2021, including the exemption of export decommissioning of packs supplied to the UK from the EEA; consideration of small markets dependent on Great Britain medicines supply; and a grace period for sanctions for breaching EU law for certain violations.
- **December 27:** The Swiss NMVO (SMVO) announced that as of December 18, 2020, and as a result of the COVID-19 pandemic, Switzerland's Federal Office of Public Health (BAG) is currently unable to make a binding statement as to when the Swiss EU FMD analogue, Article 17a, will come into force.
- **December 27:** The Irish NMVO (IMVO) has extended its "use and learn" period into the first months of 2021, so that alert-generating packs may still be dispensed unless there is other evidence that they may be falsified.
- **December 20:** The MHRA updated its guidance on "Supplying authorized

medicines until December 31, 2021," stating there is now a one-year "grace period" that delays the requirement for export decommissioning on packs with marketing authorizations valid in Northern Ireland. This includes packs with UK-wide marketing authorizations and EU-centralized authorizations. This grace period does not cover marketing authorizations valid only in Great Britain.

- **December 20:** The Medicines/Devices Bill, which confers powers on the UK government to regulate medicines and a falsified medicine system, is in the "Report" stage in the House of Lords, where further scrutiny and eventual changes can still be made beginning on January 12, 2021.
- **December 20:** EMVO updated its fee model table for 2021 – 2022. These include one-off onboarding fees as well as annual NMVO fees.
- **December 20:** The Austrian NMVO (AMVO) released v4.0 of their product coding rules, providing updated guidance on multi-market packs and recommendations/best practices in a number of packaging and specification-related areas
- **December 20:** The Finnish NMVO (FiMVO) released a new version of its alert management SOP, which now incorporates handling of additional alerts being received by OBPs as a result of EU Hub release 1.8, EMVO has stated that with EU Hub release 1.8, MAHs are now going to receive alerts related to process or technical errors occurring downstream in distributors or pharmacies for their products.
- **December 13:** EMVO updated its draft set of Brexit-related questions. There are two important areas of pending guidance:
    - Operational guidance from the UK Medicines and Healthcare products Regulatory Agency (MHRA) for the 12-month "Implementation Period" in Northern Ireland for EU FMD, importation, and batch testing
    - A decision by the European Commission on whether to allow a reported 3- to 6-month "grace period" for decommissioning of products exported to Great Britain, allowing On-Boarding Partners (OBPs) to temporarily

continue their EU Hub serialization/reporting processes.

- **December 13:** Multiple On-Boarding Partners (OBPs) reported a sharp increase in alerts following the latest EU Hub release, which now forwards all product alerts to the OBP, even those caused by downstream errors.
- **December 13:** No update on the Medicines/Devices Bill, which confers powers on the UK government to regulate medicines and a falsified medicine system.
- **December 6:** EMVO published a draft set of Brexit-related questions based on the SecurMed/EMVO meeting in late November.
- **December 6:** The Medicines/Devices Bill, which confers powers on the UK government to regulate medicines and a falsified medicine system, will now proceed to the “Report” stage in the House of Lords, where further scrutiny and eventual changes can still be made. No date has been set, which indicates that a new UK-standalone system will not be in place by the end of the Transition Period on December 31, 2020.
- **December 6:** Iceland’s NMVO, ICEMVO, has stated that with EU Hub release 1.8, Marketing Authorization Holders (MAHs) are now going to receive alerts for their products when downstream process or technical errors occur at distributors or pharmacies.
- **November 29**: EMVO presented a range of topics at the FMD Implementation Workshop for industry stakeholders, including change management and governance; the false-positive alert reduction program SEA; and the Alert Management System (AMS) project.
- **November 29:** EMVO and SecurMed co-hosted a one-hour session on how the EMVS would change as a result of Brexit, and consequent actions and options for manufacturers who serve Northern Ireland, Great Britain, and European markets who may share those packs. Guidance on FMD phase-in for Northern Ireland in 2021 is still awaited and discussions are ongoing for a temporary derogation of Article 22 (export decommissioning) in the beginning months of 2021.

- **November 29:** The Medicines/Devices Bill, which confers powers on the UK government to regulate medicines and a falsified medicine system, will now proceed to the “Report” stage (date to be determined) in the House of Lords, where further scrutiny and eventual changes can still be made.
- **November 22:** EMVO has confirmed the production deployment of EU Hub release 1.8, which will begin on December 5 at 20:00 CET and continue until December 6 at 08:00 CET at the latest. Most of the enhancements are on the back end.
- **November 22:** SecurMed released a statement from the UK FMD Working Group for Community Pharmacy, outlining the future of FMD Safety Features in Northern Ireland and Great Britain. It confirmed that end users, including wholesalers, pharmacies, and hospitals that are not based in Northern Ireland (but not manufacturers who are connected to the EU Hub) will be automatically disconnected from SecurMed on December 31, 2020.
- **November 22:** The Medicines/Devices Bill, which confers powers on the UK government to regulate medicines and a falsified medicine system, continues to undergo vigorous debate in the House of Lords, with additional amendments made to the bill this week.
- **November 15:** Iceland’s NMVO (ICEMVO) communicated changes to their Solidsoft-blueprint system, including the exclusion of the “day” field in the 2D data matrix while verifying packs as well as better management of alerts that are generated as a result of Intermarket Transactions (IMTs).
- **November 15:** The Czech Republic NMVO (NOOL) published a process for MAHs to request exemptions for the application of safety features, though such requests are not accepted unless the product has already been QP-released and the serialisation/reporting cannot be easily rectified.
- **November 15:** The Medicines/Devices Bill, which confers powers on the United Kingdom government to regulate medicines and a falsified medicine system, continues to undergo debate in the House of Lords. However, many topics in this debate are focused on regulatory areas other than counterfeiting

(for example, cannabis licensing).

- **November 15:** The UK Government and European Commission agreed to phase in medicines regulations for Northern Ireland after the Brexit Transition Period. This phased process would last until December 31, 2021 and covers batch testing, importation regulations, and EU FMD provisions. The MRHA is expected to provide further guidance on implementation.
- **November 8:** Several Arvato-blueprint NMVSs have either undergone successful system upgrades or are planning upgrades in the coming days. While downtimes for these NMVSs may be possible, the upgrades are generally planned for evening hours after pharmacies are presumed to be closed.
- **November 8:** The United Kingdom NMVO, SecurMed, published that it will delay its announcement of 2021 MAH fees pending a final outcome of negotiations between the EU and UK for the post-Brexit Transition Period and definitive government guidance on EU FMD in the UK.
- **November 8:** EMVO posted an announcement on the current plan for the UK NMVS to remain connected to the EU Hub and become the UKNI MVS to support the default post-Brexit Transition Period scenario in which EU FMD continues to apply in Northern Ireland (NI). EMVO is working with the European Commission and Member States to discuss labelling, multi-market packs, and a possible grace period.
- **November 8:** The Medicines/Devices Bill, which confers powers on the United Kingdom government to regulate medicines and a falsified medicine system, will next be discussed in Committee stage (a line-by- line examination) in the House of Lords on 11 November. Several amendments have already been proposed.
- **November 1:** The Czech Ministry of Health is allowing MAHs to apply for exemptions in cases where it is not possible for end-users to verify the safety features, including anti-tamper devices and serialised unique identifiers. The exemption applies only to batches released by a Qualified Person.

- **November 1:** The Swedish verification system, e-Vis, advised users on the end of its 3-step alert-category stabilisation period on November 1. This means that all alerts must be reconciled before products can be dispensed. e-Vis notes that exemption requests from manufacturers will be accepted in cases where safety feature application errors cannot be rectified. In addition, e-Vis, which uses the SolidSoft blueprint, advised users of the system's update to version 7.1 on November 11. On-Boarding Partners (OPBs) are likely to notice improvements to Inter-Market Transaction (IMT) triggered alerts as well as the elimination of the "day" value consideration in the expiry date while verifying the unique identifier.
- **November 1:** The Medicines/Devices Bill, which confers powers on the United Kingdom government to regulate medicines and a falsified medicine system, is now scheduled to enter the Committee stage (a line by line examination) in the House of Lords on November 4. Current commentary in the House of Lords is focused on how the bill will make the UK more attractive to pharmaceutical manufacturers as well as the risk of drug shortages fueled by UK currency fluctuations under a no-deal scenario.
- **October 25:** EMVO has asked that on-boarding partners' technical teams confirm that their security protocols (TLS 1.2 or higher) are up to date, and, if they are not, to contact EMVO by October 30, 2020.
- **October 25:** Multiple NMVOs continue to remind NMVS end users—including distributors, 3PLs, pharmacies, and hospitals—to renew their connection certificates before they expire at the upcoming two-year mark.
- **October 25:** Due to an upgrade of Arvato-blueprint NMVSs from late October to early November, NMVOs have announced possible unexpected downtimes and recommend that end users ensure that reporting retry mechanisms are operational.
- **October 25:** PMVO Portugal states that the transition period in Portugal is still in force until further notice. Alerts are to be communicated via email using a supplied Word template.

- **October 25:** PMVO Portugal advises end users—primarily wholesalers—to send the National Healthcare Reimbursement Number (NHRN) when scanning 2D data matrix product identifiers. Validation between the NHRN and the GTIN is expected at a future date.
- **October 25:** The Medicines/Devices Bill, which confers powers on the United Kingdom government to regulate medicines and a falsified medicine system, is now scheduled to enter the Committee stage in the House of Lords on October 26.
- **October 25:** The United Kingdom regulatory authority (MHRA) has published an additional series of guidance documents for the post-Brexit Transition Period, mostly regarding Northern Ireland. It also expanded its previous guidance on supplying medicines to Northern Ireland with various case studies.
- **October 25:** Brexit negotiations between the EU and the UK have resumed and are now entering an “intensive” phase that began on October 22.
- **October 18:** Multiple NMVOs have reminded NMVS end users—including distributors, 3PLs, pharmacies, and hospitals—that Digital Certificates must be renewed every two years. Twenty months after the 2019 FMD implementation, companies are advised to review their initial connection dates and renew their certificates as needed.
- **October 18:** The United Kingdom regulatory authority (MHRA) has published guidance on supplying medicines to Northern Ireland prior to the end of the Brexit Transition Period on December 31, 2020 at 11:00 p.m. UK time. Questions remain for medicines placed in the market after January 1, 2021.
- **October 18:** The Medicines/Devices Bill, which confers powers on the United Kingdom government to regulate medicines and a falsified medicine system, will enter the Committee stage in the House of Lords on October 19. This past week, parliamentary discussions have focused on a potential “circuit-breaking” lockdown in the UK because of a surge of new COVID cases.
- **October 18:** Brexit negotiations between the European Union and the United

Kingdom remain at an impasse. The EU has stated a goal to reach a deal by the end of October.

