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Good Communication Practices between the public and private sector

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LIST OF ACRONYMS:

ABPI	Association of the British Pharmaceutical Industry
ACS	Anti-counterfeiting Stakeholders' Group
AIFA	*Agenzia Italiana del Farmaco* (Italian Medicines Agency)
BAEPD	British Association of European Pharmaceutical Distributors
BAPW	British Association of Pharmaceutical Wholesalers
BGMA	British Generic Manufacturers Association
CoE	Council of Europe
DRA	Drug Regulatory Authority
EDQM	European Directorate for the Quality of Medicines and Healthcare
EMEA	European Medicines Agency
EU	European Union
GCP	Good Communication Practice
GPhC	General Pharmaceutical Council
HMRC	HM Revenue and Customs
IP	Intellectual Property
IPR	Intellectual Property Rights
MHRA	Medicines and Healthcare products Regulatory Agency
MoU	Memorandum of Understanding
NAS	*Nuclei Antisofisticazioni e Sanità* (Police force on health matters)
PFIPC	Permanent Forum for International Pharmaceutical Crime
PIC/s	Pharmaceutical Inspection Co-operation Scheme
PSI	Pharmaceutical Security Institute
RAS	Rapid Alert System
SOCA	Serious and Organized Crimes Agency
SPOC	Single Points of Contact
UK	United Kingdom
UKBF	United Kingdom Border Force
UNICRI	United Nations Interregional Crime and Justice Research Institute

1. INTRODUCTION

Counterfeit medicines are a multifaceted problem. The research UNICRI conducted during the SAVEmed project, and that is presented in deliverables D 7.1 and D 7.2[1], clearly highlights that several factors have to be taken into account when planning and implementing a strategy aimed at countering this phenomenon. The same deliverables present how the involvement of organized crime accelerated the evolution of the problem, rendering counterfeit medicines a veritable mass production and distribution industry.

Some elements of these researches have to be particularly highlighted for the purpose of this report, as they show the complexity reached by counterfeit medicines today and how the response to this problem needs to bring together several stakeholders from the public and private sector.

First of all, counterfeit medicines are present all around the globe in both the so-called "developing" and "developed" countries. It is a global problem and no country in the world is completely free from it. Furthermore, the interviews that UNICRI conducted in 15 EU Member States as part of the process leading to the preparation and finalization of deliverables D 7.1 and D 7.2, highlighted that a clear distinction has to be made with reference to the legal and illegal supply chains.

With the term "legal supply chain" we intend the distribution system that passes through the delivery system established by the national regulatory frameworks respecting the distribution licenses and agreements in place between manufacturers, distributors and pharmacies. With the term "illegal supply chain" we intend the distribution mechanism that happens outside of the approved and regulated channels of distribution, as in the case of medicines illegally sold via the Internet or in the case of diversion.

[1] Deliverable D 7.1 is dedicated to the analysis of the strategies implemented by organized crime for the production and trade of counterfeit medicines while deliverable D 7.2 is dedicated to researching the issue of counterfeit medicines online. Both deliverables are available for download in UNICRI website.

The legal supply chain in the various EU countries is usually highly regulated by the respective Drug Regulatory Authorities (DRAs) with a series of controls and safety procedures in place. This limits the possibilities that counterfeit medicines enter the market. However, and notwithstanding these controls, there have been cases where fake pharmaceuticals found a breach in the system and were sold by regular pharmacies or have been found in hospitals. One of the reasons that may facilitate the entry of counterfeit medicines into the legal supply chain is its complexity, which has been extensively presented in deliverable D 7.1. Suffice to say in this report that several actors participate at different stages to the production and distribution systems and that clear regulation and legislation defining their roles and responsibilities is still not in place. The recent EU "Falsified Medicines" Directive (2011/62/EU) has, however, changed the situation and started a crucial improvement in the harmonization of the regulatory process across EU countries that will fully unfold its results in the next years.

The illegal supply chain, on the other hand, teams with counterfeit medicines. The research UNICRI conducted under deliverable D 7.2 confirmed that criminals are exploiting every possibility they have to reach consumers with minimum risks. As presented in the mentioned deliverable, the huge spread of the Internet as a marketplace has allowed counterfeiters to offer their products enjoying the high degree of anonymity that is usually granted by this mean of communication. As a consequence, even in those countries where Internet sales of medicines are allowed and controlled – as in the United Kingdom – it is very easy to find counterfeit medicines sold over the Internet and pretending to be genuine products, creating a serious risk for the public. Attracted by lower prices or by the possibility to obtain a medical product without a prescription, several consumers fall prey of online criminals offering counterfeit medicines online – usually via a fake online pharmacy pretending to be an authorized online seller and/or via spam messages flooding citizens' mail inboxes.

