

# MEMORANDUM OF UNDERSTANDING

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## Heads of Agencies Group (HAG)

This Memorandum of Understanding is entered into by and between:

1. **AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS (AEMPS),**
2. **AGENZIA ITALIANA DEL FARMACO (AIFA),**
3. **AGENZIA NAZIONALE PER I SERVIZI SANITARI REGIONALI (AGENAS),**
4. **AUSTRIAN INSTITUTE FOR HEALTH TECHNOLOGY ASSESSMENT GmbH (AIHTA),**
5. **AUTORIDADE NACIONAL DO MEDICAMENTO E PRODUTOS DE SAUDE, I.P (INFARMED),**
6. **DACHVERBAND DER ÖSTERREICHISCHEN SOZIALVERSICHERUNGSTRÄGER (DVSV),**
7. **FEDERAAL KENNISCENTRUM VOOR DE GEZONDHEIDSZORG – CENTRE FÉDÉRAL D'EXPERTISE DES SOINS DE SANTÉ (KCE),**
8. **FOLKEHELSEINSTITUTTET (NIPH),**
9. **GEMEINSAMER BUNDESAUSSCHUSS (GBA),**
10. **HAUTE AUTORITÉ DE SANTÉ (HAS),**
11. **HEALTH INFORMATION AND QUALITY AUTHORITY (HIQA),**
12. **LÄÄKEALAN TURVALLISUUS- JA KEHITTÄMISKESKUS (FIMEA),**
13. **NATIONAL CENTRE FOR PHARMACOECONOMICS (NCPE),**
14. **RED ESPAÑOLA DE AGENCIAS DE EVALUACIÓN DE TECNOLOGÍAS SANITARIAS (REDETS)**
15. **REGIONE EMILIA ROMAGNA (RER),**
16. **RIJKSINSTITUUT VOOR ZIEKTE- EN INVALIDITEITSVERZEKERING - INSTITUT NATIONAL D'ASSURANCE MALADIE-INVALIDITÉ (RIZIV-INAMI)**
17. **STATENS LEGEMIDDELVERK (NOMA)**
18. **STIFTUNG FÜR QUALITÄT UND WIRTSCHAFTLICHKEIT IM GESUNDHEITSWESEN (IQWIG),**
19. **TANDVÅRDS- OCH LÄKEMEDELSFÖRMÅNSVERKET (TLV),**
20. **ZORGINSTITUUT NEDERLAND (ZIN),**

individually referred to as a “Party” or collectively as the “Parties”, the “HAG” or the “Collaboration” considering:

- 1.1 The Proposal for the Development of the Heads of Agencies Group,
- 1.2 Information on the HOFA-DEV Working Group (Project Plan),
- 1.3 Survey questions,
- 1.4 Overview of all responses,
- 1.5 Breakdown of votes for the additional questions,

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- 2.1 JA3 Heads of Agencies Meeting (HOFA) – Minutes from 29 October 2020,
- 2.2 JA3 Heads of Agencies Meeting (HOFA) – Minutes from 4 March 2021,
- 2.3 JA3 Heads of Agencies Meeting (HOFA) – Minutes from 26 May 2021.

*Note. All documents listed above are available as annexes to this Memorandum of Understanding,*

and,

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on health technology assessment and amending Directive 2011/24/EU. COM/2018/051 final - 2018/018 (COD).

THE PARTIES AGREE AS FOLLOWS:

### 1. AIMS OF THE COLLABORATION

This agreement seeks to setup a new EU/EEA-based HTA-focused collaboration network, namely the “Heads of Agencies Group” or “HAG”. The Parties will come together in a group that will be comprised of the heads of European HTA agencies. As outlined in the *Proposal for the Development of the Heads of Agencies Group* (1.1, p.16), the group’s main objectives will be as follows:

- To support the development of the basis for joint work on all HTA activities at EU level within the model of EU cooperation anticipated by the Regulation on HTA and determined by the final wording of this Regulation once it comes into force.
- To support the preparation of national systems and capacities for the adoption of the HTA Regulation.
- To support the joint work performed at the technical and scientific level by HTA bodies across Europe.
- To advise policy makers and relevant EU and national institutions on matters regarding HTA, particularly cooperation in HTA.

### 2. SCOPE OF THE COLLABORATION

As outlined in the *Proposal for the Development of the Heads of Agencies Group* (1.1, p.16):

The Heads of Agencies Group shall be a forum to raise, highlight and discuss matters of strategic character that are of relevance for HTA bodies across Europe.

Strategic directions and recommendations determined by the HAG will be related to EU HTA cooperation and the Regulation. The HAG shall observe and closely guide the work performed at the technical and scientific level, as well as provide input on the organisation and administration of future HTA cooperation.

