Stichting Nederlandse Medicijnen Verificatie Organisatie

On April 9, 2019 the NMVO Board established the following policy regarding the exchange of data from the NMVS with third parties[1]

1 Introduction

1.1 The Netherlands Medicines Verification Organisation ("NMVO") manages a database in order to prevent drug falsification: the Netherlands Medicines Verification System (NMVS). The database has been operational since 9 February 2019.

1.2 Each medicine packaging has a unique code. Manufacturers, MAH's and wholesalers ensure that each unique code is entered into the database. Pharmacists ensure that the code on the packaging is compared with the database with every drug dispensing.

1.3 Each "movement" of a medicine packaging is thus recorded in the database. It is also known who registers such a "movement". This results in a large amount of data. These data are commercially sensitive and sometimes privacy sensitive. How does NMVO deal with these data?

1.4 This is explained below, divided in several topics. The explanation shows that data may only be exchanged with public regulators (in practice mostly the Dutch Healthcare and Youth Inspectorate – *Inspectie voor Gezondheidszorg en Jeugd*) and those involved in a potential falsification of medicines.

2 Protection of the database

2.1 The technical security of the database is strict. Unauthorized persons have no access to the database. Security against hacking, DDoS-attacks, malware and other threats is kept up to date.

2.2 Guarantees are also in place by means of binding contracts. Thousands of MAH's wholesalers and pharmacists are connected to the database after an agreement has been signed. With them, as well as with their ICT service providers, strict agreements have been made concerning security. If security is not in good order, they can be disconnected from the system immediately.

2.3 Vis a vis the database, the affiliated parties are only authorized to do what the regulations set forth. This is, in short, the introduction of data from medicinal products brought into circulation and deactivation of them at the moment the medicinal products are dispensed to the public. This is all the affiliated parties are authorized do with the database. The data in the database itself remain invisible to them and cannot be downloaded or otherwise processed or edited.

2.4 With these measures NMVO excludes that industry, government, regulators or others can obtain or use the data, except when the regulations so require.

2.5 NMVO stresses that the regulations only require exchange of data from the NMVS with regulators and with parties involved in a potential falsification of medicines.

3 Which data can or should NMVO exchange?

3.1 What data NMVO may or should exchange is laid down in the Delegated Regulation (EU) 2016/161 of 2 October 2015 from the European Commission, supplementing Directive 2001/83/EC of the European Parliament and of the Council by adopting detailed rules on the safety characteristics of the packaging of medicinal products for human use (hereinafter referred to as "Regulation").

3.2 NMVO sets forth that there is no other basis for a data exchange[2].

3.3 Which data can or should NMVO exchange according to the Regulation? We describe this in the following paragraphs.

---

[1] NMVO is at all times empowered to amend these policy intentions. The policy intentions do not bind NMVO to contract or third parties.

[2] However, it might be that in a civil, tax or criminal procedure, NMVO would be obliged to submit data from the database. This is already subject to strict, evidence-law rules and the scope of this risk is very limited.

3.4 *Data on the operation of the database*

3.4.1 NMVO is obliged to inform the authorities about the correct functioning of the database. The relevant authority in the Netherlands is the Dutch Healthcare and Youth Inspectorate – *Inspectie voor Gezondheidszorg en Jeugd* (IGJ). Data exchange in this context never regards the data themselves, but the way in which these are processed in the system.

3.4.2 In the first five years after 9 February 2019, a report must be submitted annually, after that submission happens once every three years (article 37 (e) Regulation).

3.4.3 There is also a general obligation to grant IGJ access in order to monitor the functioning of the database (article 39 (a) Regulation), e.g. for monitoring processing speed, availability of the system, number of registrations and de-activation of medicinal packaging, etcetera.

3.4.4 Access for surveillance also applies to supervision on investigations by NMVO into potential incidents of falsification of medicines (see article 39 (a) of the Regulation). This, too, concerns supervision of processes, which in principle does not require access to concrete data.

3.4.5 Therefore, NMVO's policy is that this monitoring shall in principle not regard substantive data. Commercially or privacy sensitive data should thus remain out of the picture.

3.4.6 As stated before, these data on the processes mentioned above are exclusively exchanged with IGJ.

3.5 *Audit trail and information*

3.5.1 The NMVS keeps a complete overview ("audit trail") of all operations involving a unique identification code, of the users performing these operations, and of the nature of the operations. The audit trail is associated with a unique identification code of a pharmaceutical packaging. The *audit trail* is retained for one year.

