

# MEMORANDUM OF UNDERSTANDING

BETWEEN



**AIFA**

*Italian Medicines Agency*

and

**EUPATI**

*European Patients' Academy on Therapeutic Innovation*

## **1. PARTIES**

### **AIFA**

The **Italian Medicines Agency** (hereinafter AIFA), with registered office in Rome, Via del Tritone no.181, 00187, Italy, VAT registration Number : 08703841000 duty represented by Prof. Luca Pani, Director general.

AIFA is the national authority responsible for medicines regulation in Italy. It is a public body operating autonomously, transparently and according to cost-effectiveness criteria, under the direction of the Ministry of Health and under the vigilance of the Ministry of Health and the Ministry of Economy.

### **EUPATI**

The "**European Patients' Academy on Therapeutic Innovation**" (hereinafter EUPATI ), with legal address: 145, route de Thionville, L-2611 Luxembourg, Reg-Number: F 448 duty represented by Dr.Ingrid Klingmann on behalf of the EUPATI Executive Committee.

EUPATI in an Innovative Medicines Initiative-sponsored project, initiated and led by major umbrella patient organizations, represented by its Executive Committee, is supported by the European Federation of Pharmaceutical Industry Associations (EFPIA) and run by a strong multi-stakeholder Consortium.

EUPATI will provide scientifically reliable, objective, comprehensive information to patients on the research and development process of medicines.

## **2. PURPOSE OF MOU**

In order to promote and facilitate the participation of the patients and citizens as partners in all aspects of learning about the medicines development pathway and usage processes, AIFA and EUPATI have agreed to enter into this MOU on patients' empowerment and education with the scope to build competencies and expertise.

## 2.1 Due TO:

The mission of AIFA is to promote good health through medicines and to meet patients' needs by supporting innovative science.

The mission of EUPATI is to develop and disseminate objective, credible, correct and up-to-date public knowledge about medicines R&D and to raise awareness about the benefits of patients partnering in medicines development.

Patients are, as regulators and industry, at the heart of every regulatory process and decision.

Patients seem to be raising their voices in more and more settings that used to be the general purview of regulators and industry.

That involvement has raised the need to explain to patients exactly how that process works, the standards have to be improved and should consider regulatory aspects.

## 2.2 This MOU sets out:

In future, the participation of the patients in the regulatory decisions is seen as an important issue. While AIFA is intending to increasingly involve patients into its regulatory processes it can be difficult to find knowledgeable patients who can fulfil this role.

AIFA and EUPATI cooperation could get a solid buster for promoting an educational process in patients and/or their family members in regulatory science and processes.

The collaboration between EUPATI and AIFA:

- could increase the potential "work-force" in such an educational process
- could increase the public awareness of the importance to include the patients' perspective into the institutional decision making process.

## **3. RESPONSABILITIES**

All agreements herein are subject to, and will be carried out in compliance with, all applicable laws, regulations and other legal requirements of both parties.

### *3.1 AIFA*

AIFA will offer to support potential future EUPATI expert training courses or EUPATI's educational meetings, with its knowledge in the field of medicines e.g. through contributing to the faculty as well as offering free course venue and catering at the AIFA Headquarter.

AIFA will efficiently contribute to the development of the concept and activities for enhanced patient education in regulatory science and processes in Italy.

Since so far none of the Regulatory Authorities in “EUPATI countries” have a direct involvement, in their respective countries, with the local EUPATI representatives (NLT and ENP), AIFA with its collaboration with NLT, and later ENP in Italy, will represent a “role-model” on how to interact with local EUPATI National Platform, its representatives and initiatives.

To concretely develop such a model of collaboration, AIFA could become an official member of the “Italian ENP Management Board” contributing with its experience and territorial competence to the development of the education of patients on regulatory science and processes about human medical products.

AIFA is willing to set up dedicated procedures for this project according to the project needs in collaboration with EUPATI.

### *3.2 EUPATI*

EUPATI, with its international network and environment, represents the ideal tool for speeding up the patients organizations' and lay public's involvement in the strategic decision-making process of Regulatory Authorities.

EUPATI, which has its own Regulatory Advisory Board consisting of representatives from BfArM-Germany, SwissMedic-Switzerland, MHRA-UK and EMA-EU, could be extremely useful for homogenizing the relations between Patient Organisations and Regulatory Agencies of EU member states across Europe.

EUPATI will raise awareness about the benefits of patients partnering in medicines development, will contribute to increase the number of patients expert in R&D and thus improve the capacity of

competent patients to correctly inform the Institutions about patients' perspective for the purpose of the decision making process.

EUPATI foresees to reach out to three audiences:

1. Expert level:

Patient Experts, EUPATI Ambassadors, and Patient Journalists, trained within the EUPATI Certificate Training Programme, based on an academic modular structure.

EUPATI will select 100 patients for such a Certificate Training Programme which are expected to complete the courses.

2. Education Level:

Advocacy Leaders from Patient Organisations, provided with the EUPATI "Toolbox" including cutting edge educational material for patient advocates, including print material, slide shows for face-to-face presentation, Internet-based "eLearning" courses, webinars and videos, complemented by face-to-face events. 12.000 patient representatives are expected to use the Toolbox.