- **October 11:** The European Medicines Verification Organization (EMVO) announced a December 2020 production release date for the EU Hub via release v1.8. Improvements include more robust alert generation and processing. EMVO reminded on-boarding partners (OBPs) that the 2016 schema will no longer be supported as of this release.
- **October 11:** The Latvian Medicines Verification Organization (LZVO) published perspectives on the direction of the EMVS, including using data for better management of COVID-19 medicines, synchronizing user data with official registries, and managing the unresolved process arising from Brexit
- **October 11:** United Kingdom: The Medicines/Devices Bill, which confers powers on the UK government to regulate medicines and a falsified medicine system, will enter the Committee stage in the House of Lords on October 19. This represents a five-delay postponement from the original timetable.
- **October 11:** United Kingdom: The Medicines and Healthcare products Regulatory Agency (MHRA) published guidance on supplying medicines to Northern Ireland prior to the end of the Brexit Transition Period on December 31, 2020.
- **October 11:** United Kingdom: The Medicines and Healthcare products Regulatory Agency (MHRA) scheduled several training sessions on managing the numerous changes in the country's medicines framework in the post-Brexit Transition Period. Several guidance documents on marketing, licensing, and clinical trials were published on September 1, 2020 but are subject to further revision.
- **October 4:** The European Medicines Verification Organization (EMVO) published the latest edition of its European Union Falsified Medicines Directive (EU FMD) Monitoring Report. According to the report, the rate of alerts generated during scanning is trending downward and currently stands at .5% of total scans.

- **October 4:** Germany’s National Medicines Verification Organization (NMVO) updated its frequently asked questions (FAQ) document with additional procedures relating to returns, recalls, and product pack status changes.
- **September 27:** Germany’s National Medicines Verification Organization (NMVO) published the third version of its Frequently Asked Questions document. New questions and answers added to the document cover product returns, handling expired packs, and product withdrawals.
- **September 27:** ACS PharmaProtect, which manages technical aspects of Germany’s NMVO, is hosting a web conference on Nov 12, 2020. The conference will give users of the country’s National Medicines Verification System (NMVS) an opportunity to discuss alert management experiences.
- **September 27:** Germany’s Federal Association of Pharmacists published a detailed alert management aid for pharmacists that includes flowcharts, helpdesk contacts, and details about the product information pharmacies are required to have on hand.
- **September 20:** The United Kingdom's Medicines Verification Organization, SecurMed, announced that UK industry stakeholders are working with the European Medicines Verification Organization (EMVO) to set up a Medicines Verification System for Northern Ireland by the end of the transition period on December 31, 2020.
- **September 20:** Members of the UK Parliament have submitted amendments to a bill that if passed would allow the government to regulate medicines and anti-counterfeiting systems. The amendments aim to narrow the scope of data collection and better align with the European Union Falsified Medicines Directive (EU FMD) from a regulatory perspective.
- **September 20:** The European Commission has threatened to take legal action against the UK government if the UK Internal Market Bill becomes law. The Bill, which passed through the House of Commons with a comfortable majority, contravenes some provisions of the UK's withdrawal agreement with the EU.

- **September 20:** After recently passing a law requiring a fifth data element in medicine packs, Bulgaria's Ministry of Health is reconsidering its approach. The ministry is now considering a “look-up” directory that would use Global Trade Identification Number (GTIN) and national medicine number mapping.
- **September 13:** Finland’s National Medicines Verification Organization (NMVO) published instructions for dispenser uses cases that involve pharmacies borrowing packs from one another. The guidance states that community pharmacies should decommission upon dispense to the patient. Hospital pharmacies, which may have already decommissioned the packs upon receipt, should inform the borrower of the pack’s decommissioned status to avoid generating alerts.
- **September 13:** Latvia’s State Agency of Medicines issued a list of changes that will take place in that country—and likely in other European Union countries—after the Brexit transition period has ended. Some of the topics covered in the list include licensing considerations, import procedures, and qualified person residency.
- **September 13:** Latvia launched a customer portal that enables marketing authorization holders (MAHs) in the country to manage their company information, contracts, invoices, and other information on file with the NMVO.
- **September 13:** Norway’s NMVO held a workshop with business leaders and representatives from the European Medicines Verification Organization (EMVO). The group discussed value-added services that can be enabled using European Union Falsified Medicines Directive (EU FMD) serialization requirements as a foundation. Topics covered included improving communication between supply chain entities and using artificial intelligence to detect valuable business insights.
- **September 13:** The European Commission published a preparation document for companies doing business in the United Kingdom (UK) after the Brexit transition period ends. The document summarizes the pace of Brexit negotiations, preparedness plans, and customs and licensure rules outlined by

the UK government.

- **September 13:** The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) published 26 guidance documents on various aspects of medicines and devices for the post-Brexit transition period. The packaging guidelines state that EU FMD safety features, including the unique identifier and anti-tamper device, will be allowed on UK packs provided other UK packaging requirements are met.
- **September 13:** A second reading of UK's Medicines and Medical Devices Bill took place in Parliament on September 2. The reading generated a debate on the risks of the UK straying too far from the EU regulatory framework.
- **September 13:** Estonia's NMVO enacted stricter rules for dispenser alert management that allow dispensation of alert-generating packs only if there is documented evidence that falsification has been ruled out.
- **September 13:** Sweden's NMVO announced an extension to the country's stabilization period. The stabilization period will now end on September 30, 2020.
- **August 30:** Germany's National Medicines Verification Organization (NMVO) and the German Pharmacy Association published guidelines for end users on how to return goods to the manufacturer. To prevent falsification alerts when returning medicines, pharmacies should not decommission packs. If necessary, they can reverse decommissioning that have been performed. But "destroyed" or "stolen" statuses cannot be undone.
- **August 30:** The European Commission updated its FAQ document on Unique Device Identification (UDI). The FAQ addresses many aspects of packaging and labelling with UDI and product identifier information.
- **August 23**: Slovakia's National Medicines Verification Organization (NMVO) announced that the country's stabilization period has been extended until February 8, 2021. The extension is due to the high number of alerts still being generated and concerns related to the COVID-19 health crisis.
- **August 23:** Bulgaria has finalized and published a law that adds a national

drug code as a fifth element to the unique identifier. Implementation timelines have not been communicated.

- **August 23:** The European Commission has published an “Aide Memoire” to help pharmacies prepare for National Competent Authorities (NCA) inspections of their European Union Falsified Medicines Directive (EU FMD) compliance. The publication is the latest in a series of reports. Previous reports covered inspections of NMVOs, pharmaceutical companies, and wholesalers.
- **August 16:** The Czech Republic’s National Medicines Verification Organization (NMVO) updated its European Union Falsified Medicines Directive (EU FMD) alert management tool to version 2.2. The new version adds functionality for administering users with varying levels of access and permissions.
- **August 16:** SecurMed, the company created to implement the United Kingdom's National Medicines Verification System (NMVS), is considering arrangements for medicines serialization after the Brexit transition period ends. One option would disconnect end users in England, Scotland, and Wales from the European Medicines Verification System (EMVS), while users in Northern Ireland remain connected.
- **August 16:** The UK’s Department of Health and Social Care published a letter containing guidelines for Brexit readiness for medicines suppliers. Recommendations include stockpiling six weeks of medicines on UK soil. The letter stated that additional regulatory guidance will be coming soon.
- **August 16:** The European Commission published a new version of its Safety Feature Q&A with four new questions and three revised ones. Topics addressed include marketing authorization holder (MAH) management of contract manufacturers (CMOs); the need for each warehouse and pharmacy physical location to have its own NMVO connection; and clarifications on unlicensed products.
- **August 16:** The UK’s House of Lords has scheduled a second reading of The

Medicines and Medical Devices Bill on September 2, 2020. If passed, it would confer powers on the UK government to establish a pharma regulatory framework.

- **August 16:** Estonia's NMVO published a new requirement for supply chain stakeholders to report suspected falsifications through a national competent authorities (NCA) portal beginning on September 1, 2020.
- **August 16:** Germany's Federal Ministry for Drugs and Medical Devices is now investigating some L5 alerts. This could involve contacting individuals at dispensing locations.
- **August 16:** Germany's NMVO is advising supply chain stakeholders that they should not attempt to decommission expired packs—for example, by marking them as "destroyed"—because that will trigger an alert.
- **August 16:** Malta's NMVO recently offered an overview of upcoming SolidSoft releases to medicines suppliers. Planned improvements include new functionality to support verification policies enacted through the EMVS.
- **August 16:** Romania's NMVO is publishing a bi-weekly breakdown of national alerts on its website. While a significant number are due to end-user issues like scanner misconfiguration, incorrect or missing data in the EU Hub continues to be a root cause.
- **August 16:** Romania's NMVO reports that a recent upgrade to its NMVS has provided authorities with additional alerting and analytics capabilities.
- **August 16:** The European Medicines Verification Organization (EMVO) cancelled its planned September 16, 2020 workshop due to COVID-19 concerns.
- **August 16:** EMVO published an announcement advising stakeholders to configure whitelists and firewall settings using static IP addresses that they have provided. The addresses are valid for the Integrated Test Environment (ITE), the Integrated Quality Environment (IQE), and Production environments.
- **July 26:** Bulgaria passed a new law that regulates the addition of new data elements to the product identifier required under the European Union Falsified

Medicines Directive (EU FMD).

