

ARTICLE:

# THE ELECTRONIC PRESCRIPTION OF MEDICATION IN A NETHERLANDS HOSPITAL

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**A large Dutch hospital is currently implementing a system for the Electronic Prescription of Medication (EPM). Given the serious nature of prescriptions, there is a need for strong authentication. In order to fulfill this need, a set of standards and a framework for authentication is being created. In doing so, the hospital has run into implementation issues concerning the authentication process. Prominent among these issues are the legal ones. One of the problems that arise is the lack of acceptance amongst doctors and other professionals of electronic signatures for electronic prescriptions. The article will address the discrepancies between Dutch law and practice, and will offer an insight to the solutions found for the hospital involved.**

## **Discrepancies between law and practice**

More and more Dutch hospitals are implementing a system for electronic prescription of medication for reasons of medication safety and efficiency. The forthcoming Medication Dossier that should have been implemented on 1 January 2006 with the purpose of increasing safety concerning medication, plays an important role in the implementation of new prescription systems. Obtaining the electronic authorization of the doctor should be taken into account when designing such a system. However, it is not so straightforward for a doctor to use an electronic signature. If doctors do not accept this new electronic system, implementation of an EPM could fail. If a doctor does not give his authorization for the prescription from the hospital pharmacy, then the medicine will not be distributed. In practice, this does not mean that medication is not distributed by the pharmacy if a prescription has not been authorized. This article

discusses the discrepancies between law and practice and tries to offer a solution to the authorization of prescriptions and medication orders.

## **Electronic signatures**

The Directive 1999/93/EC of the European Parliament and of the Council of 13 December 1999 on a Community framework for electronic signatures (OJ 19.1.2000 L13/12) is implemented in the Dutch Civil Code (BW), the Telecommunications Act (Tw) and the Economic Offences Act (WED).

Article 2(1) of the Directive and article 3:15a paragraph 4 BW define the electronic signature as: “data in electronic form which are attached to or logically associated with other electronic data and which serve as a method of authentication.” According to article 3:15a paragraph 1 BW the electronic signature has the same status as a manuscript signature if the method used for authentication is sufficiently reliable and taken the purpose of the signature and all other circumstances into account. Besides the ‘regular’ electronic signature, the EU Directive provides for an advanced electronic signature in article 2(2) that is generally considered more secure. Article 3:15a paragraph 2 BW sets six requirements which an electronic signature must meet in order to be considered as sufficiently reliable:

- it is uniquely linked to the signatory;
- it is capable of identifying the signatory;
- it is created using means that the signatory can maintain under his sole control;
- it is linked to the data to which it relates in such a manner that any subsequent change of the data is detectable;
- it is based on a qualified certificate;
- it is generated by secure-signature-creation device.

The advanced electronic signature consists of a unique public and private key that are inseparably linked to each other. Such a public and private key (capable of being deployed within a Public Key Infrastructure) is based on symmetric keys; the private key of the person in control of the digital signature and the public key for those who are allowed to obtain access to the data. A certification-service provider (in practice commonly known as Trusted Third Party or TTP) records who belongs to which key within the digital certificate. Electronic signing is done with the private key (usually a personal identification number). The recipient of the data then uses the public key to verify the message.<sup>1</sup> Besides the distinction between regular and advanced electronic signatures, the Directive also draws a distinction between regular and qualified certificates. A regular certificate is an electronic confirmation that interconnects data to a certain person for the purposes of verification of the signature and confirms the identity of that person. A qualified certificate is more secure. Among others, a qualified certificate should contain the following information:

“an indication that the certificate is issued as a qualified certificate, the identification of the certification-service-provider and the State in which it is established, an indication of the beginning and end of the period of validity of the certificate, limitations on the scope of use of the certificate, if applicable”.<sup>2</sup>

If all requirements are fulfilled, the electronic signature can be regarded as legally equivalent to hand-written signatures. This does not mean that if electronic signatures do not meet the requirements, they cannot be regarded as legally binding (article 3:15a paragraph 6 BW). It depends on any agreements there may be between contracting parties, (such as the prescribing doctor and the delivering hospital pharmacy), the transaction and purposes of sending the data whether the electronic signatures can be regarded as legally binding. It is open for a judge to confirm the legal force of the electronic signature. The following paragraph sets out the rules for signing the prescription the distinction between ‘regular’ and ‘special’ prescriptions.