3. Information level:

Patients & health-interested public, served by the EUPATI Internet Library on therapeutic innovation, explaining, e.g. specific aspects of the development process of medicines and related products (medical devices, combination products etc.) for patients and consumers with low (health) literacy. It is envisaged that this will reach 100.000 individuals.

#### **4. TOPIC OF EUPATI TRAINING COURSES**

Discovery of Medicines & Planning of Medicine Development

Non clinical testing and pharmaceutical development

Exploratory and confirmatory Clinical Development

Clinical Trials

Regulatory Affairs, Medicinal product safety, Pharmacovigilance and Pharmacoepidemiology

HTA principles and practices

## 5. CREDITS

Every result of the joint projects will be used in coordination by the parties, recognising the specific role played in the activity by the other party.

## 6. AIFA-EUPATI COOPERATION GOALS

AIFA and EUPATI will share the sources of educational materials (what is already available in Italy and what EUPATI can provide through its channels) and will potentiate the effectiveness of the educational process for patients and citizens.

Under the collaboration umbrella AIFA-EUPATI, it will be possible to develop local projects (e.g. “Empowerment dei pazienti e decision making” currently in preparation by the AIFA colleagues and still to be shared and jointly discussed with the Italian NLT) for the empowerment of patients to express their needs with the necessary competence in regard to the regulation decision.

AIFA and EUPATI (through its National Liaison Team and EUPATI National Platform) are willing to cooperate in order to organize a 12 month Training Course in Italian language to be held in Italy for Patients and Patient Representatives on the Medicines Research & Development Process, under the leadership of AIFA.

Such a 12 month training course in Italian language will be organized by AIFA on the basis of the available educational material produced by EUPATI. In fact AIFA will have the possibility to use the EUPATI informatics platform for the foreseen e-learning part of the course (providing the translation in Italian language of the lessons’ contents) as well as AIFA will have the possibility to use all the educational material available on the EUPATI platform and web site.

The frontal lessons foreseen also for such an Italian Training Course will be delivered by experts from AIFA or EUPATI or Academia, duly selected by an *ad hoc* created AIFA-EUPATI Selection Panel under the guidance of the AIFA-EUPATI Executive Committee which, through an AIFA-

EUPATI Operational Committee will be responsible for the implementation of the AIFA-EUPATI Training Course in Italian language as well as for the monitoring of the implementation progresses.

The teaching methodology of the training modules of the Training Course in Italian language will rely on the EUPATI e-learning and face-to-face training sessions already available in English language. This course in Italian language will use the educational material produced by EUPATI (after assessment of the contents) that will be translate into Italian language.

## **7. COMMUNICATION**

An ideal timing for announcing the AIFA-EUPATI collaboration will be in September/October 2014. AIFA and EUPATI will communicate the cooperation through

- the media
- the web site
- the newsletters and social network
- conferences and communications plan finalized.

## **8. PROJECT'S FOLLOW UP**

AIFA and EUPATI will establish a procedure in order to follow up the project outcomes.

## **9. DURATION**

The collaboration between AIFA and EUPATI is aimed to go beyond the five year horizon of the official duration of the EUPATI project; such a collaboration is expected to translate in an education system in progress for citizen and/or their relatives, coordinated by the EUPATI National Platform (ENP) in collaboration with AIFA and supported by local financing strategies managed by AIFA for the prolonged sustainability of such an advanced educational system.

## **10. TERMS OF COOPERATION**

The present MoU, as a mere expression of the intent between the parties to cooperate, shall not be considered legally binding and enforceable on either Party.

This MOU in no way restricts either of the Parties from participating in any activity with other public or private agencies, organizations or individuals.

The agreement between the Parties should be considered in terms of mutual assistance: as such, no fee will be requested for the duties agreed by the Parties except when the parties agree differently. Nothing in this MOU authorizes or is intended to obligate the Parties to expend, exchange, or reimburse funds, services, or supplies, or transfer or receive anything of value.

## **9. CONCLUSIONS**

The collaboration between AIFA and EUPATI, through the increase of the public awareness of the importance of the presence of patients and/or their relatives within institutional bodies, will promote and facilitate the access of Italian patients and citizens to certified national and international training courses, education and information on the regulatory science and research processes about human medical products.

AIFA, in collaboration with the Italian EUPATI National Platform, will support the continuity and the consolidation of such a patients' educational system, initially promoted by EUPATI, by providing faculties and expertise provision, for setting up an AIFA-EUPATI Training Course in Italian language on the Medicines Research & Development Process, as well as further local courses in research & development process of medicines and regulatory environment which will continuously increase the level of awareness and competence of Italian patients and citizen.

- **ATTACHMENT : Information on EUPATI Project**



This MOU is signed in Rome, Italy, on July the 3<sup>rd</sup> 2014, in four copies in English.

For and on behalf of **AIFA**:

**Prof. Luca Pani**

General Director AIFA

Signature: \_\_\_\_\_



For and on behalf of the **EUPATI** Executive Committee :

**Dr. Ingrid Klingmann**

EUPATI Work Package 2 Chair

Signature: \_\_\_\_\_



Date: .....

03 July, 2014