3.5.2 Pursuant to article 37 (f) of the Regulation, IGJ may, with respect to a unique identification code, ask for submission of the audit trail. NMVO must hand over these data. These can, in part, be privacy sensitive data. This is allowed on the basis of the AVG if a legal basis for it exists. This legal basis is constituted by the Regulation.

3.5.3 The Same applies to "information" with respect to a particular unique identification code (pursuant to article 36 (i) of the Regulation). The Regulation does not determine what this information should be. Apart from the *audit trail* and information on the nature of the medicinal product the database does not contain any information.

3.5.4 Data on an audit trail or a particular unique identification code is exchanged with IGJ nnly.

3.6 *Compliance with the Regulation by MAH's, manufacturers, wholesalers and pharmacists*

3.6.1 NMVO must draw up reports on the basis of which the competent authorities can check whether MAH's, manufacturers, wholesalers and pharmacists, meet the requirements of the Regulation. NMVO must submit these immediately (article 36 (j) and article 37 (g) Regulation). Only IGJ is entitled to these reports.

3.6.2 NMVO does not see any active role for itself in reporting non-compliance to IGJ. Neither does NMVO see an obligation to perform any follow-up actions after delivery of such a report to IGJ. Only if IGJ is requesting a report, NMVO must submit immediately. This means that NMVO shall be creating and storing the reports on the system and IGJ will be granted access to these reports at its first request.

3.6.3 Non-compliance will be prevented and combatted as much as possible by NMVO itself. Since the system is in operation, we see that non-compliance often happens unintentionally. However, this non-compliance may lead to many alerts that do not need to be related to actual falsification of medicines. These disrupt the functioning of the organisation because, according to the Regulation each alert must be investigated. Any communication thereon with the parties concerned is not disclosed by NMVO to third parties.

3.7 Potential incidents of falsification of medicines

3.7.1 The Regulation sets forth that NMVO shall:

> *"provide for the immediate investigation of all potential incidents of falsification flagged in the system in accordance with Article 36(b) and for the alerting of national competent authorities, the European Medicines Agency and the Commission should the falsification be confirmed;*
>
> *(Article 37 (d) Regulation);*

3.7.2 NMVO gets alerts in case something is wrong when a unique code on a medicines packaging is scanned for deactivation by a pharmacist. This happens when the code is not recognized or has previously been deactivated. These alerts do not contain any personal data. The pharmacist is pseudonymized. This means that a number appears, instead of the name of the pharmacist.

3.7.3 An alert must first lead to investigation. NMVO carries out that investigation itself. It is obliged to do so. Only if that investigation leads to a confirmation of the falsification, a warning goes out to IGJ, the European Medicines Agency and the Commission.

3.7.4 It is not required to submit details that are commercially or privacy sensitive. However, for the purpose of further action by authorities, all or some of that information could be necessary, and to the extent that this is the case, NMVO will cooperate with the authorities.

3.8 Pharmacovigilance or pharmaco-epidemiology

3.8.1 According to the Regulation, IGJ must have access to the database for pharmacovigilance or pharmaco-epidemiology (Article 39 (c) Regulation).

3.8.2 Pharmacovigilance regards the adverse effects of a drug on an individual.

3.8.3 Pharmaco-epidemiology regards adverse effects of a drug on a population.

3.8.4 NMVO does not see how the data in the database can contribute to either of those. Except when it is clear that pharmacovigilance or pharmaco-epidemiology can be served by these data without there being other possibilities to do so, NMVO will not co-operate.

3.8.5 List of Wholesalers

3.8.6 For a medicinal product with a unique identification code, a list of wholesalers designated by the Marketing Authorisation Holder for storage and distribution must be uploaded (see article 33 (2) (h) of the Regulation).

3.8.7 NMVO must provide this list to controlled wholesalers in order for them to determine whether they should check the unique identification code of a particular medicinal product (article 36 (g) Regulation). NMVO should observe privacy rules. This means, in this case, that the data of the wholesalers concerned are shared on the basis of a legal rule and this is therefore permitted under the AVG, but that only those data which serve the legal purpose should be provided. NMVO believes that, in order for the wholesalers to be known to the recipient, it is only the name of the wholesalers concerned that needs to be communicated.
