EMVO GLOSSARY

Term	Acronym	Definition
Affiliation		The connection to a Party, any company or incorporated body that controls or is directly or indirectly controlled by such Party. For the purposes of this definition, "control" means ownership of 50% (fifty per cent) or more than 50% (fifty per cent) and/or the right to exercise the vote of 50% (fifty per cent) or more of all the voting shares and/or the ability to appoint the majority of the directors.
Affordable Medicines Europe	AME	The association representing Europe's licensed parallel distribution industry, an integral part of the European pharmaceutical market that adds value to society by introducing price competition – especially for patented medicines – and a supplementary layer of product safety. One of EMVO's founding members and stakeholder.
Alert Management System	AMS	A system which aims to maximise the efficiency of alert management in the EMVS when the level of alert rate reaches a steady state (target 0,05%). The AMS supports EMVS users (OBPs, MAHs, NMVOs and end-users) to change alert statuses and communicate with other parties involved in an alert investigation, depending also on the landscape at national level in each Member State.
Arvato	ARV	A company providing a software solution for the NMVSs (as managed by the NMVOs). One of the two EMVS (blueprint) IT suppliers, together with Solidsoft Reply.
Authorised Representative	AR	The duly appointed and authorised by a subscriber organisation to act on their behalf and represent them in the proceedings.
Blueprint Supplier	BPS	The NMVOs' supplier responsible for the technical structure and maintenance of the data base, using the blueprint approach EMVO proposed to the NMVOs, which builds on the legal and IT architecture employed by EMVO. There are two blueprint suppliers: Arvato and Solidsoft Reply.
Centrally Authorised Medicinal Products	CAP	Any medicinal product with correct representation of: (a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients; (b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or (c) its history, including the records and documents relating to the distribution channels used. This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.
Certificate	CER	The proof that is needed to maintain the security of the system during the processing of any action
Certificate Signing Request	CSR	A message sent from an applicant to a registration authority of the public key infrastructure in order to apply for a digital identity certificate.
Change Advisory Board	CAB	It relates to a Customer Group and is composed of IT-, QA-, and Business representatives of NMVOs which belong to the Customer Group. The purpose of the board is to govern (approve or reject) a proposed change within its customer group. The CAB will govern : 1)Change- and Fix Requests initiated by the Customer Group itself. a)After a quality review and alignment with the members of the customer group, the CR can be issued to the EU CCB secretary for EU Governance. 2)Change- and Fix Requests initiated by other Customer Groups a)These change requests are to be evaluated by the customer group on system and process impact. The Customer Group Representative will approve or reject the Change request in the EU CCB, based on the position of the CAB.
Change Request	CR	A request that intends to manage the change at European level. Its content is focused on the impact of the change on other systems within the EMVS and the interaction between the different Customer Groups required to approve and implement the change in a controlled manner.
Company Type		It relates to an OBP company and is either an original pack manufacturer (OPM) company or a parallel distributor (PD) company. Each company type has different authorisations in the EU Hub.
Connection Provider/ Gateway Provider		A third-party contractor engaged by the OBP, who assists in whole or part of with the development, implementation, provision, use and/or operation of the OBP interface to the EU Hub via a Gateway Connection. Every OBP Gateway Connection Provider has to be promoted by at least one OBP in the On-boarding Process.
Contract Manufacturing Organisation	CMO	A company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing.
Copy of Proof	CoP	An objective document attesting that the Authorised Representative has the authorisation to sign on behalf of the company and therefore to legally bind it. For example, it can consist of an excerpt of the Trade Register, an excerpt of the Bulletin of Act or of the status of the company, in order to certify the position of that person in the management board or in a senior position. It is needed in order to enable EMVO to approve the Participation Agreement the OBP is required to send to EMVO as well as to further pursue the legitimacy check.
Corrective Action and Preventive action	CAPA	Long term actions that aim to prevent a Quality Event form occurring or re-occurring. Corrective Action: Action to prevent recurrence of an unwanted event. Preventive Action: Action to prevent a potential unwanted event from occurring.
