



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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# EMA's API General Terms and Conditions of Use (Terms of Use)

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# Table of Contents

1. Introduction.....	3
2. Terms and conditions of use of EMA APIs.....	3
3. API Key Definitions .....	4
4. Accessing an EMA API.....	5
4.1. Registration .....	5
4.2. Conditions of Use .....	5
4.3. Data Protection .....	6
4.4. EMA API Licence .....	7
4.5. Communications Between EMA and Users.....	7
4.6. Termination, suspension and removal of uploaded content .....	7
5. Using EMA’s Services .....	8
5.1. Copyright and other Intellectual Property Rights .....	8
5.2. Storage of Data .....	8
5.3. Reliance on an EMA API.....	8
5.4. Modifications to Terms .....	9
5.5. Modification, Discontinuation or Termination of an EMA API.....	9
5.6. Miscellaneous .....	9

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# 1. Introduction

An Application Programming Interface ("API") is a technical mechanism or channel, which provides programmatic access to a software service. In that regard, it is intended to enable the exchange of information between two or more applications.

APIs are used to implement interoperability requirements and are a component of a service.

The life cycle of EMA services is governed by customer-oriented IT service management principles and processes.

Key service management processes used by the EMA include:

- Service Design Management supporting the design of new IT services;
- Service Transition Management supporting the implementation and deployment of IT services; and
- Service Operation Management supporting the effective and efficient delivery of IT services.

Please refer to the relevant service documentation available on the EMA website for detailed information on how the above-mentioned processes would apply to an EMA service. These services fall outside the scope of the present document, which is intended to address the Terms and conditions of use of EMA APIs.

In general, the terms and conditions of use of an API service set out the rights and responsibilities between a person or an organisation using a service and the service provider. A person or an organisation using a service must agree to accept and comply with such terms in order to use the service.

## 2. Terms and conditions of use of EMA APIs

These terms and conditions of use ("Terms") govern access to and the use of the Application Programming Interfaces ("APIs") that are developed and operated by EMA. EMA has developed APIs to enable its partners and stakeholders' (such as, but not limited to, national competent authorities, academia and industry) systems to exchange data managed by the European Medicines Regulatory Network (EMRN) and its partners.

Please read these Terms carefully before using an EMA API. Access to and use of an EMA API is subject to prior acceptance of these Terms.

Any reference to "Terms" herein includes also:

- EMA API General Terms and Conditions of Use;
- API Documentation produced in the context of a particular EMA API.

All EMA APIs must refer to this General Terms and Conditions of Use, in addition to any API specific terms of use they may have.

EMA reserves the right at any time to change the terms, conditions, and notices under which the APIs are offered, including but not limited to these Terms.

The Terms are intended to ensure that EMA can implement the appropriate measures, as and when required, to protect its Services. Such measures are also intended to protect the interests of stakeholders. In general, recourse to any extraordinary measures, such as, the discontinuation or termination of an EMA API without prior notice, will be applied as a matter of exception.

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### 3. API Key Definitions

In these Terms, the following definitions shall be used:

**API** – Application programming Interface. The technical mechanism or channel, which provides programmatic access to a (software) **Service**.

**API Documentation** – The documentation, data and information (including specific terms and conditions of use applicable to the particular EMA API and registration rules, if applicable) that EMA provides regarding the use of the EMA **API**.

**API Specification** – Definition of how an EMA API behaves and how the API links with other **APIs**. It explains how the API functions and the results to expect when using the **API**.

**Credentials:** a piece of information that is sent from one computer to another to check that a user is who they claim to be or to allow someone to see information.<sup>1</sup>

**Data** – means any data and content uploaded, posted, transmitted or otherwise made available by **Service Consumer** via the **Services**, including messages, files, comments, profile information and anything else entered or uploaded into the **Service** by a **Service Consumer**.

**Personal Data** – For the purpose of these Terms the definition of Article 4(1) of *Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data*<sup>2</sup> ("GDPR") as well as in Article 3(1) of *Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data*<sup>3</sup> ("EUDPR") applies: "personal data" means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person".