- **July 26:** The United Kingdom has updated their recent statement on Brexit and is reiterating that EU FMD still applies in the UK until the transition period ends on December 31, 2020.
- **July 26:** Estonia's National Medicines Verification Organization (NMVO) published a quantitative assessment detailing a three-week "test period" that focused on the handling of alerts in pharmacies. Results indicate gaps in end-user awareness of verification obligations; significant under-reporting of error investigations to the NMVO; scanning of non-scoped products; and little differentiation between alert types and recommended response.
- **July 26:** Switzerland's NMVO published a guide designed to educate pharmacy end users on how to manage alerts and special rules for scanning in Switzerland. For example, pharmacies are reminded to avoid re-scanning packs that were decommissioned as exported from EU, because this will generate an L5 alert.
- **July 26:** Poland's NMVO republished its guideline for end-users on differentiated responses according to L5 alert type, noting that the most common root cause is a scanner misconfiguration that changes letters in the user interface and results in a mismatch with National Medicines Verification System (NMVS) data.
- **July 26:** The European Medicines Verification Organization (EMVO) has made additional announcements about its upcoming Alert Management System (AMS), stating that its main objective is to manage alert investigations and not to reduce alerts. The system is expected to go live in Summer 2021 and will be accessible via web and mobile apps, as well as through a plug-in to the gateway connection interface.
- **July 26:** Germany's NMVO is reiterating that market authorization holders (MAHs) must comply with Good Manufacturing Practice (GMP) regulations and Good Documentation Practice (GDP) processes when the status of recalled batches to "recall." That means changing the status before the recall is

carried out to help ensure the legal and secure handling of such medicines.

- **July 26:** The European Medicines Agency (EMA) published the second version of its Substance, Product, Organization, Referentials (SPOR) implementation guide, the EU's long-awaited pharmaceutical master data system that connects to the EMVS and other systems. The final version is expected go live before the end of 2021.
- **July 26:** Bulgaria is considering adding a national drug number to its EU FMD master data. It's unclear whether this information will be used as an additional data point that must match for successful verification.
- **July 26:** Estonia's NMVO has clarified its policy on alert management, stating that there is no need for medicines quarantine if the dispenser is otherwise convinced that packs are genuine. The EMVO will reach out to MAHs, if necessary, in an attempt to resolve any alerts within a two-day window.
- **July 26:** The German Information Center for Pharmaceuticals updated its specifications for unique device identification (UDI) for medical devices, more closely aligning their PZN system with other coding frameworks in the EU.
- **July 26:** In response to COVID-19, Germany's Ministry of Health is mandating the stockpiling of certain intensive care medicines from Oct 31, 2020 to Mar 31, 2021.
- **July 5:** Latvia's National Medicines Verification Organization (NMVO) announced amendments to the Latvian Pharmacy Law that increase administrative fines for people or institutions that fail to verify medicines according to Falsified Medicines Directive (FMD) obligations. Larger fines will be imposed for the import, export, or distribution of counterfeit medicines or active pharmaceutical ingredients (APIs).
- **June 28:** Due to the COVID-19 pandemic, there has been a delay in the implementation of changes to Bulgaria's Medicines Act that would impose fines for non-compliance with the European Union Falsified Medicines Directive (EU FMD).
- **June 28:** Estonia's NMVO instituted a three-week testing period—from June

22 to July 12—for pharmacies, hospitals, and wholesalers to scan each Data Matrix barcode and submit alert resolutions to the State Agency of Medicines. Estonia's formal stabilization period ends in September 2020.

- **June 28:** Denmark's NMVO published webinars with details about alert management processes and its online alert management tool. The management tool webinar includes a video tutorial showing onboarding partners (OBPs) how to resolve alerts in the country's National Medicines Verification System (NMVS).
- **June 28:** Austria's NMVO announced that an EMVS-wide change will be implemented in the fall. When the change is made, the EMVS will match only month and year of the Data Matrix expiry date. Currently, the day is also matched.
- **June 28:** Austria's NMVO held an online event on alert management which included and audience Q&A segment tactics for reducing alerts were presented. Tactics include frequent communication with alert-generating users and filtering out of Indian packs from verification and decommissioning requests. Austria consistently has one of the lowest alert levels in the EU.
- **June 21:** The Czech Republic's National Medicines Verification Organization (NMVO) unveiled version 2.1 of its alert management tool, which offers bulk upload and export-to-.xls options.
- **June 21:** Sweden's NMVO announced that the country's stabilization period will end on Sept. 30. Prior to the announcement, the plan to phase out the stabilization period was on hold due to the COVID-19 pandemic.
- **June 14:** The European Medicines Verification Organization's (EMVO's) latest Monitoring Report indicates an overall alert rate of 0.58% of total scans. That is a decrease from the previous period of about 0.7%. Alert rates vary nationally from .02% to more than 3%.
- **June 14:** EMVO published a Letter of Announcement stating that Onboarding Partners (OBPs) should use the Emergency Medicines Verification System (EMVS) for its aggregation capability, rather than trying to engineer the

capability themselves. OBPs that build their own aggregation capabilities could create EMVS security risks, according to EMVO.

- **June 14:** The European Medicines Agency (EMA) published a sample of the European Union (EU) pharmacovigilance database, which contains about 160,000 active substances listed by country and marketing authorization holder. The database is available to the public.
- **June 7:** The National Medicines Verification Organization (NMVO) for the United Kingdom (UK) announced that European Union Falsified Medicines Directive (EU FMD) will continue to be applicable until the end of the Brexit transition period, currently set for December 31, 2020.
- **June 7:** The Nordic region's Pharmaceutical Information Center, in conjunction with GS1, published a new guideline asking pharma companies to include GS1 product codes on primary packaging on some products as a way to reduce medication errors and improve patient safety.
- **June 7:** Finland's NMVO published version 2.0 of its Alert Handling Guideline. The latest version includes new details on root causes of alerts and instructions for managing them.
- **June 7:** The Federal Union of German Associations of Pharmacists and SecurPharm published new information for pharmacies on managing double-scan alerts. The announcement also states that in the future, regulatory authorities will have the ability to automate audit trails, which are currently generated through manual queries of the European Medicines Verification System (EMVS).
- **June 7:** The European Commission (EC) updated its timetable for preparing the main acts and measures on Medical Device legislation. The goal is to have a fully functional. European Databank on Medical Devices (EUDAMED) by mid-2022, with a number of intermediate deadlines leading up to final implementation.
- **May 31:** The European Medicines Verification Organization (EMVO) is retracting its recent guidance regarding the use of URLs, as opposed to

absolute IP addresses, for firewall permissions. EMVO is now recommending that traffic from the EU Hub to onboarding partners (OBPs) be whitelisted using an absolute IP address in corporate firewalls.

- **May 31:** Denmark's National Medicines Verification Organization (NMVO) is offering a training session for manufacturers that will cover the country's alert management system. The training session is scheduled for June 23.
- **May 31:** The European Medicines Agency (EMA) and other regulatory authorities released a plan to enable agencies to continue performing core activities during the COVID-19 pandemic. Under the plan, Member States are responsible for prioritizing assessments and approvals of vaccines and medicinal products for COVID-19 treatment.
- **May 31:** The European Commission (EC) and other regulatory authorities published an update to their Q&A document on regulatory simplification measures in light of COVID-19. The update includes additional information on change management processes and Good Distribution Practice (GDP) and Good Manufacturing Practice (GMP) relief.
- **May 24:** The European Medicines Verification Organization (EMVO) announced that supply chain stakeholders in the United Kingdom (UK) will stop product verification as of January 1, 2021. The UK will also shut down its National Medicines Verification System (NMVS) as part of the Brexit process. This is expected to have implications related to master data; decommissioning of European Union (EU) packs that are headed for the UK; and management of multi-market packs.
- **May 24:** Authorities in Spain announced a new process that compares product codes to the National Healthcare Reimbursement Number (NHRN) encoded in the DataMatrix. Inconsistent data will generate falsification alerts.
- **May 24:** France's NMVO has established a process that enables "Exploitants" to register and provide contact information for serialization issues, alerts, invoicing, etc. The Exploitant is the party that is legally responsible for the quality of a medicinal product placed in France's market.

- **May 24:** Poland's NMVO announced a new alert analysis service for pharmacists. The service sends alerts via email to notify pharmacists about false positives due to over-the-counter scans; pre-Falsified Medicines Directive (FMD) batch releases; and uppercase and lowercase scanner issues, among other things. The emails also provide details on how to manage the alerts.
- **May 24:** Lithuania's NMVO published the full set of batches and Global Trade Item Numbers (GTINs) loaded into the country's NMVS thus far. The published data includes pack quantities per product code, but it does not include serial numbers.
- **May 17:** The European Court of Justice is considering four questions related to European Union Falsified Medicines Directive (EU FMD) repackaging and trademarking requirements. The questions stem from the case of a parallel importer and a manufacturer who disagree on the level of physical repackaging necessary to meet EU FMD safety feature requirements.
- **May 17:** Germany's National Medicines Verification Organization (NMVO) published the English version of its list of frequently asked questions for pharmaceutical companies. Several questions have been added on the topic of alert management. The article also notes that National Medicines Verification System (NMVS) functionally that enables German marketing authorization holders (MAHs) to upload data directly has been disabled until further notice.
- **May 10:** Finland's NMVO updated a Q&A article on its website that covers European Union Falsified Medicines Directive (EU FMD) alerts. When alerts are raised, it's generally up to dispensers to resolve them before providing a pack to a patient, according to the NMVO. Dispensers may also be required to take photographs of packs that raise alerts and place packs aside rather than return them to the wholesaler.
- **May 10:** Germany's NMVO updated its list of frequently asked questions for pharmaceutical companies.
- **May 10:** The Coordination Group for Mutual Recognition and Decentralized

Procedures - Human (CMDh) is updating its guidance on mutual-recognition and decentralized-procedure products. The updates will reflect the implications of the Brexit withdrawal agreement and transition period. Formal publication is expected soon.