Customer Group	CG	A group using a specific software solution. Currently, there are three Customer Groups: - The Arvato Customer Group (using the Arvato National System) - The Solidsoft Customer Group (using the Solidsoft National System) (all together referred hereinafter as 'NMVO Customer Groups') and - The EMVO Customer Group (using the EU Hub)
Customer Service Representative	CSR	The point of contact between EMVO and an On-Boarding Partner, that provides information about services and responds to customer requests and complaints.
Data Protection Laws		The General Data Protection Regulation (EU) 2016/679 ("GDPR") and any equivalent legislation in the jurisdiction where a party is established, including any applicable supplementing national legislation regarding the collection, use and processing of Personal Data.
Delegated Regulation	DR	The Commission's Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use.
Divestiture & Acquisition	D&A	A divestiture is the disposal of a business unit through sale, exchange, closure, or bankruptcy. An acquisition of a company occurs when all or part of a company is purchased by another company.
Downtime		A type of interruption within EMVO's EVI tool whereby a system is not available (down). It is envisaged that communication with this system will not be possible for the duration of the published entry.
End-User		Any wholesaler, pharmacy or other person authorized or entitled to supply medicinal products to the public as foreseen under the EU Directive on Falsified Medicines and the Delegated Regulation or as otherwise foreseen under applicable law.
EU Change Control Board	EU CCB	The governing body of all Change and Fix requests within the EMVS. All Requests are analysed by the EU IT Team and reviewed by the EU QA team. The EU CCB Representatives approve or reject Requests. The EU CCB also aligns on other topics like e.g. the EMVS Roadmap.
European Association of Euro-Pharmaceutical Companies	EAEPC	The former name of Affordable Medicines Europe (AME), one of EMVO's founding members and stakeholders.
European Association of Hospital Pharmacists	EAHP	An association that represents and develops the hospital pharmacy profession within Europe in order to ensure the continuous improvement of care and outcomes for patients in the hospital setting, through science, research, education, practice, as well as sharing best-practice and responsibility with other healthcare professionals. One of EMVO's affiliate members and stakeholders.
European Directorate for the Quality of Medicines	EDQM	A Directorate of the Council of Europe that traces its origins and statutes to the Convention on the Elaboration of a European Pharmacopoeia. It has also served as EMVO's auditor in the past.
European Economic Area	EEA	An economic union reassembling the Member States of the European Union (EU) and three countries of the European Free Trade Association (EFTA) (Iceland, Liechtenstein and Norway; excluding Switzerland). It seeks to strengthen trade and economic relations between the contracting parties and is principally concerned with the four fundamental pillars of the internal market, namely: the free movement of goods, people, services and capital.
European Federation of Pharmaceutical Industries and Association	EFPIA	A European association that represents the biopharmaceutical industry operating in Europe. One of EMVO's founding member and stakeholders.
European Healthcare Distribution Association	GIRP	An umbrella organisation for full-service healthcare distributors in Europe. It represents the national associations of over 750 pharmaceutical wholesalers serving 34 European countries, as well as major international and pan-European healthcare distribution companies. One of EMVO's founding members and stakeholders.
European Hospital and Healthcare Federation	HOPE	An association of Representatives of hospital federations established to meet regularly and discuss questions and problems relative to hospitals. One of EMVO's affiliate members and stakeholders.
European Hub	EU Hub	The component of the EMVS under the responsibility of EMVO that serves as a central information and data router according to Article 32, para. 1, a) of the Delegated Regulation for the transmission of Data to or from National Systems; it is set up and managed by EMVO.
European Medicines Agency	EMA	A decentralised agency of the European Union (EU) responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU.
European Medicines Verification Organisation	EMVO	A non-profit legal entity that is responsible to set up and manage a central information and data router ('hub') in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.
European Medicines Verification System	EMVS	The system for medicines verification that has been set up and is managed in accordance with Chapter VII of the Delegated Regulation; it consists of the European Hub and the National Systems, and allows the End-Users to verify the authenticity of medicinal products in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.
European Medicines Verification System Information	EVI	A tool on EMVO's website enabling notifications to inform its subscribers about EMVS' systems events.
Falsified Medicines Directive	FMD	The Directive 2011/62/EU of 8 June 2011 (FMD), amending Directive 2001/83/EC on the Community code; it is a legislative act relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, as well as, where appropriate, the relevant implementing national laws in the relevant EEA Member States.
