



CALL FOR EXPRESSION OF INTEREST

TO SELECT INDUSTRY EXPERTS

TO PARTICIPATE IN TRACK AND TRACE (T&T) INTEROPERABILITY PROJECT

The International Coalition of Regulatory Authorities (ICMRA) is seeking industry experts to participate in its project on interoperability of Track and Trace (T&T) systems for medicines.

ICMRA is a voluntary, executive-level, strategic coordinating, advocacy and leadership coalition of regulatory authorities that intends to provide a global architecture to support enhanced communication, information sharing, crisis response and address regulatory science issues. More information about ICMRA can be found [here](#).

Supply Chain Integrity is a strategic priority for ICMRA and it has focused its attention on T&T systems due to their key role in ensuring integrity of the medicines supply chain.

The project

Production and distribution of medicines are globalized and rapid exchange of information among regulatory authorities is integral to the protection of the supply chain integrity and patient safety. T&T systems could contribute to rapid exchange of information. However, so far these systems have been designed and implemented with a local or regional focus, without consideration as to their interoperability with other such systems.

Building on work already done by the World Health Organization's (WHO) Substandard and Falsified (SF) Medical Products initiative (previously Member States Mechanism), ICMRA collected information on existing and planned T&T systems for medicines around the world. Based on this information it developed recommendations on how existing and planned T&T systems could be better aligned globally, to allow for interoperability. These recommendations have been published on the ICMRA website and can be consulted [here](#).

As a next step in this project, ICMRA is now establishing a **working group** to facilitate implementation of the principles in the recommendations document. Because this work needs expertise from both regulators and industry, ICMRA has decided to launch this call for expression of interest to identify potential experts from the industry with appropriate knowledge in T&T systems. ICMRA is seeking to nominate a maximum of ten industry experts, representing as broad a geographical spread as possible.

The participants in the working group are expected to work towards the following deliverables:

- More detailed guidance on common technical features to enable interoperability of T&T systems
- Capacity building tools for jurisdictions wishing to implement T&T systems
- Solutions/tools for systems to become interoperable, applicable to both new systems and already existing ones.
- Analysis of technical aspects related to interactions between alert systems and T&T systems
- Identification of solutions to overcome barriers to exchange of information between different T&T systems (including e.g. data ownerships and confidentiality issues)

The expected duration of the project is one year. This may be extended, if necessary. The project will be led by one of the regulatory agencies participating in ICMRA, who will report regularly to the ICMRA Executive Committee and plenary.

Any outcome of the project will be adopted by the ICMRA plenary. All outcomes will be made public and published on the ICMRA website.

Terms of engagement of pharmaceutical industry experts

Pharmaceutical industry experts will work with ICMRA on a voluntary basis. Their work and time will not be remunerated or compensated.

The experts will participate in the working group in their personal capacity. They will not be able to represent the interest of any individual company, but can represent trade organisations. Affiliation to trade organisations already working on supply-chain integrity systems would be an advantage.

The experts will commit to maintain confidentiality of the content of draft documents until they are published and of discussions at teleconferences and meetings held in the context of the project.

Requested level of engagement

The working group will meet on a regular basis, typically via tele- or audioconferencing facilities. Group members are expected to carry out preparatory work and provide their technical contribution during meetings for the expected duration of the project (1 year).

Face-to-face meetings of the working group may exceptionally be organised, depending on the need. Experts will participate at their own expense.

Selection process

Elements which ICMRA will take into account for the selection of experts:

- Knowledge of the technological aspects of T&T systems (in particular T&T systems for medicines)
- Experience in implementation of T&T systems (in particular T&T systems for medicines)
- Involvement in trade organisations engaging in supply-chain integrity systems
- Previous experience of working with regulators

ICMRA is seeking a wide geographical spread and this might be considered in the selection process. The expression of interest should include

- completed form provided in annex 1
- CV that describes how the candidate's experience matches the selection elements described above
- Declaration of honour in annex 2

Expressions of interest received by the deadline will be evaluated and a decision will be taken at an ICMRA plenary meeting.

All experts having expressed interest will be informed of the outcome.

Submission of the expression of interest

Expressions of interest should be sent by email only to emainternational@ema.europa.eu by **15th January 2019**.

Annex 1: Expression of interest¹

I am interested in participating in the International Coalition of Medicines Regulatory Authority (ICMRA) Working Group on Track & Trace (Supply Chain Integrity)

| Contact details | |
|--|--|
| Name | |
| Address | |
| Telephone number (including country code) | |
| Email address | |
| Company | |
| Are you a member of a trade organisation engaged in supply-chain integrity? If yes, please provide name and address of the trade association (including website) | |

All fields must be completed

¹ Please compile and send the scanned copy to emainternational@ema.europa.eu by **[Date TBC]**, together with the signed declaration of honour (annex 2) and a recent CV

Annex 2: Declaration of honour

I, the undersigned, hereby declare:

- I commit and I have the capacity and available time to work with ICMRA as per the requirements of the call for expression of interest
- I commit to work with the International Coalition of Medicine Regulatory Authorities in the best interest of public health, and to not pursue any commercial interest in this work, neither in my interest or that of the company(ies) I work for
- I commit to maintain confidentiality of the content of draft documents until they are published and of discussions at teleconferences and meetings held in the context of the Track and Trace Interoperability project
- The information in my Curriculum Vitae is true and accurate, to my best knowledge.

Name, date and signature²

² Please sign and send the scanned copy with annex 1 to emainternational@ema.europa.eu