Along the same lines goes a recent tendency registered in several EU Member States, where national DRAs faced cases in which food supplements sold in "natural" or "sexy" shops were in reality masking an active pharmaceutical ingredient. The majority of the

DRAs in the EU do not have a direct power of inspection with regards to foodstuff, and criminals have used this method to bypass the more stringent regulations and controls that are in place in the field of medicines if compared to those on foodstuff. The risk posed by these products is serious and some DRAs in Europe are starting to look for ways in which they can intervene to protect consumers.

Both in the case of online sales and in the case of food supplements, it is very interesting to point out how criminals have been able to rapidly adapt to emerging technologies and to new opportunities, developing market strategies and distribution practices in a very fast and effective way. This demonstrates the operational capacity of to create a new challenge for law enforcers, regulators and legitimate producers.

Finally, one element must be stressed at the end of this introductory part. The entire production and distribution process of counterfeit medicines is very often managed – at a certain stage – by organized criminals and frequently by transnational organized crime. This element is the result of UNICRI research in this field and is also presented in the outcomes of the reports at the core of deliverables D 7.1 and D 7.2. This factor adds a criminal element to the complexity of the problem, which clearly presents itself not only as a public health issue and surely not just as an IPRs issue.

Given the complexity of the counterfeit medicines phenomenon, and in view of supporting the preparation of an appropriate response which takes into consideration its multifaceted nature, UNICRI implemented deliverable D 7.3, which is aimed at assessing ways to improve public-private cooperation in this field. In particular, the deliverable researched and evaluated the possibility of setting up an anti-counterfeiting stakeholders' group (ACS) to support the development and establishment of increased cooperation practices between the pubic and the private sector in the fight against counterfeit medicines.

2. Methodology

The approach followed by UNICRI for the implementation of deliverable D 7.3 has been both proactive and reactive, being able to adapt to the existing scenarios and re-think the strategy to overcome obstacles and problems of cooperation.

Since the very beginning, UNICRI identified the scope and aim of the Good Communication Practice (GCP) and the ways in which its possible concrete application had to be piloted. In this regard, it is useful to highlight how the SAVEmed project was proposing two different elements within the same deliverable.

The starting point is the actual creation of the Good Communication Practice, aimed at guiding Governments willing to improve the fight against counterfeit medicines by establishing a cooperation mechanism between the public and private sector. The second element is the test of the GCP, in order to assess its functioning and evaluate its application and effectiveness.

There are several reasons urging Member States to step up their anti-counterfeiting strategies and create a solid alliance with the private sector. The recognition of these reasons constitutes the pillar upon which the entire creation and testing of the Good Communication Practice is based.

First of all, and as we have mentioned in the introduction to this deliverable, counterfeit medicines call for a collective response and an increase in cooperation among the various stakeholders holding knowledge and expertise which is useful to counter their production, trade and diffusion. This cooperation needs first to be increased between public authorities and then to be extended to private entities.

The second element is the need for creating a real difficulty for criminals involved in this activity. An increase in communication and cooperation is a powerful step to prevent the perpetration of this crime, overcoming problems created by lack of coordination between stakeholders and the existence of loopholes in their respective competences.

In this regard, involving the private sector in the anti-counterfeiting strategy is a fundamental move which has the potential to create a win-win situation. Producers are essential for the identification of suspected counterfeit products seized or intercepted by law enforcers, but limiting their role to this element is surely not in line with the contribution they can bring to the fight against counterfeit medicines. The private sector has specialized anti-counterfeiting departments which are very active in following the activities of counterfeiters and collect evidence on their operations. They possess a remarkable knowledge that needs to be shared with law enforcers. They also represent the best option for law enforcers when they need to receive information very quickly in order to initiate or to properly follow a case of counterfeit medicines. On the other hand, if a cooperation mechanism is in place, the private sector has the possibility to stress with the public authorities the importance of concentrating efforts in particular areas of work or on the need to rapidly respond to information they collected on new suspected cases.