Fix Request	FR	A corrective action to be performed for the EU Hub, SSR, ARV.
Information		Any information or guidance relating to the operation of an EMVS' system figuring on the EVI tool, either being a Known Issue, a Downtime or Maintenance, which is not used to communicate malfunctions of any of the EMVS' systems.
Initial Requester	IR	The person who submits the on-boarding registration request for the OBP company.
Integrated Quality Environment	IQE	The dedicated environment for validating OBP solutions and qualifying users.
Inter Operability Testing	IOT	A test performed between the EU Hub's and national systems' releases. An IOT is used to determine the impact of changes or new functionalities (made in one system) on all EMVS systems.
Intergrated Test Environment	ITE	The dedicated environment for developing OBP solutions.
International Organization for Standardization	ISO	An international standard-setting body composed of representatives from various national standards organisations.
Known Issue		A type of interruption of the EVI tool whereby some functionalities of an EMVS system may not be functioning as intended some of the time for the duration of the published entry.
Legitimacy Check	LC	The check performed on all companies on-boarding to EMVO, to ensure that only legitimate companies in scope of the FMD access the EU Hub and the EMVS.
Letter of Announcement	LoA	A public-facing communication provided by EMVO. This announcement provides information about key EMVS topics Stakeholders, NMVOs or OBPs should be aware of.
Letter of Intent	LoI	A document containing a declaration of the intentions of the writer.
Marketing Authorisation Holder	MAH	The organisation which owns the serialisation data and which is accountable for uploading the data to the EU Hub (e.g. XYZ Sales Company in EU member country). Possibly an affiliate of the OBP; for smaller companies, the MAH and OBP could be the same.

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Term	Acronym	Definition
Master Service Agreement	MSA	A contract reached between parties, in which the parties agree to most of the terms that will govern future transactions or future agreements.
Medicines for Europe	M4E	A group of medicinal companies that provide medicines that European patients, healthcare professionals and healthcare systems rely on to treat the most acute and chronic diseases ailments covering a wide range of diseases from cardiovascular, to diabetes and cancer; associating better access to the most effective therapies. One of EMVO's founding members and stakeholders.
Merger & Acquision	M&A	Mergers and acquisitions are transactions in which the ownership of companies, other business organisations, or their operating units are transferred or consolidated with other entities.
National Competent Authority	NCA	A medicines regulatory authority in a EEA Member State that is, amongst others, primarily responsible for the authorisation of medicines available in the EEA that do not pass through the centralised procedure.
National Institute of Standards and Technology	NIST	A physical sciences laboratory and a non-regulatory agency of the United States Department of Commerce. Its mission is to promote innovation and industrial competitiveness.
National Medicines Verification Organisation	NMVO	The non-profit legal entity (entities) that is (are) responsible to set up and manage a national and/or supranational repository(ies) in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation.
National Medicines Verification System	NMVS	The national or supranational repository of the EMVS according to Article 32, para. 1, b) of the Delegated Regulation under the responsibility of one NMVO; it is connected to the European Hub and allows the End-Users to verify the authenticity of medicinal products in accordance with the provisions of the EU Directive on Falsified Medicines and the Delegated Regulation
NMVO Project Managers Community	PM Community	A group consisting of all the Project Managers of the NMVOs.
Non-Disclosure Agreement	NDA	A legally binding contract that establishes a confidential relationship. The party or parties to an NDA agree that sensitive information the receiving party(ies) may obtain from the disclosing party(ies) will not be disclosed but only under specific conditions.
OBP Contract Partner Number	OBP CP	The contract partner number of the OBP. It follows the format CPXXXX with X=number and can be found in the top right corner of all pages of the Participation Agreement the OBP has in place with EMVO.
On-Boarding Fee		The one-time fee which covers the administrative costs related to the On-boarding process, the costs attached to the legitimacy check and the technical costs of connecting the On-boarding Partners (OBP) with all its MAHs to the EU Hub.
On-boarding Partner	OBP	The company or organisation which is the contracting party of EMVO in the Participation Agreement and represents the affiliated entities that hold marketing authorisations for products for which the OBP uploads product and pack data to the EU Hub to be transferred to the National Systems.