**EMA** – the European Medicines Agency.

**EMA API** – An **API** provided by EMA.

**Service** – The work / activities carried out by EMA. A Service includes the collection of capabilities which are offered and made available to one or more **Service Consumers**. It includes all the supporting resources and infrastructure needed to perform a particular business function or process.

**Service Consumer** – Users of the Service(s) provided by EMA which underpin the API.

**Service Provider** – The entity responsible for providing the IT solutions and/or business services, which underpin the API, to end users and organizations. With regard to **EMA APIs**, EMA is the **Service Provider**.

**Third Party Application** – Any software application, website, or product created or **Service** offered using the **EMA API**.

**Third Party Service Consumer** – Users of the **Service(s)** provided by **Service Consumers** of EMA's **Service(s)**, which underpin **EMA APIs**.

**User** – a natural or legal person or system authorised to use an EMA API and uses an EMA API to access the Services, develop Applications or any other purpose.

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<sup>1</sup> <https://dictionary.cambridge.org/dictionary/english/credential>

<sup>2</sup> Available : <https://eur-lex.europa.eu/eli/reg/2016/679/oj>

<sup>3</sup> Available: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32018R1725>



**Role** – Job function or title which defines an authority level.

**Access privilege or Permission** – An approval of mode of access to a resource such as data entities or systems. Permissions are assigned to roles, which in turn are assigned to users.

**Role-based access control (RBAC)** – An approach to restrict access to resources, to authorised users only.

**Elevated access privileges** – Access privileges not available to all users.

## 4. Accessing an EMA API

EMA shall provide Users with access to an EMA API in accordance with the below provisions. Each EMA API provides an API Specification to facilitate its use and adoption.

### 4.1. Registration

Access to EMA API capabilities will require registration. The decision to provide registration data is entirely optional; however, if you elect not to provide such information you will not be able to access these capabilities.

EMA Account Management<sup>4</sup> is a secure online platform where Users can request and manage access to EMA applications. EMA's Account Management is also the self-registration & access management system for APIs.

Each API Documentation will describe the applicable registration process and explain which User roles have access to which specific functions and data of the relevant API.

### 4.2. Conditions of Use

In using an EMA API, you must always behave in a civil and respectful manner. In addition, when using an EMA API you agree to the following:

- a) You are responsible to maintain the confidentiality of the credentials provided by EMA to access its APIs. EMA will keep your credentials confidential in accordance with its Privacy Policy.
- b) You are responsible for all activity that occurs under your credentials.
- c) You will ensure that any non-public data, classified as confidential or restricted, retrieved via the API with elevated access privileges, will not be accessible to Third Party Service Consumers who have not been granted appropriate access privileges. The data classification mechanism will be specified as metadata, i.e. data classification information provided in additional attributes, or in the API documentation.
- d) You will not transmit any computer worms, viruses, or any code of a destructive nature.
- e) You will not attempt to reverse engineer or otherwise derive source code, secrets or know-how in the Services or portion thereof.
- f) You will not attempt to use an EMA API in a way which:
  - i. exceeds or circumvents restrictions on access and use;
  - ii. exceeds reasonable request volumes;

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<sup>4</sup> <https://register.ema.europa.eu/identityiq/home.html>



- iii. constitutes excessive or abusive usage;
  - iv. fails to comply or is inconsistent with any part of the API's Terms of Service.
- g) You must notify EMA immediately of any breach of security or unauthorised use of your account. This includes any unauthorised access, use, disclosure or destruction of Data. You will work with EMA to immediately correct any security deficiency and will immediately disconnect any intrusions or intruder. In the event of any security deficiency or intrusion involving an EMA API or Data, you will make no public statements regarding such deficiencies or intrusions (e.g. press, blogs, social media, bulletin boards, etc.) without prior written and express permission from EMA in each instance.
- h) You agree to connect to an EMA API in accordance with the instructions laid down in the relevant API Specification.
- i) An EMA API must not be used for any unlawful purpose. You agree to use an EMA API in accordance with all applicable European and international legislation, in particular, but not limited to intellectual property law and data protection law.
- j) You shall refrain from abusive usage of an EMA API and shall not attempt to gain authorised access to, disturb or deactivate an EMA API. This includes but shall not be limited to the potential introduction of viruses, worms, Trojan horses or other forms of malware in an EMA API.
- k) You agree not to collect or harvest any Personal Data, including account names, from an EMA API, nor to use the communication systems provided by an EMA API for any commercial solicitation purposes. You agree to process any Personal Data in accordance with Section 3.3 (Personal data processing by Users).