### The electronic signature and the ‘regular’ prescription

In contrast to the relations between a family physician

and the city pharmacy where the term ‘prescription’ is used, hospitals use the term ‘medication order’. The Dutch Law does not mention such a term, but uses the term ‘prescription’. If the sole distribution of medication is meant, there is no difference between a prescription and a medication order. The report “Distribution of medication within healthcare institutions” summarises the term as follows: ‘a medication order is an instruction to a nurse with regard to the administration of medication.’<sup>3</sup> The medication order can also be used to acquire medicines (not being general stock) that are mentioned on the order. As a result, the medication order becomes a prescription and the pharmacist should handle the prescription accordingly. The only difference, therefore, between a medication order and a prescription, is that the latter contains an instruction to the nurse on the administration of the drugs. The medication order should therefore comply with the legal rules on the distribution of prescription drugs.

According to article 5(2) of the Regulation on the distribution of medication on prescription only (Regeling U.R.-geneesmiddelen; further RURg), a prescription (also that particular part of a medication order) should meet the following requirements (on the basis of paragraph 1 a pharmaceutical product should only be distributed if a written request is received): the request must be signed and contains the name, address and capacity of the requester, and the name and quantity of the pharmaceutical products.

The prescription must be authorized by the prescriber (doctors, dentist and obstetricians). The authorization must also contain a name and signature, whether or not electronically. It must be clear and indisputable who signed the prescription, which makes it obvious who is responsible for the authorization. Without a signature, the pharmacy cannot distribute the medication, and this signature must be in place before the prescription is sent to the pharmacy.<sup>4</sup> The meaning of article 5 paragraph 2 RURg clearly shows that permitting a person other than the prescriber sign the prescription is, in principle, not allowed. In view of the use of electronic signatures, there is reason to refer to article 3:15a paragraph 5 BW, which defines the term signatory as follows: ‘The signatory is a person who holds a signature-creation device’. Even though this should not lead to the conclusion that the person signing the message is also the drawer of the message, the signatory is the one that is identified as the sender of

<sup>1</sup> Also: TK 2000–2001, 27 743, nr. 3 Explanatory statement for the implementation of Directive 1999/93/EC (Dutch only).

<sup>2</sup> Directive 1999/93/EC Annex I. and TK 2000–2001, 27 743, nr. 3 2 Explanatory statement for the implementation of Directive 1999/93/EC, p. 3

(Dutch only).

<sup>3</sup> Geneesmiddelendistributie binnen inrichtingen voor gezondheidszorg. Rapport 30. Leidschendam: Staatstoezicht op de volksgezondheid. 1980, p. 14, 24–25, 28 (Dutch Only).

<sup>4</sup> Zie: I.H. van der Sijs, T.F.M. Hooghiemstra, ‘Hoe het moet, hoe het mag en hoe het zou kunnen. Juridische aspecten van elektronisch voorschrijven in ziekenhuizen’, *Pharmaceutisch weekblad*, 17 september 2004, jaargang 139 nr. 38, p. 1224–1228 (Dutch Only).

the message, and in this case, as the rightful requester of the prescription. The signatory does not have to sign his request for medication distribution solely with his signature, but also with his name and capacity. It would therefore not be logical to assume that somebody other than the requester (such as a colleague) can sign the prescription, even if this other person has the competency to do so. In the Electronic Prescription of Medication system, there is a possibility to authorize prescriptions from other prescribers as long as the signatory has the authority. As a result, the signature will no longer correspond with the initial prescriber of the medication.

### Electronic signatures and ‘special’ prescriptions

A prescription or medication order containing multiple medicines cannot contain medicines listed under the Opium Act.<sup>5</sup> Like the RURg, the Decree on the prescription and ordering of products covered by the Opium Law<sup>6</sup> requires in article 1(1)(1) that a prescription is required to contain the name, address and capacity of the requestor. What deviates from the RURg is the second paragraph. According to article 1(2) of the Decree, the prescription should be written in ink and should be accompanied by a full signature.

The first question leads to the conclusion that a prescription, as mentioned in the Opium Act, cannot be produced electronically, because the article refers to a prescription written in ink. In practice, such prescriptions are not hand written but electronically produced. Producing a prescription in ink can also mean that the prescription is printed on an inkjet printer, which automatically fulfils the requirements. There is no requirement that the prescription should be written by hand. Since the reasoning behind the Opium Act is that medicines listed in this Act can only be distributed under stringent conditions, it does not follow that in view of safety of prescriptions, that electronic production is prohibited. In view of medication safety, this is favourable; a handwritten signature no longer needs deciphering, and there is no doubt about the requested pharmaceutical and quantity. In hospitals that intend to implement and have implemented the EPM, prescriptions based on the Opium Law are electronically authorized. Such an electronic signature is not contrary to the law, even though the Opium Act is not equipped for such signatures yet. The EU Directive

regards electronic signatures with a qualified certificate as legally equivalent to hand-written signatures, so adjustment of the Opium Law to allow electronic prescriptions and authorization is recommended in view of the far-reaching development of electronic appliances in healthcare.