- **May 10:** The European Medicines Agency (EMA) updated its list of frequently asked questions about parallel distribution activities.
- **May 3:** The European Medicines Verification Organization (EMVO) published a Technical Info Pack for onboarding partners (OBPs) on the topic of European Medicines Verification System (EMVS) alerts and notifications.
- **May 3:** Estonia's National Medicines Verification Organization (NMVO) released details on the obligations of marketing authorization holders (MAHs), wholesalers, and dispensers during the European Union Falsified Medicines Directive (EU FMD) transition period. Packs that generate alerts can still be dispensed if they are deemed genuine. But MAHs should be ready to respond within two working days if the NMVO asks questions about such products.
- **May 3:** Germany's NMVO issued guidance for dispensers and wholesalers designed to help them understand how to identify the right contact person when, for example, a potential falsification alert is received. The NMVO also provided guidance to pharma companies on the information they should expect to receive from dispensers.
- **May 3:** The German Federal Ministry of Health is currently allowing non-serialized vaccines to be sold in German pharmacies on an exceptional basis under its Medicinal Products Act. Reasons for the decision include short vaccine supply and risks related to unvaccinated patients who may develop complications from COVID-19.
- **May 3:** Iceland is among several countries preparing to upgrade its National Medicines Verification System (NMVS) to version 6.2. The new release will resolve minor bugs, make more reports available to the European Medicines Agency (EMA), and discontinue support for obsolete security standards.
- **May 3:** Due to the COVID-19 crisis, Ireland's NMVO announced that it is

delaying plans to end the country's EU FMD use-and-learn period.

- **April 26:** The European Medicines Verification Organization (EMVO) successfully released EU Hub version 1.7.01, despite an incident during maintenance work that resulted in a partial outage. An investigation into the root cause of the outage is underway.
- **April 26:** EMVO is advising onboarding partners to use and reference EU Hub endpoint URLs instead of absolute IP addresses. This is because outbound EU Hub IP addresses can dynamically change when Microsoft renews components of its infrastructure, and such changes are beyond EMVO's control.
- **April 26:** Following the recent publication of its alerts management process, Denmark's National Medicines Verification Organization (NMVO) will host two online training sessions for marketing authorization holders on May 26 and June 23. The first session will cover the alert management process, while the second will focus on using the alert management tool.
- **April 26:** The Coordination Group for Mutual Recognition and Decentralized Procedures - Human (CMDh) published new procedures for implementing regulatory provisions during the COVID-19 crisis. The objective of the guidance is to promote regulatory flexibility while simplifying and accelerating administrative procedures.
- **April 26:** Despite COVID-19 concerns, the United Kingdom (UK) reiterated its position that it will not ask the EU for an extension of the Falsified Medicines Directive transition period beyond Dec 31, 2020. The UK cites additional uncertainty such a request would create, more payments to the EU, and a need to control its own affairs as reasons for the decision.
- **April 26:** The European Commission (EC) announced a delay in the implementation of the Medical Device Regulation (MDR) until May 2021. The decision also pushes back the full rollout of the European Database on Medical Devices (EUDAMED). Under the updated rules, the EC must announce full functionality of EUDAMED by March 25, 2021.
- **April 12:** The European Commission and the European Medicines Agency

issued new guidelines for marketing authorization holders (MAHs). The guidance covers the United Kingdom's withdrawal from the European Union and includes information on marketing authorizations, importation, batch release processes, parallel trade, and pharmacovigilance, among other topics.

- **April 12:** The European Commission published a draft mandate to postpone the enactment of the European Union Medical Device Regulation (MDR) from May 2020 to May 2021 due to COVID-19 concerns. The proposal will next go to the European Parliament for vote on April 16.
- **April 5:** The European Medicines Verification Organization (EMVO) reports that it has successfully deployed EU Hub Release version 1.7 to the Integrated Test Environment and Integrated Quality Environment. The production release of the new version is scheduled to launch on April 18, with a projected downtime of eight hours.
- **April 5:** EMVO issued new guidance reminding industry stakeholders that onboarding partner (OBP) operations involving the withdrawal of product codes or batch recalls are irreversible and prevent pack decommissioning for product that is already in the market.
- **April 5:** Lithuania reintroduced its EU FMD stabilization period, which is projected to remain in effect until 30 days after COVID-19 protection measures have ended.
- **April 5:** Austrian authorities are limiting pack scanning requirements for hospitals due to staff shortages during the COVID-19 crisis. Institutions without fully automated scanning processes are currently allowed to scan one sample per product and shipment when receiving large orders.
- **April 5:** Sweden's regulatory authority put "Step 3" of the country's EU FMD stabilization period on hold while the COVID-19 crisis continues to rage. Step 3 centers on a requirement for resolving A2 and A3 alerts.
- **April 5:** Denmark's National Medicines Verification Organization (NMVO) is requiring that OBPs verify one pack per batch to ensure that data has been properly uploaded to the EU Hub.

- **March 29:** The European Medicines Verification Organization (EMVO) released a deployment plan for EU Hub v1.7 and is on track to unveil the production version of the system on April 18, 2020. Users are reminded to upgrade to the 2018 version of the onboarding partner interface prior to April 18th because the 2016 version will no longer be supported after that date.
- **March 29:** The United Kingdom's Department of Health and Social Care (DHSC) announced that the country is prepared to deal with the impact of the COVID-19 pandemic. The (DHSC) reports that the country has stockpiles of generic medicines on hand if there are supply problems or significant increases in demand.
- **March 22:** The European Medicines Verification Organization (EMVO) and various National Medicines Verification Organizations (NMVOs) published announcements regarding staff working from home and the continued availability of services during the COVID-19 crisis. No changes to stabilization periods or alert management processes have been announced.
- **March 22:** Switzerland expects feedback on the public consultation for Article 17a—the Swiss implementation of the European Union Falsified Medicines Directive (EU FMD)—to be submitted in late March or early April. But the law is not expected to go into effect before 2021. EU FMD compliance in Switzerland is currently optional.
- **March 22:** Latvia's NMVO published new content with EU FMD guidance for the general public, including a "customer journey" video that illustrates the verification and decommissioning procedure that patients are likely to encounter at local pharmacies.
- **March 15:** The European Commission updated its "Safety Features for Medicinal Products for Human Use: Questions and Answers" document. The new version includes additional information about wholesaler connectivity to National Medicines Verification Systems (NVMSs) and clarification on packaging for centrally-authorized parallel trade products.
- **March 15:** Officials from the European Union and the United Kingdom are

discussing several issues around patient safety and the supply of medicines. Topics include batch testing, regulatory cooperation, pharmacovigilance database access, the fate of EU FMD, and many other related matters.

- **March 8:** The European Medicines Verification Organization (EMVO) published an extensive summary following a February workshop with regulatory stakeholders. The report contains insights learned in the first year since the European Union Falsified Medicines Directive (EU FMD) went into effect. The report also includes details on new alert management initiatives.
- **March 8:** EMVO issued guidance on using "retrospective upload" functionality and master data versioning when adding product master data to the European Medicines Verification System (EMVS). Additional guidance is expected to be released in the coming months.
- **March 1:** The European Medicines Verification Organization (EMVO) announced a three-week testing period for EU Hub Release 1.7. Testing will take place during late March and early April in the EU Hub's Integrated Quality Environment.
- **March 1:** Hungary recently transitioned to a stricter version of the country's stabilization period. Under the updated rules, wholesalers are required to report many alert issues encountered when verifying or decommissioning serial numbers.
- **March 1:** Slovakia's National Medicines Verification Organization (NMVO) announced that it is phasing out the country's stabilization period between now and August 31, 2020. The NMVO is also ramping up end-user training on alert management.
- **March 1:** SecurMed announced that the United Kingdom will continue adhering to the European Union Falsified Medicines Directive (EU FMD) and be part of the Emergency Medicines Verification System (EMVS) until December 31, 2020. If there is no agreement between the UK and EU by then, SecurMed will decommission the UK National System and return the data to EMVO, which is analyzing the impact of such a shutdown on the EMVS.

- **February 23:** The European Medicines Verification Organization (EMVO) reports that the average European Union (EU) alert rate reached 0.79% and continues to trend downward. EMVO is aiming for a target alert rate 0.05%.
- **February 23:** EMVO announced that EU Hub v1.7 is planned for release at the end April 2020. New functionalities include reports for authorities on parallel trade products, re-design of intermarket transactions, and better performance of the pack disclosure report, which is sometimes used to diagnose alerts.
- **February 23:** Ireland’s National Medicines Verification Organization (NMVO) announced a phased ending to the countries “Use and Learn” stabilization period. For wholesalers dealing with parallel trade products, the stabilization period will end in March. For wholesalers, it will end in May. For dispensers, it will end in September.
- **February 23:** The Czech Republic’s NMVO upgraded the country’s online alert management system and is developing an application program interface for manufacturers to integrate alert information into their own systems. The NMVO also scheduled online training for onboarding partner users in early March.
- **February 16:** Lithuania's National Medicines Verification Organization (NMVO) announced that the country’s stabilization period has ended. The NMVO also published guidelines for alert handling and quarantining products when certain categories of alerts are generated.
- **February 12:** The European Medicines Verification Organization (EMVO) issued a press release celebrating "one year of successful operation across Europe." The release highlighted several milestones for EMVO over the past year, including the connection of 28 countries, 2,500 marketing authorization holders, and over 100,000 wholesalers, pharmacists, and hospitals to the European Medicines Verification System (EMVS).
- **February 12:** Slovakia's stabilization period ended on February 9, 2020. However, the country's National Medicines Verification Organization (NMVO) is

still allowing pharmacists to dispense medicines with alerts until August 31, 2020. The NMVO is also requiring wholesalers to verify one pack per batch in addition to their Article 20 obligations.

- **February 12:** Sweden's NMVO announced that pharmacists may no longer dispense medicines that generate an "expiry date mismatch" alert.
- **February 12:** Austria's "Stabilization Phase" has ended and the country is now beginning its "Start Phase." During this phase, stakeholder organizations are expected to correct errors discovered during the stabilization period. Organizations that fail to do so may face sanctions. However, alerts still do not prevent dispensation of medicines.
- **February 2:** The European Medicines Agency, the Heads of Medicines Agencies, and the European Commission published a report that focuses on key principles for managing electronic product information in the European Union (EU). The report also covers an initiative designed to support the digital transformation of EU healthcare. Among other things, the initiative will encourage stakeholders to standardize document formats for better interoperability across healthcare systems.
- **February 2:** The European Medicines Verification Organization (EMVO) announced that the 2016 schema of the onboarding partner interface will no longer be supported after mid-April when Hub version 1.7 is slated for release.
- **February 2:** Finland’s National Medicines Verification Organization (NMVO) published alert processing instructions for a variety of use cases that industry stakeholders can reference now that the country’s stabilization period has ended.
- **February 2:** Lithuania’s NMVO published the batch and Global Trade Item Number information present in the Lithuanian National Medicines Verification System. The report is in .xls format and is accessible to the public. Serial numbers are not listed.
- **February 2:** SecurMed—the United Kingdom (UK) organization charged with implementing the Falsified Medicines Directive (EU FMD)—announced that EU

FMD and the Delegated Regulation will continue to apply in the UK at least until the end of the country's transition period on December 31, 2020. Now that Brexit is official, the future of FMD in the UK will depend on the details of the Future Economic Partnership, a trade deal that will be negotiated in the coming months.