This is the basis justifying the need to establish and improve cooperation and communication at the national and international level between the public and private sector on counterfeit medicines. UNICRI's action started by researching the experiences already existing in this field, with the aim of acquiring knowledge and preparing a preliminary draft containing the most important topics to be included in the Good Communication Practice.

Following the same methodology that provided excellent results in the other deliverables managed by UNICRI, we decided to share the preliminary draft and its findings with a group of experts, in view of obtaining suggestions and reinforce the channels of cooperation needed to create and test the Good Communication Practice.

The preliminary drafting of the GCP was, therefore, conducted in parallel with the identification of the three countries participating in the pilot, following the scheme adopted in the SAVEmed description of work. This latter phase represented one of the most problematic moments in the implementation of the entire deliverable, since Germany and Poland (two of the three countries identified to participate in the pilot)

refused to cooperate. UNICRI quickly adapted its strategy and identified two countries with a noticeable experience in the field of public-private cooperation against counterfeit medicines which could represent an added value for the deliverable. These countries were Italy and the United Kingdom. The third country to be involved, Romania, was identified since the very beginning and immediately agreed to cooperate.

During a first roundtable meeting organized in Turin to discuss the approach to the GCP and strengthen the cooperation, it was immediately evident that the mix created by the three participating countries in the pilot (with two countries owning a noticeable experience in the field and the third one willing to put words into practice) contained a very high potential that could lead to a result of the deliverable surpassing initial expectations. We understood since the very beginning that this deliverable had not only the potential to create and pilot the GCP but to permanently establish an anti-counterfeiting stakeholders' group against counterfeit medicines in Romania, following the example of what had already been achieved in Italy and the United Kingdom.

It was for this reason that UNICRI decided to structure the pilot in two different and parallel phases: an observation phase - focused on analyzing the establishment and functioning of the cooperation mechanisms in Italy and in the United Kingdom; and a concrete phase - aimed at implementing all necessary efforts to pilot the effectiveness of established GCPs and test the possible replication of these mechanisms in Romania, thus leading to the establishment of an anti-counterfeiting stakeholders group in this country dedicated to the fight against counterfeit medicines.

The main contents of the GCP, the subdivision of work among the three participating countries and the timetable for the way forward in each participating countries, were agreed during a second roundtable held in Turin. This allowed UNICRI to rely on a shared approach aimed at: monitoring the work of existing GCPs in Italy and the UK; collect information and input for the structuring of the new GCP in Romania; plan the implementation of the GCP in Romania.

Both Italy and the United Kingdom presented their model of GCP during the roundtable, showing their creation process, structuring, problems encountered, and functioning in practice. Given the similarity of the respective legislative frameworks, Romania decided to preliminarily follow the model of the Italian experience. A focal point was identified within the Romanian Public Ministry, actually in charge of the fight against counterfeiting at large. During a mission that UNICRI conducted in Romania in June 2013, the Romanian focal point confirmed the advancement of work and that several National Authorities together with the private sector expressed their interest in participating to the establishment of an anti-counterfeiting stakeholders group against counterfeit medicines.

The following chapters will describe the two phases into which Deliverable 7.3 was divided: the observation phase on the description of the creation and functioning of the GCP systems in place in Italy and in the UK; and the practical phase aimed at creating a model of GCP applicable in every country with a concrete test phase in Romania.

3. Pilot phase

Both the Italian and British cooperation mechanisms were influenced by the Single Points of Contact model developed by the Council of Europe. For this reason it is interesting to present its creation and evolution.

3.1 A basis for cooperation on counterfeit medicines set up at the European level: the SPOC system of the Council of Europe

- The Committee of Experts of the Council of Europe

In 2008, the "Committee of Experts in minimizing public health risks posed by counterfeiting of medical products and related crimes" replaced the former "Ad hoc

group on Counterfeit Medicines" of the Council of Europe (CoE) that was established in 2003.

The "Ad hoc group" was actually entrusted with a comprehensive programme of work focused on the protection of public health and the enhancement of possibilities for co-operation between Member States and other stakeholders concerning counterfeit medicines and different pharmaceutical crimes.[2] The approach and the composition of the "Ad hoc group" were multisectorial, due to the nature of the problem.