An EMA API may be used only in accordance with these Terms and cannot be used for unfair commercial purposes.

You may not sell, sublicense, or redistribute content or EMA's software applications or incorporate them (or any portion of them) into another product, without EMA's prior authorisation.

You may not reverse-engineer, decompile, or disassemble the software applications or otherwise attempt to derive the source code (except where expressly permitted by law) or the communications protocol for accessing the Services or EMA's networks. You may not modify, adapt, or create derivative works from the software applications or remove proprietary notices therein.

When using the EMA API you agree to comply with EMA's copyright and limited reproduction notices as shown on the EMA corporate website.<sup>5</sup> In particular, but not limited to, you acknowledge that information and documents made available on the Agency's webpages are public and may be reproduced and/or distributed, totally or in part, irrespective of the means and/or the formats used, for non-commercial and commercial purposes, provided that the Agency is always acknowledged as the source of the material. Such acknowledgement must be included in each copy of the material.

### **4.3. Data Protection**

EMA processes personal data in accordance with [Regulation \(EU\) 2018/1725](#).

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<sup>5</sup> <https://www.ema.europa.eu/en/about-us/legal-notice>



Where registration is required for using a particular EMA API or User's Personal Data are otherwise processed by EMA in the context of providing EMA API relevant information will be provided in specific privacy statements on how your data is processed in relation to the use of the particular EMA API.

In such cases, by using the EMA API you agree that any Personal Data provided by you may be processed by EMA in accordance with the specific privacy statement. EMA's General Privacy Statement is located here: <https://www.ema.europa.eu/en/about-us/legal/privacy-statement> where you will find the privacy statements on specific data processing operations carried out in relation to your use of an EMA API.

### **Personal data processing by Users**

By using an EMA API you might access Personal Data. You may only process such Personal Data in compliance with EU data protection legislation, in particular, Regulation (EU) 2016/679 (GDPR) and Regulation (EU) 2018/1725 (EUDPR); and in accordance the particular data protection policy/statement applicable to the accessed webpage(s)/databases as well.

#### **4.4. EMA API Licence**

Subject to your acceptance and compliance with the Terms, EMA grants you a limited, non-exclusive, non-transferable, non-assignable licence to use the EMA APIs within your own development.

The User shall not distribute or grant an unauthorised third-party access to the API.

#### **4.5. Communications Between EMA and Users**

When in your registration data you have provided your email address and agreed to the following, EMA may contact you for the below purposes:

- a) EMA reserves the right to send electronic mail to notify you in relation to the use of an EMA API. EMA may also implement an automated alert system informing you of changes or additions to an API. EMA reserves the right to disclose information about your usage and demographics for statistical purposes in an aggregated form. It will not reveal your personal identity in connection with the disclosure of such information.
- b) EMA may contact you via e-mail regarding your participation in user surveys, asking for feedback on current APIs or prospective APIs. This information will be used to improve the APIs and better understand EMA's users, and any information EMA obtain in such surveys will not be shared with third parties, except in aggregate form.

#### **4.6. Termination, suspension and removal of uploaded content**

Your use of an EMA API is subject to your ongoing compliance with these Terms. You acknowledge and agree that EMA may terminate and/or suspend your access to any part or feature of an EMA API without prior notice in case you fail to comply with these Terms or any other guidelines and rules as published by EMA.

Failure to comply with these Terms may result in the removal of any content uploaded using an EMA API.

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## 5. Using EMA's Services

You understand that when using an EMA API, you will be exposed to content provided by third parties not under EMA's control from a variety of sources, and that EMA is not responsible for the accuracy, completeness, utility, safety, or the protection of intellectual property rights of or relating to such content.