On-boarding Partner Portal	OBP Portal	The web-based platform provided by EMVO that allows OBPs to set-up their connection to the EU Hub.
Original Pack Manufacturer	OPM	A pharmaceutical company holding a marketing authorisation (MA) and placing medicines on a given market. In the context of batch release, the company uploads product codes and pack data into the EU Hub.
Parallel Distributor	PD	A holder of either specific product authorisations issued by national competent authorities in an abbreviated procedure or the holder of an EMA distribution notice.
Participation Agreement	PA	The agreement that establishes the contractual framework and conditions for its on-boarding on the EU Hub and EMVS, including the conditions for the grant of rights that are necessary for the performance thereof.
PC Ownership Change		The transfer of the ownership of a Product Code from one OBP/organisation to another, as a resulf of incorrect data upload to the EU Hub or of D&A/M&A.
PC Ownership Change Fee		A fee applied to the incorrect owner or the acquirer of an affected PC(s) once a PC ownership transfer has been performed successfully.
Pharmaceutical Group of the European Union	PGEU	The voice of Community Pharmacy in Brussels. The PGEU's main objective is to advance the contribution of Community Pharmacists to European health systems, society and individual patients. One of EMVO's founding members and stakeholders.
Product Master Data	PMD	The product code and the target market that OBPs need to upload when connecting to the EU Hub.
Product Pack Data	PPD	The transactional data, associated with the upload of batches and serial numbers.
Production Environment	PRD	The dedicated environment for the upload of OBP operational data that has been qualified to be released on the market.
Quality Event	QE	Unwanted event that might impact the integrity of the data within the EMVS, the safety of patients or the compliance of the EMVO processes and/or systems with applicable regulatory requirements.
Service Fabric	SF	A specific component of Microsoft Azure to maintain the process of a system
Single Point of Contact	SPOC	The key contact person for EMVO that is appointed by the Authorised Representative of an OBP to be in charge of the correspondence between the OBP and EMVO. The SPOC is responsible for providing the requested information on behalf of the OBP company on the OBP Portal in order to proceed with the on-boarding process and establish a connection to the EU Hub.
Software Development Kit	SDK	All technical standards for the development, implementation, testing, and operation of an EMVS system interface in connection with another EMVS system.
Solidsoft Reply	SSR	IT provider for the implementation and operation of the EU Hub. SSR is also a company providing a software solution for the NMVSs (as managed by the NMVOs). One of the two EMVS (blueprint) IT suppliers, together with Arvato.
Stakeholder	STK	A Stakeholder (STK) is a party that has an interest in a company and can either affect or be affected by its operations and business. EMVO's founding stakeholders are EFPIA (The European Federation of Pharmaceutical Industries and Associations), Medicines for Europe (The European Generic and Biosimilar Medicines Association), PGEU (The Pharmaceutical Group of the European Union), GIRP (The European Healthcare Distribution Association) and Affordable Medicines Europe (Former EAEPC). EMVO's affiliate stakeholders are EAHP (European Association of Hospital Pharmacists) and HOPE (European Hospital and Healthcare Federation).
Statement of Work	SOW	A document within a contract that describes the work requirements for a specific project along with its performance and design expectations.
System Acceptance Testing	SAT	An assessment of a system's functionality to verify whether the system behaves as intended based on the functional specifications.
Technical Advisory Group	TEAG	A group of representatives of the EMVO Stakeholder associations, EMVO and the NMVOs that provides the EMVO Board and Stakeholders with advice on technical matters.
Third Party Logistics	3PL	A legal entity that has been contracted by a MAH for storage and distribution purposes.
Unique Identifier	UI/UID	The safety feature enabling the verification of the authenticity and the identification of an individual pack of a medicinal product; it consists of the product code, serial number, batch number, national reimbursement number (if required) and batch expiry date.
User Acceptance Testing	UAT	The testing performed by the end-user or the client to verify/accept the software system before moving the software application to the production environment.
User Requirement Specification	URS	All specifications (including, without limitation, all governing principles; use cases; exceptions, exception handling and alerts; non-functional, operational, and test harness requirements; and additional requirements of the EMVS), and updates within the EMVS.