The group will, however, avoid intervening at a political level in such a way that it will not interfere with healthcare matters that fall within the remit of EU/EEA Member States.

### 3. FUNCTIONS OF THE COLLABORATION

As outlined in the *Proposal for the Development of the Heads of Agencies Group* (1.1, p.16):

To fulfil its objectives, the Heads of Agencies Group shall, where appropriate and without prejudice to national settings, be able to:

- Establish a structure and specific communication pathways for members of the HAG in order to facilitate information sharing.
- Formulate recommendations for joint work at EU level within the model of EU cooperation on HTA anticipated by the adopted Regulation on HTA.
- Formulate recommendations for the activities of the Coordination Group in accordance with the Regulation on HTA.
- Maintain close communication channels with decision-makers across the product lifecycle.
- Enter into exchange and collaborate with other EU and international HTA networks, working together in order to avoid the duplication of efforts.
- Enter into exchange and collaborate with the EUnetHTA 21 Consortium and a potential post-Joint Action 3 EUnetHTA Network.

In undertaking its functions, the HAG should strive to ensure a high level of transparency in all processes and procedures within the group and thus towards the member organisations represented in HAG as well as in its interaction with any external Parties.

As the HAG is a self-constituted voluntary group made up of EU/EEA Member States, it has no reporting obligation to the European Commission (EC). However, in order to meet its main objective to support and steer European cooperation in HTA, during the bridging period, links to the EC and any relevant committees initiated by the HTA Regulation will be explored (as stated in the proposal, chapter 4.1.13).

### 4. LEGAL BASIS

This Collaboration will operate according to applicable national and EU law.

### 5. EXPECTED OUTCOMES

The JA3-specific Heads of Agencies Group (HOFA), was a vehicle for collaboration within Europe and was responsible for increasing the convergence of European HTA systems, supporting implementation of joint products and facilitating dialogue and an open exchange of information between EU/EEA Member States. As its successor, the HAG will seek to build on this work in line with its objectives in order to prepare for a future EU HTA system, taking the HTA Regulation into account.

### 6. ROLES

As outlined in the *Proposal for the Development of the Heads of Agencies Group* (1.1), this agreement establishes the following roles as required for the functioning of the HAG:

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### (1.1, p.17) **The Heads of Agencies:**

The Heads of Agencies Group shall be an EU/EEA Member State based body composed primarily of representatives from HTA bodies, agencies or departments that, from an organisational point of view, are governmental, public or standalone independent organisations connected to the healthcare system. These organisations should have appropriate HTA expertise and an official mandate in the field covered by the Regulation on HTA. Likewise, they should work in a scientifically independent manner at a national or regional level and should be free of conflict of interest.

An EU/EEA Member State will ideally be represented by an independent HTA agency or department (or more than one, if applicable). In the case of EU/EEA Member States in which such a body is not present, the Member State shall decide by which organisation it would like to be represented in the HAG, considering the criteria outlined above.

In order to have a strong strategic and guiding role in the activities leading up to the EU HTA system, the HAG will include as many EU/EEA Member States as possible. In any case, the participation of each country will be contingent upon the eligibility of the representing organisation. Countries outside the EU/EEA will not be represented in the HAG.

Each organisation will be represented in the HAG by its head of agency or highest-ranking officer of its HTA activities. Individuals who have the capacity to make decisions on behalf of the Head can act as his/her substitute in the group if strictly necessary and for a limited period of time.

All organisations that were part of the HOFA group in the context of EUnetHTA Joint Action 3 will have the opportunity to be initial members of the HAG.

To become a member of the HAG, eligible organisations who are the HTA representatives of their country, can submit an application to the Secretariat. Applications will be reviewed by the Secretariat and the Chair and new memberships will be accepted through a vote among members of the HAG (according to the agreed upon decision process).

### (1.1, p.18) **The Chairs and Vice-Chairs:**

The chairperson is the presiding officer of the HAG. Once appointed, the Chair acts neutrally in the best interest of the HAG as a whole.

In addition to the Chair, two Vice-Chairs should be appointed. The Vice-Chairs would have similar responsibilities to the Chair and would be able to step in to substitute the Chair where necessary.

### (1.1, p.19) **The Secretariat:**

The Secretariat shall facilitate and support the work of the HAG, ensuring coordination, consistency and continuity of the work and activities of the group.

## 7. RIGHTS AND RESPONSIBILITIES OF COLLABORATING PARTIES

Each Party is to actively participate in the activities of the HAG and undertake all reasonable endeavours to perform and fulfil promptly, actively and on time, all its agreed upon responsibilities. Parties are to:

- Promptly notify the Secretariat of any significant problem and delay likely to affect the progress of the Collaboration, and;

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- Inform the other Parties of relevant communication they receive from Third Parties in relation to the activities of the Collaboration.