The second question is whether the signature required by the Opium Law on the prescription necessarily needs to be a full signature. Since the RURg does not mention the requirement for a full signature but just signature, signing the prescription can also be done with initials. Even though the law does not mention this possibility, it is possible to derive from initials, the name of the person who purported to sign the message. This might be a reason to accept initials as a signature. In view of the electronic signature, this is not unusual; there is no distinction between an electronic initial and an electronic signature. It is either signed or not signed.

### Hospital practice

Prescribing medication listed under the RURg or the Opium Act is a daily practice in a hospital. Since medicines are increasingly prescribed electronically, it is important to pay attention to the way prescriptions are authorized. The hospital’s Electronic Prescription of Medication system uses a username and password as the current means of authorization. Article 2(3) of the EU Directive, in conjunction with article 3:15a paragraph 5 BW, indicates the meaning of the term signatory: ‘a person who holds a signature-creation device and acts either on his own behalf or on behalf of the natural or legal person or entity he represents.’ Practice shows that when a competent person prescribes a prescription, separate authorization is not necessary. If a person that is not authorized draws up the prescription, separate authorization is necessary. The doctor must know the drawer of the prescription (usually a nurse). The software system provides this information; the authorizing doctor can see who filed the prescription, and at what time, for the purpose of authorization. One question is whether an electronic signature by means of a username and password is sufficiently reliable as the law requires. Even though the use of a username and password is a common method, it cannot be regarded as sufficiently reliable taken the purpose of the signature – distributing medication – into consideration. The distribution of medication should be

<sup>5</sup> *Wet van 12 mei 1928, tot vaststelling van bepalingen betreffende het opium en andere verdoovende middelen*, <http://wetten.overheid.nl/cgi-bin/deeplink/law1/title=Opiumwet> (Dutch only).

<sup>6</sup> *Besluit voorschrijven Opiumwet-middelen*, <http://wetten.overheid.nl/cgi-bin/deeplink/law1/title=Besluit%20voorschrijven%20Opiumwet-middelen> (Dutch only).

handled with care and should remain confidential, since it is part of the medical data of the patient. The consequences of the prescription, and in this case the complete medication order, are far-reaching and should therefore be considerably secured to prevent problems. This is particularly important when taking into account the stringent rules from the Opium Act. It cannot be assumed that the use of a username and password is sufficient to protect and authorize prescriptions. Sad but true, most people still use the name of their loved one, a pet, their street name, postal code or birthday as a password.<sup>7</sup> Such a 'safety' measure will not improve the security of the medication distribution, since usernames and passwords are easily hacked even though a hospital seems like a secure environment. The request for medication is over wi-fi within the confines of an intranet, and it is anticipated in the design of the system that doctors will be able to provide authorization from their office at home, viewing the medical data on-line. In the case where the prescriber automatically authorizes the prescription by the mere fact that he or she is logged on to the system, it is essential to protect the system from infringement. If the current Opium Law can allow the use of electronic signatures, a high degree of protection of the system ought to be one of the first requirements. As stated earlier, the EU Directive regards an electronic signature as legally equal to a handwritten signature on paper as long as a qualified certificate is present. Without a qualified certificate, it is possible to argue that a hospital does not act completely in accordance with the law, unless there agreements between parties (hospital and doctors) exist in order to guarantee the legal force of the electronic signature.

In practice, a colleague, rather than the doctor, authorizes prescriptions. With one touch of a button, a doctor can authorize all distribution requests for the patient on the department he is authorized for. This means the doctor can authorize medicines for his patients that are not prescribed by him. It would not be practical to restrict this, but it is legally unthinkable, because the electronic signature longer corresponds to the requirements of the RURg. However, this practice is not illegal, because every doctor is competent to authorize and prescribe medication. In addition, if a doctor authorizes the prescriptions of others, it will be harder to find out which doctor is the true prescriber, because the electronic signature is from somebody else.

Questions from the pharmacist on quantities, indistinctness (such as contrast with allergies) or requests to change the type of medication are then complicated. The solution for this problem lies within the system itself. It is programmed in such a way that all entries are logged by user and competency, and providing people do not start to share usernames and passwords, the pharmacist can easily determine the person responsible for prescribing the medication.

### Trusted Third Parties as a solution

With the development of PKI-Government (Public Key Infrastructure), reliable electronic communication within and with the Dutch government is provided. The Central Agency for Information on Healthcare Professional (CIBG) is one of the TTPs that joined the PKI-government and meets the requirements of certificate-holders from the EU Directive. The TTP is organised in the Dutch Unique Healthcare Provider Identification Register (UZI-register), which takes care of the provisions of certificates in the healthcare sector. The UZI-Register provides an electronic passport (an UZI-card) with a PIN code to permit health care providers to authenticate and identify the sender, which guarantees the confidentiality of the data through encryption and by entering digital signatures.