In 2004, the "Ad hoc group" examined a series of possible models to be implemented in order to improve risk management procedures in place across the several bodies and stakeholders involved in the fight against counterfeit medicines, both in the public and private sector, at the national level. At the same time, the group considered measures to enhance the cooperation between the Member States, in particular by implementing a system of Single Points of Contact (SPOC) in the various countries that could receive inputs and promptly react in case of need. The improvement of information exchange and the adaptation of rapid alert systems to counterfeit medicines were also at the core of the "Ad hoc group" activity.[3]

After a series of conferences held between 2006 and 2007, the "Ad hoc group" translated all the outputs/conclusions into a strategy aimed at developing practical measures and tools for enhancing the response implemented by public and private stakeholders against counterfeit medicines, also in view of improving their cooperation. These measures, which were actually responding to European regional needs, could have in principle applicability also beyond Europe.

- The Single Points of Contact

[2] AIFA, EDQM, (2011), Counterfeit Medicines. Facts and practical advice, p.72
[3] Ibid., p.73

"Effective and efficient action against the counterfeiting of medical products is based on several pillars: adequate drug regulatory (legal) framework, sufficient capacity for investigation and enforcement, and close collaboration among stakeholders including the private sector (the pharmaceutical industry)"[4]. These elements were at the core of the Council of Europe strategic view against counterfeit medicines and led to the creation of the SPOCs network

The model for a network of SPOCs was developed by the aforementioned "Ad hoc group" of the CoE and was adopted for the first time in 2007. From a practical perspective, the established model foresees the existence of a network of entities responsible for receiving and managing notifications regarding medical products suspected of being counterfeited. Drug Regulatory Authorities, customs administrations, police forces and judicial authorities are usually among the stakeholders involved in the network at the national level. The importance of co-operation with the private sector, industries, health professionals and other stakeholders is also recognized.

The model developed by the CoE clearly responds to the need of enhancing multi-sectorial cooperation in a field of activity that may greatly benefit from the support and contribution of a variety of actors from the public and private sectors, both at national and international levels. This recognition is the basis for establishing the concept of the SPOCs networks both at local and global level. At the same time, it plays a pivotal role in exhorting countries to verify the existence of similar systems in their legal/administrative framework and assess their effectiveness, in view of harmonizing the possible implementation of similar networks. The existence of a model aimed at guiding countries in this respect and harmonizing the functioning of the network should also facilitate the work of those member states willing to do a significant step forward in the fight against counterfeit medicines.

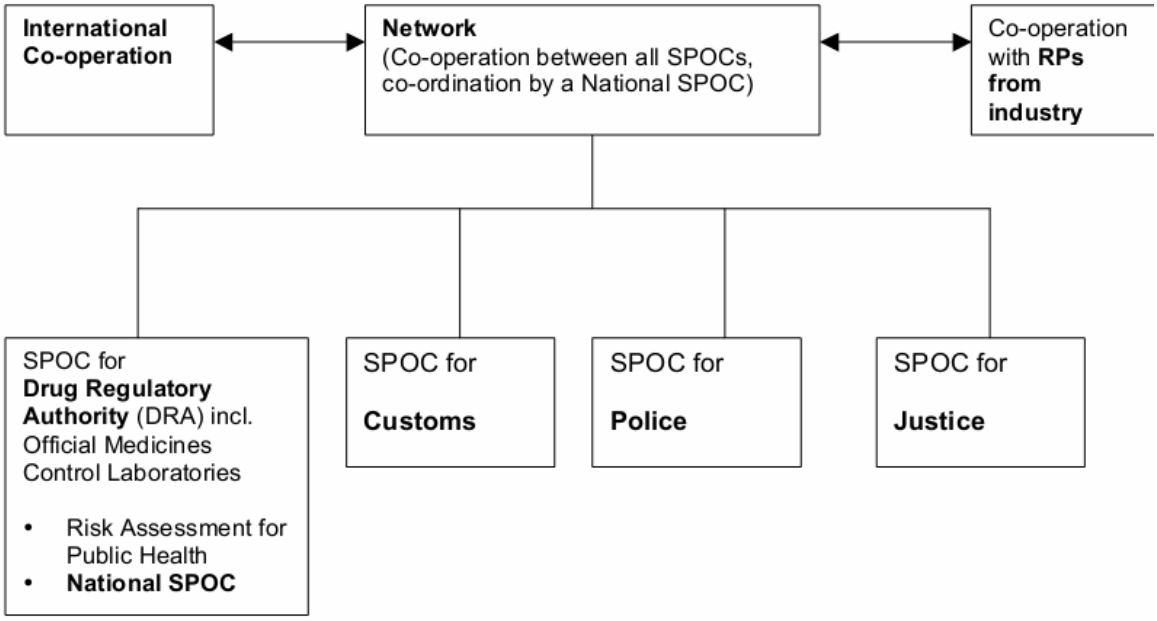
With regards to the structure of the network, the SPOCs and the networks have to be linked to each other constantly, also across Member States. It is clear that a national