- **January 26:** Estonia's National Medicines Verification Organization (NVMO) announced that it is extending the country's European Union Falsified Medicines Directive (EU FMD) stabilization period until September 2020. No further details were provided.
- **January 26:** The European Medicines Verification Organization (EMVO) published a Monitoring Report which found that the average EU alert rate during the final weeks of 2019 was just over 1%. The five countries with the highest alert rates are Spain, Netherlands, Ireland, Portugal, and United Kingdom.
- **January 26:** Finland's NMVO announced that it is ending the country's EU FMD stabilization period on January 31. After this deadline, all alerts must be resolved before medicines are dispensed. The NMVO adds that the "unknown product code" is now classified as an error, as opposed to an alert.
- **January 26:** The European Medicines Agency published a paper on good manufacturing practices for market authorization holders (MAHs) and is accepting public commentary until April 17, 2020. The paper covers expectations for MAHs under EU FMD and provides information about data residency.
- **January 26:** The European Federation of Pharmaceutical Industries and Associations (EFPIA) published a new report that offers advice to industry stakeholders on how to fight the drug shortage problem in Europe. The EFPIA reports that the causes of drug shortages include production issues, consolidation of manufacturing, unintended impacts of pricing policies, and problems within the supply chain.
- **January 26:** United Kingdom Prime Minister Boris Johnson has signed into law

an agreement that will withdraw the UK from the EU on January 31. The bill took more than a year to pass in Parliament.

- **January 12:** France's Ministry of Health announced a transition period before companies must comply with the European Union Falsified Medicines Directive (EU FMD). The Ministry did not specify when the transition period will end. The Ministry also reports that there is a 3-5-year plan in place for the European Medicines Verification System (EMVS) to support aggregation. Finally, the Ministry promoted a new means to securely transmit product codes between suppliers and hospitals.
- **January 12:** France's Medicines Verification Organization (MVO) has issued extensive new guidance for supply chain stakeholders. The guidance includes detailed analysis on how to manage alerts and provides companies with an interactive "Alert Analysis" tool.
- **January 12:** France has announced a plan to connect all of the country's approximately 22,000 pharmacies to the National Medicines Verification System (NMVS). Pharmacies can expect to receive their credentials within a few days.
- **January 12:** The EU FMD Expert Working Group, a network of EU Member State regulators, has published its latest meeting minutes. The group expects marketing authorization holder inspections to ramp up in the future. It also expects National Competent Authorities to use newly available analytics reports to enforce EU FMD provisions and identify delinquent actors.

2019

- **December 29:** Slovenia's National Medicines Verification Organization (NMVO) announced that its European Union Falsified Medicines Directive (EU FMD) stabilization period has ended. The organization says it is now moving into an operational phase where "all stakeholders will need to prosecute their legal commitment to its full extent."
- **December 29:** Lithuania's NMVO has extended the country's EU FMD transition period for a second time. The transition period will now end on

January 30, 2020.

- **December 15:** The European Medicines Verification Organization (EMVO) has successfully deployed EU Hub Release v1.6.04. The latest update was implemented as an emergency fix for issues within SolidSoft national systems that were preventing some National Medicines Verification Systems from obtaining software upgrades.
- **December 15:** Denmark's National Medicines Verification Organization (DMVO) has published its first set of National Competent Authority (NCA) reports, and more NCA reports are expected this month. Analytics from these reports are expected to support GxP audits across the supply chain as Falsified Medicines Directive transition periods come to an end.
- **December 8:** The European Medicines Verification Organization (EMVO) released a more detailed version of its guidance on the European Medicines Verification System Information (EVI) tool. EVI monitors systems like the EU Hub, the EU Gateway, and the Onboarding Partner Portal and alerts users to issues and downtime.
- **December 8:** EMVO updated its divestitures and acquisitions guidance for onboarding partners (OBPs) that acquire additional market authorization holders (MAHs). The update details the impact on product codes, OBP fees, and clarifies requirements on batch ID uniqueness.
- **December 8:** EMVO's new Monitoring Report shows a steady downward trend in the number of alerts being generated. Currently, about 1.5% of scans generate alerts, compared to about 2.5% four weeks ago.
- **December 8:** Norway's National Medicines Verification Organization (NMVO) is extending the country's stabilization period to January 20, 2020. NVMO officials say no further postponements will be granted.
- **December 1:** The European Medicines Verification Organization (EMVO) announced plans to move its customer Help Desk from Estonia to Brussels, Belgium, where EMVO headquarters are located. The move is planned for the beginning of 2020.

- **December 1:** The Coordination Group for Mutual Recognition and Decentralized Procedures for Human Medicines (CMDh) published new guidance for marketing authorization holders that produce common packages for different European markets.
- **November 24:** The European Commission published new guidance for wholesalers on how to prepare for European Union Falsified Medicines Directive (EU FMD) audits. Topics covered include warehousing procedures, record keeping, and general advice on adhering to EU FMD regulations.
- **November 24:** The European Medicines Verification Organization (EMVO) announced that another falsification alert is being generated due to scanner misconfigurations. EMVO advices onboarding partners to ignore the "manualentryflag" during investigations.
- **November 17:** The European Medicines Verification Organization (EMVO) published Version 11 of its OBP Onboarding Guideline. The guideline features a new section that explains the options and outcomes associated with managing product codes in the event of a transfer between OBPs.
- **November 10:** The European Medicines Verification Organization (EMVO) announced the successful deployment of v1.6.02 to the EU Hub production environment, which was upgraded Saturday, November 2.
- **November 10:** EMVO is working with SecurMed and Arvato to set up a "proxy" system designed to maintain business continuity in the event of a no-deal Brexit, according to EMVO officials who spoke at the recent GS1 India conference.
- **November 10:** The National Medicines Verification Organization (NMVO) for the Netherlands announced that refunds will be given to marketing authorization holders for initial entrance and onboarding fees. The refunds will be issued over the next five years.
- **November 3:** The European Medicines Verification Organization (EMVO) announced that in the event of a no-deal Brexit, onboarding partners (OBPs) can continue to upload data to the European Medicines Verification System in

the same manner they are currently using.

- **November 3:** SecurMed, the nonprofit organization that delivers the Medicines Verification System for the UK, and supply chain consulting firm Excellis Health Solutions published practical suggestions for manufacturers and dispensers on how to manage packs exported from India, which often conflict with EU FMD requirements and have been generating false alerts.
- **October 27:** The European Medicines Verification Organization (EMVO) has released version 4.0 of its Master Data Guide. Among other things, the latest version includes guidance on product master data versioning. It also adds emulated markets based on the 2018 schema.
- **October 27:** EMVO announced the deployment date of EU Hub Release 1.6 to the Production Environment (PRD). Release 1.6 will be ready for use in PRD at 9am (CET) on Saturday, November 2.
- **October 20:** The Icelandic Medicines Verification Organization (ICEMVO) has issued new guidance following the end of the country's European Union Falsified Medicines Directive (EU FMD) stabilization period. The announcement includes recommended actions for managing alerts and timelines for on-boarding partners (OBPs) to report alert-cause resolution.
- **October 20:** The European Medicines Verification Organization (EMVO) issued a letter of announcement reminding OBPs that for multi-market packs, master data, batch data, and pack data must be loaded to the national systems for each market to which the pack can be distributed. EMVO made it clear that the rule applies even for countries that are listed as part of the approved cluster, but do not actually receive the physical product.
- **October 20:** EMVO has cited mismanagement of "batch recall" functionality by OBPs as a key source of falsification alerts. EMVO also reiterated that batch recall operations are to be performed once only per batch, that they are irreversible, and that no further pack status changes are to be performed on recalled packs.
- **October 20:** SecurMed, the nonprofit organization that delivers the Medicines

Verification System for the United Kingdom, is making plans to combat confusion in the event of a “no-deal” Brexit. The organization is proposing that the UK maintain its connection to the EU Hub for a brief time following Brexit to enable further planning and a “wind-down” period.

- **October 20:** The Czech Republic's Medicines Verification Organization has released an online tool that enables Marketing Authorization Holders to perform reconciliation and root-cause analysis for alerts generated in the Czech National System.
- **October 13:** Iceland’s National Medicines Verification Organization (NMVO) announced that its European Union Falsified Medicines Directive (EU FMD) stabilization period has ended. Stakeholders are now required to record, investigate, and report alerts from the Iceland’s Medicines Verification System and the European Medicines Verification System.
- **October 13:** Denmark’s NMVO also announced that its stabilization period has ended. Denmark’s regulator, the Dutch Health and Youth Care Inspectorate, is taking a risk-based approach to enforcement, focusing initially on stakeholders not connected to the country’s National Medicines Verification System (NMVS) and those with poor or missing scanning histories.
- **October 13:** Slovenia has extended its EU FMD stabilization period to November 30 for hospital and retail pharmacies. Wholesalers are entering business-as-usual mode and can no longer distribute medicines that generate alerts until those errors are resolved. Exceptions can be granted to wholesalers to prevent drug shortages.
- **October 13:** Sweden is phasing in the end of its stabilization period and is applying an error-based approach as opposed to the stakeholder-based model applied elsewhere. As part of that initiative, Sweden’s NMVO announced that medicine packs which generate “batch ID mismatch” alerts must not be dispensed until such errors are resolved.
- **October 13:** The European Medicines Verification Organization’s latest monitoring report shows that end-user connectivity is gradually rising while

alerts are levelling off at about 2.8% of scans. The volume of scans is slowly but steadily increasing as well.