The card can be used if the EPM is designed to handle cards and if a card reader is provided. The qualified certificate offers a solution to the problem of authorization in medication distribution. A recognisable certificate improves the reliability of the electronic communication and provides clarity for prescriber and pharmacist. Even though the hospital I based my research on is not working with a certificate yet, they recognise the necessity to do so and the system is equipped with the necessary applications. It is recommended to make sure the qualified certificate is provided as soon as possible to meet the legal standards. Hospitals are following the government's solution to use a TTP for security.

### Accepting electronic authorization

Doctors are, in some cases, and for several reasons, not prepared to sign their prescriptions electronically. The refusal to do so can be related to a lack of knowledge and trust about the digital systems, or doctors are just not prepared to authorize their prescription electronically.<sup>8</sup> Such a refusal leads to problems,

<sup>7</sup> *Conference privacy in healthcare (Privacy in de gezondheidszorg, Dutch only) organised by the Regional Privacy Committee for Healthcare, June 9th 2006, presentation by Getronics/PinkRocade on information safety.*

<sup>8</sup> *These few examples of rejecting electronic authorization are found in the Dutch hospital at which the author is conducting her research.*

because the pharmacy is no longer equipped to process paper prescriptions, and has made a conscious choice to work with digital prescription in the interests of efficiency and medication security. As previously mentioned, the pharmacy is legally obliged not to distribute medication if a description lacks a signature. Refusal to sign means that medicines cannot be distributed and the doctor cannot perform his tasks. In practice though, distribution often occurs without a written signature, but with an oral confirmation of the medication ordered. This is in contrast with the legal requirements. This has consequences for the pharmacist (who is obliged to distribute medication only if the prescription is sufficiently authorized), and for the possible liability of the doctor. Liability for the act of prescribing medicines is easy to deny if no proof of prescription exists. Without a signature, no one knows if the doctor in question truly prescribed the medicine.

Accepting paper prescriptions is also not advisable. Even though it is not legally forbidden to accept (handwritten) paper prescriptions as long as they are sufficiently authorized, it does lead to an unstable system. It might even lead to a disturbance in the introduction of electronic systems, since the explicit need for these systems will not be recognised. Especially if the choice is finally made to digitalise, one should make sure that the whole system becomes digital. The EPM is not (and should not) even be designed to process paper prescriptions, since they need to be manually fed into the system and all signatures have to be scanned in order to comply with the law. The existence of two systems, one digital and one analogue, will not lead to the desired effect of more security in medication distribution.

It is not unthinkable that the reason to refuse to sign electronically is founded in the fear for a compromised system.<sup>9</sup> It is therefore necessary to create awareness among prescribers that the system is sufficiently secure which might lead to a different perspective on electronic prescription systems. New government initiatives such as the Medication Dossier will finally force physicians to accept new technological developments in healthcare.

## The future

In the bill<sup>10</sup> for a new Law on medication, the explanatory statement takes the first step in the right direction for the acceptance of electronic signatures on

prescriptions or medication orders:

“first of all the word «document» is introduced. This term does not only refer to the traditional piece of paper signed by the prescriber including information on his identity, the patient’s identity and the required medicine, but also refers to other data carriers such as electronically drawn and sent documents. Other data carries than the traditional paper prescription requires such a protection that the prescriber sending the data can be recognised by the intended recipient (the pharmacy) based on the agreements made between parties. This requirement replaces the requirement that the prescription should always be signed by the prescriber.”<sup>11</sup>

Such a new requirement can immediately solve the problems surrounding the identity of the authorizer for the healthcare provider if the healthcare provider takes care of sufficient protection in the dispatch and uses a TTP. This bill might also lead to the earlier recommend change in the Opium Law, to equally set the standards on the authorization of prescriptions. Such a change makes it easier for hospitals to implement an Electronic Prescription of Medication system. A problem that will not be solved implementing TTPs, changing laws or acceptance by doctors, is the complicated and costly implementation of advanced electronic signatures and their protection. Taking all the problems into consideration and weighing the advantages, it is possible to conclude that the provision of electronic means for healthcare providers can help to protect medication distribution and improve efficiency.

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<sup>9</sup> There is no evidence to substantiate this point. It is the conclusion reached by the author as a result of observations made in the hospital in which the research is being conducted.

<sup>10</sup> Geneesmiddelenwet 2006, not yet in force,

accepted by the parliament in April 2006, the Senate will start their procedure for preliminary investigation as of September 2006.

<sup>11</sup> Tweede Kamer, vergaderjaar 2003–2004, 29 359, nr. 3 29; p. 29-30 (Dutch only)

<http://www.nvilg.nl/uploads/Geneesmiddelenwet-mrt2004.pdf>.