### 8. ACTING ON BEHALF OF THE COLLABORATION

Each Party will inform the other Parties of any occasion of their representatives acting on behalf of the Collaboration (e.g. when giving presentations, writing communication) for prior decision, coordination and documentation purposes.

In cases when a Party is invited to participate in various projects or other activities “on behalf of the Collaboration”, its role and responsibility as “representative” could include:

- Informing the other Parties of such involvements;
- Providing relevant information to the other Parties on the development of the new project;
- Providing information about the developments within the Collaboration.

Parties cannot express a view and take positions “on behalf of the Collaboration” unless a clear consent of the Parties is sought and received in advance.

A Standard Operating Procedure (SOP) for acting on behalf of the HAG will be developed once the MOU comes into force.

### 9. RIGHT TO DISAGREE WITH JOINT STATEMENTS, OPINIONS AND DOCUMENTS

Each Party can express a different opinion to that of the other Parties, either motivated in writing or orally. This Party can ask to have its opinion published if it concerns a publicly available production from the HAG.

The Parties are not bound to follow the conclusions of any work that is produced jointly or to use any joint work in national settings.

### 10. CONFIDENTIALITY

The Parties will treat information shared within the HAG confidentially, ensuring compliance with national and EU law.

All members of the HAG, any of their representatives or substitutes as well as members of the Secretariat who will coordinate the work of the HAG will be obliged to sign a Non-Disclosure Agreement in order to maintain confidentiality. A template will be developed together with the HAG once the MOU comes into force. The template will require sign-off from all members of the HAG.

Any forms completed by members of the HAG and their representatives will be processed, stored and handled according to the requirements as set out by the EU’s General Data Protection Regulation.

A definition of information to be considered confidential, as well as a complete SOP shall be developed on the subject once the MOU comes into force.

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### 11. INTELLECTUAL PROPERTY RIGHTS

The Parties acknowledge that nothing in this Memorandum of Understanding will affect ownership of any intellectual property rights.

A Party may, a) not use the logo of another Party unless that Party has given its prior approval in writing nor, b) promote any relationship which is beyond the remit or scope of the MOU.

### 12. DECLARING A CONFLICT OF INTEREST

All members of the HAG, any of their representatives or substitutes as well as members of the Secretariat who will coordinate the work of the HAG must complete a Conflict of Interest (COI) self-declaration form. A template will be developed together with the HAG once the MOU comes into force. The template will require sign-off from all members of the HAG.

Any forms completed by members of the HAG and their representatives will be processed, stored and handled according to the requirements as set out by the EU's General Data Protection Regulation.

A complete SOP shall be developed on the subject once the MOU comes into force.

### 13. PROCESSING OF PERSONAL DATA BY THE PARTIES

The Parties will process personal data in compliance with applicable EU and national law on data protection (including authorisations or notification requirements). The Parties may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Collaboration.

### 14. DURATION

This Memorandum of Understanding will become effective when signed by all Parties. The Collaboration under this Memorandum of Understanding will be reviewed every three years from the point of entry.

### 15. TERMINATION AND MODIFICATION

A Party may at any time withdraw from the Collaboration and terminate its involvement in the activities set out in this Memorandum of Understanding without having to communicate the reason for withdrawal. The notice period for such a withdrawal is 30 calendar days.

Notwithstanding the foregoing, it is agreed that any termination of this MOU shall be without prejudice to: (i) the orderly completion of any ongoing collaborative activity; and (ii) any other rights and responsibilities of the Parties accrued prior to the date of termination.

This MOU may be modified by mutual consent of the Parties as expressed in writing.

### 16. FINANCE

As outlined in the *Proposal for the Development of the Heads of Agencies Group* (1.1, p. 21), each Party shall cover its own costs related to the Collaboration.

17. LIABILITY

**Liability of the Parties towards each other**

As regards to any claims or damages arising in connection with the preparation and performance of the activities of the HAG, the following liability provision shall apply:

- No Party shall be responsible to another Party for indirect or consequential loss or damages such as, but not limited to, loss of profits, anticipated savings, opportunity, reputation or goodwill, loss of revenue or loss of contracts.

**Liability towards Third Parties**

Each Party shall be solely liable for any loss, damage or injury to Third Parties resulting from the execution of its assigned tasks in the Collaboration and from its use of knowledge and/or pre-existing know-how.

**This Memorandum of Understanding is designed to complement the *Proposal for the Development of the Heads of Agencies Group (1.1)*. As per the decision by the Joint Action 3 Heads of Agencies Group in their May 2021 meeting (see *JA3 Heads of Agencies Meeting (HOFA) – Minutes from 26 May 2021 (2.3)*), all signatories agree to the principles laid out in the proposal. These relate to elements including but not limited to conflict resolution, reporting and accountability, governance, operation and decision-making and quorum and voting.**

MEMORANDUM OF UNDERSTANDING

IN WITNESS THEREFORE, the Parties hereto have caused this Memorandum of Understanding to be executed as of the date stated below.