- **October 6:** The European Medicines Verification Organization (EMVO) clarified its recent recommendation that wholesalers verify one pack per batch upon receipt, emphasizing that such action is discretionary and does not replace risk-based verification obligations.
- **October 6:** EMVO's most recent Monitoring Report shows PMD uploads steadily climbing, a reduction in alert rates, and an increase in scanning volumes to about 87 million scans per week. Alerts generated via "double scanning" by end-users account for more than all other types of alerts combined.
- **October 6:** The Latvian Medicines Verification Organisation (LZVO) reports that an increasing number of NMVOs are moving to enforcement mode as stabilization periods wind down. Latvia has had no stabilization period and reports alert message resolution within two to three days.
- **October 6:** The Danish Medicines Verification Organization (DMVO) announced the end of its stabilization period as of October 1. Denmark's regulator—The Dutch Health and Youth Care Inspectorate (IGJ)—intends to focus enforcement efforts on non-connected stakeholders or those with poor scanning rates. In an effort to reduce end-user scanner errors, DMVO released several more test matrices to ensure scanners are correctly configured.
- **October 6:** The Irish Medicines Verification Organisation (IMVO) announced it is extending its "use and learn" stabilization period to January 31, 2020. When that date arrives, the stabilization period will begin a phased ending. IMVO is expected to release more details in the coming weeks.
- **September 29:** The European Medicines Verification Organization (EMVO) published Version 16 of its European Commission Safety Feature Q&A. Some of the newest additions include recommendations and advice related to serial numbers, batch characters, and the conditions under which alert investigations are launched.

- **September 29:** EMVO last week published new guidelines which recommend that wholesalers verify one pack for every batch released after February 9, 2019 upon receipt. By doing this, wholesalers will reduce the total number of alerts generated.
- **September 29:** EMVO has uncovered alleged attempts to gain financial information from onboarding partners. The organization reports the fraud attempts are linked to invoices and used addresses from EMVO and various National Medicines Verification Organizations (NMVOs). SecurMed, the nonprofit organization that delivers the Medicines Verification System for the UK, recommends that marketing authorization holders phone SecurMed to confirm invoice details prior to payment.
- **September 29:** EMVO has consolidated and updated fee models from NMVOs for 2020 and 2021. In nearly all cases, there is no change in fees between 2020 and 2021.
- **September 29:** All European Union countries using the Arvato blueprint now have a new alert format which includes new codes and descriptions. EMVO announced that all National Medicines Verification Systems (NVMSs) will follow suit in a future release.
- **September 29:** The Danish Medicines Verification Organization (DMVO) is implementing a new alert management tool it will use to follow up on every individual alert.
- **September 22:** Denmark's National Medicines Verification Organization (DMVO) has announced that the country's Falsified Medicines Directive (FMD) stabilization period will come to an end next week. Denmark's regulatory authority will begin enforcement by targeting unconnected stakeholders and entities with poor scanning habits. The DMVO also announced that an upgraded interface to the National Medicines Verification System is scheduled for release in December.
- **September 15:** The European Medicines Verification Organization (EMVO) has announced the release of version 1.6 of the EU Hub, which is scheduled

for availability in the Integrated Quality Environment (IQE) in mid-October, and in the Productive Environment (PRD) in mid-November. Some of the functionality improvements include an enhanced Product Master Data report, bulk management of sample packs, and the harmonization of time stamps with National Systems.

- **September 15:** EMVO has issued its bi-weekly update detailing status of Onboarding Partner (OBP) connections, end-user connectivity, alert rates, country analyses, and enforcement and stabilization policies throughout the European Union (EU). The EU is continuing its focus on reducing false positive alerts, and more countries are moving forward with enforcement plans.
- **September 8:** The European Medicines Verification Organisation (EMVO) has published a minor update to the User Requirement Specification for the European Union Falsified Medicines Directive (EU FMD) system. The update adds a requirement for a monitoring tool at the European Union level that is designed to identify abuses of the bulk verification functionality by pharmaceutical manufacturers.
- **September 8:** The European Commission (EC) has published a new checklist as part of its guidance in the event of a no-deal Brexit. The detailed checklist covers the steps the pharmaceutical industry needs to take to transfer marketing authorization to European Union soil, ensure localization requirements are met, and ensure proper trade and customer procedures. The EC reports that about 80% of affected products are on track for an Oct. 31 Brexit, and batch testing location exemptions are being granted on a narrow basis until Dec. 31.
- **September 8:** Belgium has become the first country to formally end its transition period for European Union Falsified Medicines Directive (EU FMD) stakeholders. The country has communicated penalties for non-compliance that range from formal warnings to criminal prosecution.
- **September 8:** France’s National Medicines Verification Organization (NVMO) has published a .xls template designed to help pharmaceutical manufacturers

systematically report falsification alerts. Many European Union NVMOs require these types of reports from marketing authorization holders.

- **September 1:** The Danish Medicines Verification Organisation (DMVO) reports that end users are expressing greater confidence with Falsified Medicines Directive (EU FMD) processes. Alert rates are dropping significantly and as a result, life sciences companies can expect authorities to ramp up enforcement operations.
- **August 25:** The EU Hub was taken offline for planned maintenance on Friday, August 23 as EMVO worked to restore the EU Hub IQE environment to Release 1.4.08. EMVO announced the rollback earlier this month after plans to unveil EU Hub Release 1.5 were cancelled due to a problem with session token renewals that resulted in many On-boarding Partners (OBPs) being disconnected from the environment. The updates planned for v1.5 will be now be merged with v1.6, which is scheduled for release in November.
- **August 25:** EMVO has reported a change in the format of falsification alert messages that are sent to Marketing Authorization Holders (MAHs) from some Arvato National Medicines Verification Systems (NMVSs). EMVO has also issued a translation table designed to help OBPs compare the new alert message format to the previous one. EMVO reports that it is currently working with NMVOs and Blueprint Providers to harmonize alert message formats across all national systems in a future release.
- **August 25:** The United Kingdom’s Medicines and Healthcare Regulatory Agency (MHRA) has updated its guidance to the life sciences industry in the event of a no-deal Brexit. The new guidance covers amendments to clinical trial processes, including how to process changes to a trial’s sponsor or legal representative, and investigational medicinal product (IMP) certification. It also explains when amendments need to be submitted to the Research Ethics Committee (REC) for review.
- **August 11:** EMVO has announced that the EU Hub Release version 1.5 will not be issued and that version 1.4.08 remains in place. The changes that were

originally scoped in v1.5 will instead be merged with those of v1.6, which is scheduled to be released in November. In a subsequent announcement, EMVO reported disconnection issues with the Integrated Quality Environment (IQE) of the European Hub as a result of the roll-back.

- **August 11:** EMVO has announced an expansion of its organization and the addition of a Chief Operations Officer to provide enhanced customer support.
- **July 21:** The EMVO newsletter (July 19) featured a segment on FiMVO (Finnish NMVO) and its recommendations for reducing alerts, including removal of the European Article Number (EAN) code if possible.
- **July 21:** EMVO reported on a lost connectivity incident between the EU Hub and the national systems of Austria, Belgium, Estonia, Finland, France, and Germany. A corrective and preventive action (CAPA) was initiated immediately to improve the relevant internal processes and systems.
- **July 21:** Version 1.5 of European Commission Safety Feature Question and Answer was published and included updates around the decommissioning of clinical trial products; batch release verification requests from wholesalers addressed to manufacturers; and the decommissioning of products by parallel importers to Italy and Greece.
- **July 21:** EMVO announced EU Hub Release 1.5 into the IQE environment, as well as upgrades for national systems in Norway, France, Denmark, and the Czech Republic. The release also calls for IQE testing by on-boarding partners (OBPs) to be completed by July 25 to ensure callbacks are received after a timestamp issue was fixed.
- **July 14:** EMVO released a position paper that encourages National Competent Authorities (NCA) to enforce EU FMD standards across the supply chain to prevent stasis during the stabilization period. EMVO suggested that compliance efforts focus on primary issues such as non-connected manufacturers and end-users; end-users that are releasing a serialized product without uploading data; IT providers with inadequate software; and end-users dispensing packs without decommissioning, among other

suggestions.

- **July 14:** EMVO released its Guideline on Divestitures and Acquisitions which encompasses detailed guidelines and templates for managing transfers of marketing authorizations between onboarding partners (OBPs). The process includes changes beyond the PMD level, extending to contracting, legacy alert handling, and potentially product coding.
- **July 14:** The European Commission released its Aide-Memoire for good manufacturing practice (GMP) inspections which include a “checklist” of potential questions from inspectors and auditors around EU FMD compliance.
- **July 7:** ZAPAZ announced that it is spearheading a semi-automated alert management system for contacting the most relevant stakeholder for a given alert type.
- **July 7:** EMVO published documents related to Divestitures and Acquisitions, including an OBP Divestitures and Acquisitions Guide.
- **July 7:** EMVO has released EU Hub v1.5 technical documentation.
- **July 7:** EMVO spotlighted ZAPAZ (Slovenian NMVO). ZAPAZ is working with end-user software providers to mitigate reasons for false alerts.
- **June 30:** EMVO released Functionality Matrix v1.6, the latest version of all scoped functionalities available across all live National Systems.
- **June 30:** National Competent Authorities (NCAs) are requesting additional system and stakeholder oversight reports which will be available between December 2019 and April 202
- **June 23:** The EU FMD spotlighted unique challenges related to Malta NMVO (MaMVO) related to the high proportion of multi-market packs in Malta.
- **June 23:** EMVO released a communication to parallel importers regarding correct uploading of master data with MAH details.
- **June 23:** EMVO is planning to reach-out with guidance to onboarding partners (OPBs) who are generating alerts because of missing product pack data and product master data.
- **June 23:** EMVO is analyzing technical issues related to intermarket

transaction timeouts.

- **June 23:** The Danish NVMO has announced that a subscription service is now available. The service allows users to customize email alert settings for notifications of EMVS disruptions.
- **June 23:** The Malta NMVO has announced that the stabilization period for wholesalers will end in August.
- **June 23:** The Polish NMVO has requested that OPBs submit an analysis of their alerts to the NMVO within two working days of receiving them.
- **June 2:** The EMVO released a new version of its On-boarding Partner (OBP) guideline for the EMVS maintenance phase. Updates include important onboarding changes and instructions for transferring Marketing Authorisation Holders (MAHs) between companies.
- **June 2:** An NMVO participatory meeting has been announced for June 28.
- **April 14:** The European Commission has extended the deadline for Brexit to October 31. If a deal is passed prior to that date, the United Kingdom will be able to withdraw from EU FMD at that time.
- **April 14:** The Medicines and Healthcare products Regulatory Agency (MHRA) published **guidelines for grandfathering marketing authorization (MA)** submissions in case of a "no deal" Brexit. The proposal states that companies will have a period of 12 months post-exit to submit information on their Centrally Authorized Products (CAPs) to the MHRA, with 33 months given after the exit date to implement changes to the MA numbers and MAH name and address for medicinal product packs.
- **April 14:**The EMVO restated that OnBoarding Partners (OBPs) need to follow up on alerts, and have provided all OBPs with points of contact to the NMVOs and email addresses to communicate end-user alert information.
- **April 14:** The EMVO also noted that OBPs are responsible for correcting mismatched expiration dates that they have uploaded. An example includes the day being listed as "OO" in the data matrix, but "31" in the EMVO upload data.