[4] Ibid., p.78

network should be set up by and between the main national authorities that have a competence on pharmaceutical crimes. As mentioned before, for most countries the relevant authorities involved are the Drug Regulatory Authorities, police forces, customs administrations and judicial authorities.

During the evolution and practical implementation of the system, the majority of the countries decided to locate the National SPOC within their DRA, while very often also the Official Medicines Control Laboratories have been identified as important partners to be involved in the network activities on a regular basis.

We present below a schematic representation of the SPOCs network[5]:



Source: CoE, Ad hoc group on counterfeit medicines (EDQM)

According to a document released by the CoE in 2007[6], after a series of consultations and meetings, the following were the main activities and objectives envisaged for the national SPOCs networks:

[5] RPs in the graphic indicates the Responsible Persons.
[6] Full document available at www.edqm.eu

- Organization of regular and ad hoc meetings and establishment of a secretariat. Collection and storing of all relevant information in a structured secure database at the level of the SPOC and the network. The network has to use a Rapid Alert Form[7] if necessary and has to create procedures for handling routine pharmaceutical crime signals and set up online training […];
- Creation by the network of procedures for handling routine pharmaceutical crime signals and organization of online trainings by means of - for example - a secure website;
- Preparation by the network of an annual report reflecting all data collected in relation with pharmaceutical crimes and presenting the identification of new trends, initiatives taken for improving legislation, training programmes initiated for the different partners and awareness raising activities;
- Updating by the network of its references at international level and setting up of procedures for co-operation, information exchange, data collection and data management;
- Notification by the stakeholders to the Central Reporting Point of the Drug Regulatory Authorities of any signal received. The Central Reporting Point informs the network if necessary.

More in detail, the terms of reference of a National SPOC within a network should be:

- Having a broad knowledge on medicinal products;
- Being experienced in enforcement in the area of pharmaceutical crime (including field investigation);
- Having a good knowledge of medicines legislation and Intellectual Property Rights (IPRs);
- Having a basic knowledge in criminal law and investigation.

In general, all SPOCs should have the following tasks and competencies:

[7] Reference is made to the RAS system operated by EMEA and PIC/s. On the basis of the existing RAS form, the Ad hoc Group developed a RAS form for specifically exchanging information on counterfeit medicines. Form available at: http://www.coe.int/t/e/social_cohesion/soc-sp/Notification E.doc

1. The SPOC represents the co-operation partner and the contact point within the network;
2. The SPOC manages incoming and outgoing information and – if required – reports a case to other national SPOCs on a need to know basis;
3. The SPOC handles the information flow in accordance with the applicable legislation on data protection. Confidential information - such as patient names and/or names of notifiers - should not be included;
4. The SPOC develops and applies a model procedure for managing cases of counterfeit medicines and pharmaceutical crime within his/her authority;
5. The DRA SPOC co-ordinates the risk assessment related to a pharmaceutical crime signal. The signal has to be identified, analyzed, evaluated and treated accordingly. The risk management procedure has to be continuously reviewed and improved. In any case, the protection of public health has the priority;
6. The operational SPOC takes the lead for the purpose of conducting investigation when appropriate;
7. The SPOC may set up a Pharmaceutical Crime Unit consisting of an operation and an intelligence section.

Each SPOC has the competence of giving detailed information to other SPOCs in the international and national networks. For what concerns the information flow, it is important to differentiate between: a) information (analyzed and interpreted data) and b) evidence (information being relevant for proceedings and which may be used in court). Only information should be exchanged between SPOCs and between countries through the SPOCs system, ensuring respect of privacy laws and legal procedures. However, no legal procedure should prevent fast information exchange in life threatening situations.

A SPOC needs not necessarily to be a single person, but may also be an entity, such as a group or a department within an agency. In the case in which the SPOC consists of several persons, only one e-mail address and one phone/fax number needs to be

indicated, in order to ensure precise contact information and to avoid unclear responsibilities.

