



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication Division

EMA individual experts' stakeholder database: patients and consumers

Frequently asked questions

Background:

The European Medicines Agency ([EMA](#)) collaborates with a large number of patients, consumers and their organisations on aspects such as information on medicines, consultation on product-specific issues and participation in workshops and meetings.

These patient and consumer experts provide the Agency with up-to-date, real life experience of living with a disease or the use of medicines, and in turn they can be directly involved in regulatory discussions on medicines for use in the EU.

Identifying the right person for each of the activities requires the use of a database; therefore EMA is expanding its internal database of stakeholders, which currently contains information on organisations, to also include individuals and their areas of interest across Agency activities.

What is the purpose of the individual experts' stakeholder database?

The database's main purpose is to identify patients and consumers to participate in EMA activities. In addition, those registering will receive information in their area of interest.

By maintaining a database with patients interested in participating in EMA activities representing different indications, EMA hopes to increase further involvement of patients and consumers in its activities, which is consistent with the transparency practices of EMA with respect to its decisions.

How do I register to be in the database?

In order to register to be included in the database, please click [here](#) and fill the application form. You will receive an automatic acknowledgement followed by a confirmation email once validated.



Is this the only way that EMA can identify patients?

No, in fact the Agency's first port of call when looking for patients is via their list of registered [eligible patients](#) and consumers' organisations. However, the increasing demand and diversity of activities requires a broader approach.

Is anyone able to be part of the database?

Yes, patients, carers and consumers are all invited to register in the individual experts' stakeholder database.

Is a background in medicine or regulatory affairs necessary?

Patients and consumers are invited because they can contribute valuable information based on their real-life experiences. A background in medicine or regulatory affairs is not necessary. EMA provides support and educational material to prepare patients and consumers invited to the Agency to participate in an activity.

In what language will the communication and activities be?

All communication and activities organised and arranged by EMA are in English. Unfortunately, there is no possibility for a translator during the activities.

What kinds of activities are patients and consumers involved in at EMA?

There are many ways to be involved at the Agency and we recommend that you consult our [Patients and Consumers pages](#) as well as our [Annual Report](#) on interactions with patients and consumers.

When and how often will I be involved in EMA activities?

It is impossible to indicate when and how often an activity in your area of interest will arise, however EMA strives to involve patients or consumers whenever it would be of added value. Opportunities for involvement are also dependent on the dossiers submitted by developers of medicines.

Is participation in EMA activities paid?

Participation in EMA activities is on a voluntary basis. If the activity involves travelling to EMA offices in Amsterdam, experts receive a travel expense allowance. Further details on the expense allowance will be explained when the activity is discussed.

Which personal information has to be provided?

To be included in the database you will have to provide your name, email address and telephone number so that EMA can contact you if an opportunity arises for you to be involved. It also means EMA can send you targeted information, based on your pre-selected preferences.

In addition, you will have to indicate your citizenship, representation (patients, consumers, carers) and membership/affiliation with patient/consumer organisations or EMA committees or working parties, if any. You will also have to indicate your areas of interest in EMA activities as well as any prior

participation in EMA activities, where applicable. Finally, you are also asked to indicate the disease/condition areas of your interest.

How will your personal data be protected?

Your personal information will be processed and stored in accordance with [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](#). Your information will not be shared with anyone outside of EMA.

For detailed information on how the Agency processes your personal data included in the EMA individual experts' stakeholder database, please read our specific privacy statement which may be found here: [link](#). You may also find this privacy statement on the online application form for registration in the database. By submitting the application form, you declare that you have read and understood the privacy statement, and that you consent to the processing of your personal data as explained in the privacy statement.

Is it possible to update my data?

Everyone included in the database will receive a personalised link enabling them to change their settings and data at any time.

How long will my data be held in the database?

Once included in the database, you will be asked on an annual basis if you wish your details to remain in the database, this is also necessary to ensure current contact details and interests are up to date. If at this time, you advise you wish to 'unsubscribe' then all of your data will be immediately removed. Removal from the database can additionally always be requested at any time by email.

Can I request to be removed from the database?

Yes, you can withdraw from the database at any time.

How will my activities be recorded in the database?

If you are involved in an EMA activity this will be recorded on your page for future reference. When you are removed from the database this data will also be deleted however information regarding your involvement in certain EMA activities may be retained in the records of those particular activities (e.g. list of participants, meeting minutes) in accordance with the retention policy applicable to those documents