FOR

**1. AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS (AEMPS)**

Signature

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MARÍA JESÚS LAMAS DÍAZ

Place (city, country)

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Date

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**2. AGENZIA ITALIANA DEL FARMACO (AIFA)**

Signature

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NICOLA MAGRINI

Place (city, country)

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Date

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MEMORANDUM OF UNDERSTANDING

**3. AGENZIA NAZIONALE PER I SERVIZI SANITARI REGIONALI (AGENAS)**

Signature

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DOMENICO MANTOAN

Place (city, country)

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Date

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**4. AUSTRIAN INSTITUTE FOR HEALTH TECHNOLOGY ASSESSMENT GmbH (AIHTA)**

Signature

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CLAUDIA WILD

Place (city, country)

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Date

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MEMORANDUM OF UNDERSTANDING

**5. AUTORIDADE NACIONAL DO MEDICAMENTO E PRODUTOS DE SAUDE, LP (INFARMED)**

Signature

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RUI DOS SANTOS IVO

Place (city, country)

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Date

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**6. DACHVERBAND DER ÖSTERREICHISCHEN SOZIALVERSICHERUNGSTRÄGER (DVS)**

Signature

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MARTIN BRUNNINGER

Place (city, country)

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Date

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MEMORANDUM OF UNDERSTANDING

**6. DACHVERBAND DER ÖSTERREICHISCHEN SOZIALVERSICHERUNGSTRÄGER (DVSV)**

Signature

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INGRID REISCHL

Place (city, country)

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Date

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**7. FEDERAAL KENNISCENTRUM VOOR DE GEZONDHEIDSZORG – CENTRE FÉDÉRAL D'EXPERTISE DES SOINS DE SANTÉ (KCE)**

Signature

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MARIJKE EYSEN

Place (city, country)

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Date

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MEMORANDUM OF UNDERSTANDING

**8. FOLKEHELSEINSTITUTTET (NIPH)**

Signature

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TRYGVE OTTERSEN

Place (city, country)

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Date

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**9. GEMEINSAMER BUNDESAUSSCHUSS (GBA)**

Signature

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JOSEF HECKEN

Place (city, country)

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Date

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MEMORANDUM OF UNDERSTANDING

**10. HAUTE AUTORITÉ DE SANTÉ (HAS)**

Signature

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DOMINIQUE LE GULUDEC

Place (city, country)

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Date

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**11. HEALTH INFORMATION AND QUALITY AUTHORITY (HIQA)**

Signature

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PHELIM QUINN

Place (city, country)

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Date

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MEMORANDUM OF UNDERSTANDING

**12. LÄÄKEALAN TURVALLISUUS- JA KEHITTÄMISKESKUS (FIMEA)**

Signature

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EIJA PELKONEN

Place (city, country)

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Date

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**13. NATIONAL CENTRE FOR PHARMACOECONOMICS (NCPE)**

Signature

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MICHAEL BARRY

Place (city, country)

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Date

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MEMORANDUM OF UNDERSTANDING

**14. RED ESPAÑOLA DE AGENCIAS DE EVALUACIÓN DE TECNOLOGÍAS SANITARIAS (REDETS)**

Signature

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ROSA MARIA VIVANCO HIDALGO

Place (city, country)

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Date

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**15. REGIONE EMILIA ROMAGNA (RER)**

Signature

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KYRIAKOULA PETROPULACOS

Place (city, country)

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Date

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MEMORANDUM OF UNDERSTANDING

**16. RIJKSINSTITUUT VOOR ZIEKTE- EN INVALIDITEITSVERZEKERING - INSTITUT NATIONAL D'ASSURANCE MALADIE-INVALIDITÉ (RIZIV-INAMI)**

Signature

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BENOIT COLLIN

Place (city, country)

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Date

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**17. STATENS LEGEMIDDELVERK (NOMA)**

Signature

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AUDUN HÅGÅ

Place (city, country)

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Date

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MEMORANDUM OF UNDERSTANDING

**18. STIFTUNG FÜR QUALITÄT UND WIRTSCHAFTLICHKEIT IM GESUNDHEITSWESEN (IQWIG)**

Signature

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JÜRGEN WINDELER

Place (city, country)

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Date

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**19. TANDVÅRDS- OCH LÄKEMEDELSFÖRMÅNSVERKET (TLV)**

Signature

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AGNETA KARLSSON

Place (city, country)

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Date

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MEMORANDUM OF UNDERSTANDING

**20. ZORGINSTITUUT NEDERLAND (ZIN)**

Signature

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TIANA VAN GRINSVEN

Place (city, country)

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Date

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