Privacy Notice for Healthcare Professionals – Early Compassionate Access Program (EAP) for MaaT013

This privacy notice explains how MaaT Pharma processes the personal data of physicians, hospital pharmacists, and other healthcare professionals involved in the Early Compassionate Access Program (EAP) for MaaT013.

It is provided in accordance with the EU General Data Protection Regulation (GDPR), the French Data Protection Act, and CNIL Deliberation n° 2022-106 of 22 September 2022.

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1. Data Controller

MaaT Pharma
70 avenue Tony Garnier, 69007 Lyon, France
Email: dpo@maat-pharma.com

MaaT Pharma is responsible for the processing of personal data relating to healthcare professionals participating in the EAP for MaaT013.

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2. Categories of Personal Data Processed

The following categories of data relating to healthcare professionals may be processed:

Identification and contact details

- surname, first name;
- professional contact information (email, telephone);
- professional address and institution.

Professional qualification and roles

- function (physician, hospital pharmacist, investigator, etc.);
- professional licence number (RPPS, equivalent identifier, or institutional credentials);
- signatures and attestations required for program participation.

Data relating to your professional activity within the program

- information relating to prescriptions, dispensing and administration of MaaT013;
- contributions to data entry in the eCRF;
- pharmacovigilance reporting required under public health legislation;
- involvement in regulatory reporting activities.

No sensitive data relating to the healthcare professional are processed.

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3. Purposes of Processing

Your professional data are processed for the following purposes:

- ensuring the proper functioning of the Early Compassionate Access Program;
- managing medical and pharmaceutical follow-up of MaaT013;
- complying with legal and regulatory obligations relating to pharmacovigilance, traceability, safety and quality;
- maintaining documentation required by the ANSM and regulatory authorities;
- managing access rights to the electronic data capture platform (eCRF);
- communicating with hospitals regarding safety, efficacy and product quality issues;
- preparing regulatory documentation, including for a potential Marketing Authorisation (MA) application.

No automated decision-making is carried out.

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4. Legal Basis

Processing is based on:

- **Article 6(1)(c) GDPR** – compliance with legal and regulatory obligations applicable to MaaT Pharma as marketing authorisation holder (pharmacovigilance, traceability, quality);
- **Article 6(1)(e) GDPR** – processing necessary for reasons of public interest in the area of public health;

- **Article 6(1)(f) GDPR** – MaaT Pharma's legitimate interest in ensuring the safe, compliant and effective conduct of the EAP.

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5. Recipients of Your Data

Only authorised personnel bound by confidentiality obligations may access your data:

Internal and external recipients

- MaaT Pharma personnel involved in EAP coordination, safety monitoring, quality and regulatory activities;
- **Clinigen** (from 1 January 2026): pharmaceutical operator (excluding pharmacovigilance), eCRF management, data management, quality control;
- **Medipha Santé**: responsible for all pharmacovigilance activities in the EAP;
- service providers, consultants, and experts assisting MaaT Pharma in preparing regulatory submissions, including a potential MA dossier;
- subcontractors acting on behalf of the above, under GDPR-compliant contractual obligations.

Regulatory authorities

- **ANSM**;
- the designated **Regional Pharmacovigilance Centre**.

Your data are never shared for commercial or promotional purposes.

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6. International Data Transfers

If any data are transferred outside the European Economic Area (EEA), such transfer is carried out in accordance with Chapter V of the GDPR, using:

- an adequacy decision;
- Standard Contractual Clauses adopted by the European Commission;
- or any other legally required safeguard.

Only data strictly necessary for the concerned activities are transferred.

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7. Data Retention Periods

Retention periods mirror those applicable to EAP regulatory requirements, in accordance with CNIL Deliberation n° 2022-106:

- **Active database:** up to two years after ANSM's approval of the summary of the final synthesis report under Article R.5121-74-6 CSP;
- **Intermediate archive:** for the duration of the compassionate access authorisation and up to **70 years** after the expiration, suspension or withdrawal of the authorisation;
- **Final stage:** deletion or irreversible anonymisation at the end of the retention period.

All retention and archiving are conducted under GDPR-compliant security conditions.

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8. Data Security

MaaT Pharma and its partners implement appropriate technical and organisational measures, including:

- restricted access based on professional role;
- secure and authenticated access to the eCRF;
- confidentiality agreements;
- encrypted communications where appropriate;
- secure hosting environments compliant with applicable standards;
- personnel training and audits.

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9. Your Rights

You may exercise the following rights under the GDPR:

- right of **access** to your data;
- right of **rectification** of inaccurate data;
- right to **restriction** of processing;

- right to **object**, on grounds relating to your particular situation, when processing is based on legitimate interest.

Certain rights may be limited due to regulatory obligations in pharmacovigilance and public health.

You may exercise your rights by contacting the MaaT Pharma Data Protection Officer.

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10. Contact Details

MaaT Pharma – Data Protection Officer (DPO)
70 avenue Tony Garnier, 69007 Lyon, France
Email: **dpo@maat-pharma.com**

You may also lodge a complaint with the French Data Protection Authority (CNIL):
www.cnil.fr