- **April 7:** The EMVO published the latest update to the **NMVO's Fee Models Status**, including a discussion of the fee model types; annual operational fee; and the volume and turnover-based models.
- **March 31:** The EMVO stated publicly at **GS1 Global Healthcare** that EU FMD is a success, and this year will be devoted to onboarding all stakeholders and managing the number of alerts being generated.
- **March 31:** The France MVO stated at GS1 Global Healthcare that only 3 out of 20,000 pharmacies in France are connected to the NMVS, with the causes including software provider readiness and labor union opposition.
- **March 31:** The Netherlands NMVO reported that dispenser scanning is becoming more prevalent as the percentage of FMD packs grow, while the number of NMVO alerts remains steady at approximately 5% of scans.
- **March 25:** The Council for the European Union published two updates to the EU's Medical Device and In Vitro Diagnostic Regulations (MDR/IVDR). The changes pertained to the requirements and interpretation of the regulations and did not affect the deadlines.
- **March 25:** The EMVO published a document outlining why all OnBoarding Partners (OBPs) and solution providers should subscribe to their status information system to ensure maximum visibility into the current operations of the EMVS.
- **March 25:** The Netherlands NMVO reported that the NMVS is working toward "steady state" and focusing on resolving long transaction times for intermarket queries.
- **March 25:** The Medicines and Healthcare products Regulatory Agency (MHRA) has published **a series of guidance documents** in the event of a "no deal" Brexit. These guidelines cover the UK and MHRA's proposed arrangements for the regulation of medicines, medical devices, and clinical trials in case the UK leaves the EU without a deal in place.
- **March 17:** Mike Thompson, Chief Executive of The Association of the British Pharmaceutical Industry (ABPI), issued a statement on March 13 regarding

industry concerns on supply disruption in the United Kingdom in the event of **a "no deal" Brexit**. He stated, "With just days remaining, we need a solution that avoids a 'no deal' Brexit and the potential harm it could cause."

- **March 17:** The Anti Counterfeit System (ACS) PharmaProtect GmbH, which is the German NMVO, held **a webinar on March 18** to provide pharmaceutical companies with an understanding of alert handling and how to process falsification alerts.
- **March 17:** The Netherlands NMVO reminded OnBoarding Partners (OBPs) that OBPs need to follow-up on alerts. Specifically, they need to pay attention to the common "batch not found" alert, which indicates serialized product has not been reported to the EMVS.
- **March 17:** The Netherlands NMVO **published guidelines** distinguishing between the 2D barcodes on EU FMD packs and India-serialized packs. The two barcodes look similar but only EU FMD packs need to be scanned into the NMVS. If an India barcode is scanned, an alert is generated from the NMVS and reported to the NMVO. India barcodes have a few key differences: a first digit that is not 0, non-GTIN linear barcode digits, and they do not include an anti-tampering device (ATD), which is required for EU FMD packs.
- **March 10:** SecurMed, which is the UK NMVO, announced changes in wording to 11 alert messages and 1 system message that are produced by the NMVS. The changes, which are effective March 17, were implemented to make the messages easier to understand and do not affect the meaning of the alerts and system message.
- **March 10:** The Netherlands NMVO advised OnBoarding Partners (OBPs) that the OBPs are receiving alerts due to issues with FMD product data. These issues could be from product data not fully being uploaded, an unknown product code being entered, or a batch not being found in the system. The Netherlands NMVO added that the Marketing Authorization Holders (MAHs) and OBPs are responsible for following up on and addressing these alerts.
- **March 3:** The EMVO is providing daily updates on 'known issues' within the

EMVS. To date, the most significant progress has been related to missing callback messages to the OnBoarding Partner (OBP), which are messages that state data has been successfully uploaded or has not been uploaded. The EMVO has reduced the scope of the missing callback messages from 1,202 product codes for 40 OBPs to 7 product codes for 5 OBPs.

- **February 24:** A **Stabilisation Period** Proposal was circulated last week, which expounds the rationale for considering a **'soft launch**' period for EU FMD. This soft launch approach has been communicated by at least 18 countries now, with varied time periods.
- **February 24:** The Arvato and SolidSoft blueprint systems continue to be updated to address alert management, multi-market pack synchronization, and other issues.
- **February 24:** The joint Liechtenstein/Switzerland National System is now connected to the EMVS, making all 30 National Systems now live.
- **February 10:** EU FMD compliance started on February 9 and it spurred a number of announcements. The European Commission published an **official announcement on EU FMD** and the launch of the European Medicines Verification System (EMVS); the EMVO announced several policies and guidelines; and multiple countries published guidelines on alert management and soft launch procedures.
- **February 10:** The European Union launched their official 6-month consultation to draft key principles for the development of systems for electronic product information (ePI) for medicines in the EU. ePI systems will also have interoperability with EHR, EU medicines portals, pharmacovigilance systems, and SPOR data management systems.
- **February 3:** The National Competent Authorities (NCAs) and National Medicines Verification Organizations (NMVOs) for Netherlands, Finland, and Latvia have published information regarding their EU FMD enforcement discretion or soft launch and alert management plans. These plans have been put together to reduce the impact to normal medicine supply during the initial

regulation phase of EU FMD.

- **January 27:** The EMVO has stated that the shared Liechtenstein-Switzerland NMVS system will be live prior to February 9, 2019. If that date is met, the entire EMVS will be live by deadline.
- **January 20:** The **Downtime and Disruption Information System** is now live on the EMVO website.
- **January 13:** The Medicines and Healthcare products Regulatory Agency (MHRA) issued **detailed guidance** on whether an institution is covered under Article 23 and the decommissioning exemptions for healthcare institutions.
- **January 13:** The MHRA released guidance for wholesalers who are onboarding to the NMVS. They also provided example scenarios where verification is and is not required for wholesalers.
- **January 6:** The Danish Medicines Agency posted procedures for stakeholders on how to handle anti-counterfeiting alerts and other notifications they may receive once EU FMD goes into effect.
- **January 6:** The Medicines and Healthcare products Regulatory Agency (MHRA) issued the government response to the 2018 public consultation on EU FMD. This response focused on national flexibilities foreseen in the regulation and the planned approach for enforcement.
- **January 6:** The MHRA issued a statement that EU FMD will proceed in the UK unless there is a no-deal Brexit.

2018

- **December 30:** EMVO has published updates to existing documents, including version 3 of the Master Data Guide.
- **December 30:** Some EU member states are speaking openly about what will happen when the deadline for EU FMD goes into effect on February 9, 2019. These discussions include thoughts on expectations and the enforcement of those regulations.
- **December 16:** The Malta NMVO has stated that their NMVS will go "live" on December 17, 2018.

- **December 9:** EMVO issued the **EMVS Functionality Matrix v1.4 update**. Additional guidance is listed in the document as to whether the functionality is "stand-alone" or "interoperable" with the EU Hub.
- **December 9:** SolidSoft has released its EMVS end user guide for configuring roles/permissions within pharmacies and warehouses.
- **December 9:** securPharm, the German NMVS, published their fee schedule for end-user connections of a one-time cost plus ongoing fees, which is a unique model in the NMVS landscape.
- **December 9:** Information is forthcoming on whether or not the Malta NMVS is connected to the EU Hub.
- **November 18:** EMVO issued an on-boarding status report as of October 2018. At that time there were: 1,062 Onboarding Partners (OBPs), 935 signed participation agreements, 786 legitimacy checks passed, 548 connected to the Quality Environment (IQE), 293 connected to the Production Environment (PRD), and 64 uploading master data.
- **November 18:** EMVO published a "Letter of Adhesion" to be signed by OBPs. This letter contained a set of conditions for non-EEA OBPs that are related to data handling and the ability of EMVO/NCAs to audit their processes.
- **November 18:** The MHRA ramped up EU FMD communication to all supply chain stakeholders, most notably regarding end-to-end EU FMD guidance and system error handling guidelines for end users. These topics were shared in this week's National Medicines Verification System (NMVS) and EU FMD TraceLink Life Sciences Cloud Community Special Interest Group sessions.
- **November 4:** The UK National System went live on October 31, 2018, representing the 27th 'live' system in the National Medicines Verification System (NMVS). The remaining systems that still need to go live in NMVS are Malta and Liechtenstein/Switzerland.
- **October 28:** The European Commission, Heads of Medicines Agencies (HMA), and European Medicines Agency (EMA) issued a letter to all EU FMD stakeholders across the supply chain reinforcing the date of February 9, 2019

for their compliance obligations.

- **October 28:** The Medicines and Healthcare products Regulatory Agency (MHRA) published guidance for implementing EU FMD, which is relevant to all supply chain stakeholders. The guidance contained almost no mention of Brexit, supporting the MHRA's previously communicated intention of focusing on the February 2019 deadline.
- **October 21:** European Commission published a letter to stakeholders outlining their obligations under EU FMD and reinforcing that all segments of the supply chain must be ready by February 9th to comply with their appropriate regulatory capabilities. The letter did not include any statements surrounding shifting the date or allowing for enforcement discretion.
- **October 21:** EMVO issued a guide regarding the treatment of overseas and minor territories in the European Union and their inclusion/exclusion in EU FMD. EMVO also released a note clarifying certain expectations around the use of the "affiliate" provision under EU FMD for OBP registration.
- **October 14:** EMVO published a NMVS Functionality Matrix that highlights current/planned capabilities across the EU Hub/NMVS system sphere.
- **October 14:** MHRA issued a request for an industry consultation asking if stakeholders would agree to revoke EU FMD from UK law if a no-deal Brexit does occur. Note: This does not mean that MHRA would like to revoke EU FMD.
- **October 7:** European Commission published **v11 of their Safety Feature Q&A**. The new version reinforced the previously published rules regarding decommissioning responsibilities.
- **October 7:** An updated NMVO fee structure was published this past week for MAHs/PI across all countries.
- **October 7:** Megros, a Danish wholesaler association, is requesting manufacturers in Denmark to submit GTINs to them before February 9, 2019 via a spreadsheet to facilitate goods receipt.
- **September 16:** Poland and Spain national systems are now connected to the

EU Hub. Once the UK is connected in the next two weeks, over 90 percent of medicine supply in Europe will be covered by live connected national systems.