Please contact the relevant EMA product team for the specific Service Level Objective (SLO) that applies to each API product.

### 5.1. Copyright and other Intellectual Property Rights

All rights concerning an EMA API are the property of EMA and are protected by European Union legislation and international legislation.

An EMA API contains content which may be protected by intellectual property rights and trademark protection belonging to third parties. Unless otherwise authorised under the terms of a separate agreement, users must refrain from engaging in any activities which would be contrary to those rights and must obtain permission for reproduction or use from these third-party right holders.

### 5.2. Storage of Data

The list below describes the key aspects of data storage related to EMA APIs:

- Caching data:

Where relevant, each EMA API will publish details of recommended cache frequency;

- Secure Storage Measures:

All API users are obliged to store EMA Data using (strong) encryption or apply other appropriate data security measures proportional to the sensitivity of data;

- Deletion at Termination:

If EMA terminates your use of an EMA API for any reason, you must permanently delete all Data and any other information that you stored pursuant to your use of the API, except when doing so would cause you to violate any law or obligation imposed by a governmental authority.

### 5.3. Reliance on an EMA API

EMA will occasionally make changes to the EMA APIs, including non-backwards compatible ones and will give notice of these changes. Also, parts of EMA's API may be undocumented, including certain methods, events, and properties. Given that these undocumented aspects of the API may change at any time, you should not rely on these behaviours.

#### **Disclaimer on the provision of EMA APIs**

The Agency's goal is to ensure that an EMA API is functional. If errors are brought to its attention, the Agency will endeavour to correct them.

However, the Agency accepts no responsibility or liability whatsoever (including, but not limited to, any direct or consequential loss or damage that might occur to you and/or any other third party) arising

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out of, or in connection with, the use of an EMA API, which is provided "AS IS" and "AS AVAILABLE" and without any warranty.

#### **5.4. Modifications to Terms**

EMA may, to its discretion, modify these Terms. EMA will post such changes online. EMA recommends that you periodically review the Terms on its website to stay informed of any updates.

If the User does not accept any such changes, the available recourse shall be to stop using EMA APIs. By continuing to use EMA APIs following any such changes, this shall indicate confirmation of acceptance of the change.

#### **5.5. Modification, Discontinuation or Termination of an EMA API**

EMA reserves the right to modify, discontinue or terminate access to an EMA API (including any part or feature, thereof) at any time and without prior notice to the User.

EMA shall not be liable to the User or any third party for any claims of any kind arise from the exercise of EMA's discretion to modify, discontinue or terminate access to or use of an EMA API.

#### **5.6. Miscellaneous**

These Terms, and any additional terms to which you agree when using particular elements of an EMA API (e.g., terms specific to a site within the EMA website or network or relating to the payment of fees for certain API content or services), constitute the entire, exclusive and final statement of the agreement between you and EMA with respect to the subject matter hereof, and govern your use of an EMA API, superseding any prior agreements or negotiations between you and EMA with respect to the subject matter hereof. In the event of any conflict between these Terms of Service and terms of a specific EMA API, these Terms shall govern.

If any provision, herein, is held to be invalid or unenforceable to any extent, the remainder of the Terms shall continue in full force and effect.

These Terms shall be governed by Union law, complemented where necessary by Dutch law.

The courts of Amsterdam, The Netherlands, have exclusive jurisdiction over any dispute related to the provision or use of EMA API.

## **6. Document History**

<b>Version</b>	<b>Who</b>	<b>When</b>	<b>What</b>
1.0	AV	13/07/2020	Initial version
1.1.	AV	18/05/2021	Add introduction section to clarify service management process.
1.2	AV	22/06/2021	Update terms and conditions to highlight exceptionality of extraordinary measures.
1.3	AV	24/07/2024	Updated authentication/authorisation mechanism, referenced EMA's Account Management system as registration platform for APIs, removed reference to regulatory processes.
1.4	AV	29/08/2024	Address comments and recommendations from EMA's legal team.

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