- **September 9:** France and Romania national systems are now connected to the EU Hub.
- **September 2:** EMVO published a new letter of announcement on the availability of the EU Hub v2.0 endpoint documentation, which outlines the updated interfaces to the EU Hub.
- **August 26:** EMVO announced additional details of the production push of the EU Hub v1.4 release; the updated NMVO fee model; and guidance on the definition of the term "designated wholesaler" and the requirements.
- **August 19:** EMVO announced specific details around the EU Hub v1.4 release, updated thoughts on randomization of the serial number for the product identifier, and clarified some details on product coding.
- **August 19:** Swiss MVO published an update to product coding guidelines.
- **August 12:** EMVO announced the official EU Hub v1.4 release plans, which will be issued from 8/13 to 8/20/18.
- **July 22:** EMVO announced that 22 national systems are now live, with virtually all national systems expected to be live by the end of September.
- **July 22:** EMVO published a Belgium-Luxembourg data management guideline for companies that are submitting pack data into the Belgium national system.
- **June 17:** Version 1.4 of the EU Hub is slated to be ready at the end of August. A new technical expert advisory group has been formed to support the EMVO, with members from each of the key industry end user segments involved.
- **June 17:** Stakeholders could not agree on a common approach for GTIN usage, so NTIN will be the national code for France starting on Feb. 9, 2019. The industry will continue to work on plans for potential GTIN usage post deadline.
- **June 10:** The Austria national system went live with 10 now in total.
- **June 10:** ABPI and industry vocalized concerns about drug supply post-Brexit.

The issues at play are drug approvals, relocation of marketing authorisations, and regulatory alignment. Note: SecurMed and the Dept of Health have stated that EU FMD will apply in the UK post-Brexit unless specifically revoked.

- **June 10:** SecurMed announced NMVO fee waiver for "micro-MAHs" who meet 2 of these 3 criteria: less than £632k UK annual revenue, less than £316k on balance sheet, and 10 employees or fewer.
- **April 29**: EMVO announced publication of the NMVO's Fee Models for EU FMD compliance on their website.
- **April 29:** Final government decree resetting scope of medicines covered by EU FMD coding and serialization has now been officially published.
- **April 21:** EMVO announced the Lithuania and Bulgaria national system connections.
- **April 15:** EMVO published new versions of the OBP Guidelines and Presentation.
- **April 15:** EMVO announced four new national systems connected to the EU Hub PRD environment: Ireland, Denmark, Sweden, and Slovenia.
- **April 8:** EMVO published update notification for OBP Portal, which will go live 4/11.
- **April 8:** EMVO published notification that they are changing their approach to the EU Hub connection, which is a subset of tests needed for connection to PRD.
- **April 1:** EMVO published NMVS connection status to the EU Hub. A total of 11 countries have national systems connected with 1 (Germany) in Production.
- **April 1:** France has officially withdrawn their scope extension for application of EU FMD serialization. The notification of this will be published in the French Gazette in next week or two.
- **March 25**: EMVO released updated product pack coding guidelines for EU FMD aligned countries.
- **March 11**: European Commission mentioned during a recent GIRP industry meeting that all but three NMVOs have been set up now (Malta, Italy, and

Greece as outliers). EC reinforced that they would like live piloting across all FMD member states by December 2018.

- **February 25:** EMVO has ended any partial certification of OBP CPs.
- **February 11:** EMVO published a short announcement on the importance for OBPs to distinguish between MAHs with and without parallel importation.
- **January 28:** The European Commission published a detailed report on the criminal and financial penalties for dangerous or falsified medicines with a breakdown of penalties by country.
- **January 28:** The UK NMVO reconfirmed their full intention that UK is going ahead with EU FMD compliance.
- **January 28:** Norway confirmed that the linear barcode can remain on packages after Feb 2019.
- **January 28:** Slovenia is now allowing GTINs for new product registrations, not just for products registered after Feb 2019.
- **January 28:** Poland's NMVO strongly refuted rumors that serial numbers and 2D barcodes were to be purchased from the NMVO.
- **January 14:** EMVO published reminder of the On-Boarding Fee step increase, strongly pushing for all participants to get signed up by 6/15 or risk a timely on-boarding to meet the 2019 deadline.

TraceLink is the leading digital platform company for organizations participating in the global healthcare value chain. TraceLink has created the world’s largest digital supply network for the healthcare and pharmaceuticals sector. It connects hundreds of thousands of firms across healthcare supply chains, providing them with end-to-end granular visibility across the supply networks on which they depend. Our platform helps modernize and enhance health supply chain management by enabling firms to better leverage new and innovative types of healthcare supply chain technology including advanced healthcare supply chain analytics—technology they can use to gather and benchmark critical healthcare supply chain metrics and identify and eliminate inefficiencies. Our innovative software solutions are helping organizations optimize healthcare supply chain management and improve patient outcomes by allowing them to better track and

monitor key hospital supply chain metrics; build greater agility and resilience into hospital supply chains; and streamline hospital supply chain management.
BlogEuropean Union Falsified Medicines DirectiveGlobal Track & TraceRegulatory/ComplianceEuropean Union
Learn more about European Union compliance solutions.

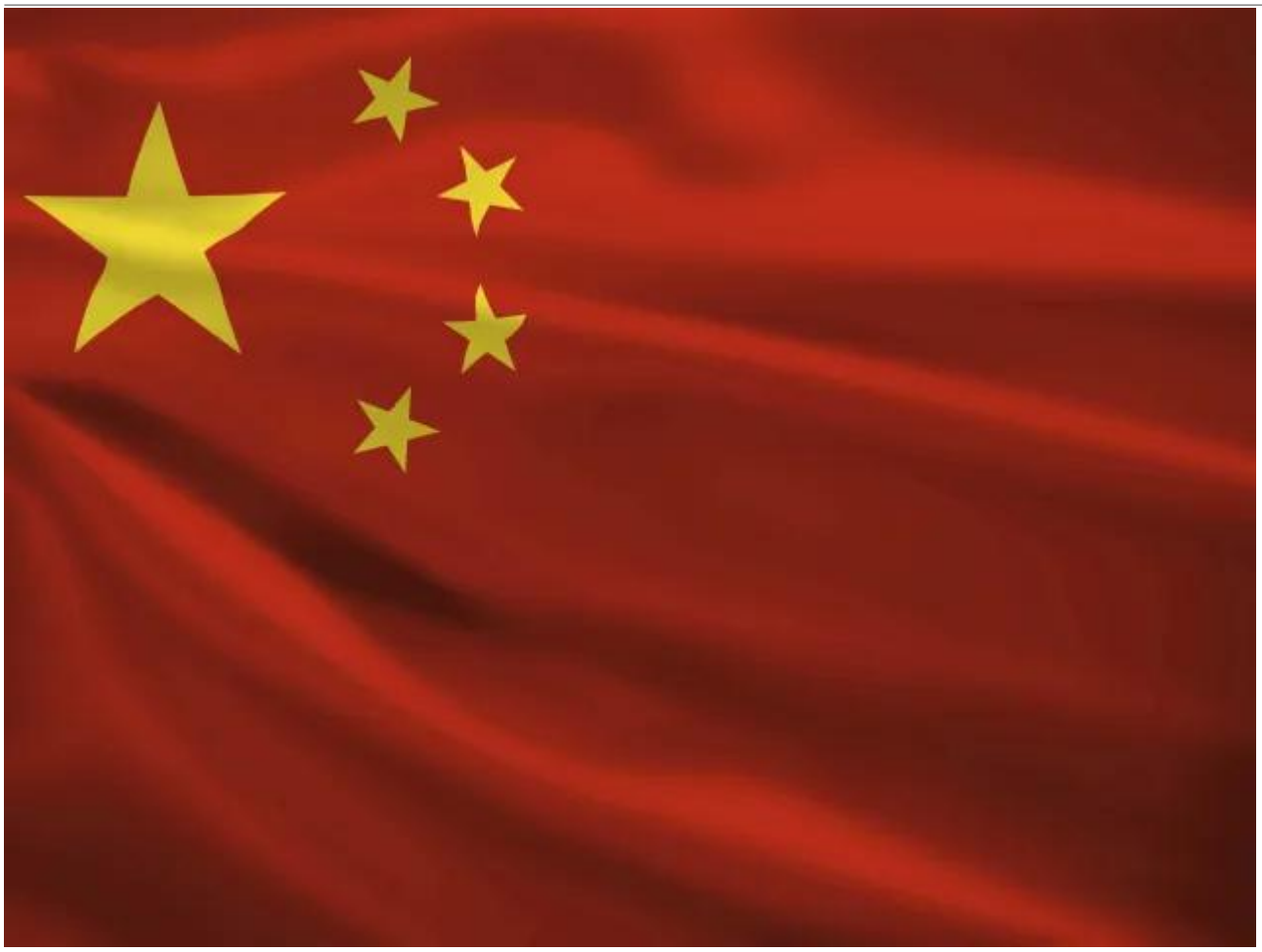
More Regulatory Updates

Worldwide Regulatory Updates

Get insights into the most recent worldwide track and trace regulatory compliance updates for the healthcare supply chain.
View More

Emerging Market Regulatory Updates

View a compilation of the most recent track and trace regulations for the healthcare supply chain in emerging markets. Get insights into compliance.
View More



China Regulatory Updates

View a compilation of the most recent track and trace regulations for the healthcare supply chain in China. Get insights into compliance updates.
View More

United States Regulatory Updates

View a compilation of the most recent track and trace regulations for the healthcare supply chain in the U.S. Get insights into DSCSA compliance.
View More