3.2 The National models followed during the pilot

This part of the report is aimed at presenting the creation and functioning of the Anti-Counterfeiting Stakeholders' (ACS) groups which have been established in the UK and in Italy. They have been both identified[8] as existing GCPs between the public and private sector in countering the phenomenon of counterfeit medicines and as models to be examined and followed during the observation phase of the pilot. The information gathering was made possible thanks to the cooperation of the UK Medicines and Healthcare products Regulatory Agency (MHRA), the Pharmaceutical Security Institute (PSI), and the Italian Medicines Agency (AIFA). Thanks to the excellent collaboration that UNICRI established with these stakeholders, who provided an in-depth description of the existing ACS group working in this field, the following issues have been analyzed and will be presented in this paper, highlighting the differences and similarities which exist in the two systems currently in place in the UK and Italy:

- The main reasons behind the creation of the mechanism and the preliminary steps for its establishment;
- The functioning of the mechanism;
- Which are the participating stakeholders, their roles and responsibilities;
- How the information flow is working.

This phase constituted a fundamental element in view of facilitating and guiding the practical part of the pilot implemented in cooperation with the Romanian National Authorities and aimed at setting up an ACS in this country

3.2.1 Italy

[8] As agreed during the roundtable dedicated to this subject that UNICRI organized in March 2012 in Turin within the framework of the SAVEmed project

As reported by the Italian Medicines Agency, the distribution of counterfeit medicines in Italy is limited to the illegal distribution chain. The tracking system in place in this country, which allows tracking and tracing of all the packages of medicines throughout the entire supply chain, is a good barrier against the risk of infiltration in the legal distribution network.

The GCP in Italy has been influenced by the SPOC system implemented by the Council of Europe. A series of inputs were collected by AIFA from the CoE in terms of models to be followed and implemented in the fight against the counterfeiting of medicines and medicinal products. According to the Italian agency for medicines, the reactive model of the SPOCs network is very practical and useful in order to channel information through the national administrations. Going even beyond the scope of the SPOC model, the practical implementation of the SPOC system by the Italian Medicines Agency resulted also in the development of a community of practice: a framework for training and apprenticeships with/to people having different level of knowledge.

Starting from the very beginning, the initial version of the GCP in Italy foresaw the creation of an anti-counterfeiting stakeholders group with the participation of selected national administrations together with specialized police forces. Shortly before the CoE seminar on counteracting counterfeiting held in Strasbourg in 2005[9], the main institutions working in Italy in the fight against counterfeit medicines – AIFA, the Italian official medicines control laboratory, Carabinieri NAS (police force working on health matters), and the Ministry of Health – started a cooperation project aimed at coordinating efforts and improving investigations.

According to AIFA, the main motive leading to the creation of the anti-counterfeiting stakeholders group in Italy was the recognition that communication and cooperation among the subjects involved in the fight against counterfeit medicines at national level

[9] Council of Europe Seminar "Counteract the counterfeiters: Limiting the risks of counterfeit medicines to public health in Europe by adequate means and measures", Strasbourg, 21 to 23 September 2005

were hindered by the lack of appropriate structures and procedures at the disposal of both the health authorities and the law enforcement agencies.

This task force quickly became the reference point for all issues related to medicines' counterfeiting: it acted as a single point of contact in order to monitor the phenomenon of counterfeiting of medicines in the country and establish adequate counter measures.

Due to its specific role as a SPOC, the taskforce also started to cooperate with some private stakeholders, such as the associations of pharmaceutical manufacturers (Farmindustria, Assogenerici), the association of pharmacists (Federfarma), parallel distributors and other public and private institutions.

An enlargement of the participation was registered shortly after, when other stakeholders were involved and the ACS opened its doors to: the Italian Customs Agency, the Ministry of Health, industries associations of pharmaceuticals' producers and distributors at different levels, associations of generics' producers and of parallel importers.

The activities of the group started in an informal manner, with relations among participants that were regulated mainly on the basis of soft law indications. Furthermore, there was no formal request coming from the EU to implement such a system. Later on, Directive 2011/62 prepared the ground at EU level for the creation of similar cooperation mechanisms, but the Italian Medicines Agency was already acting on a soft law level in order to provide effective tools for the fight against this emerging threat.

However, some formal elements were also needed and different steps were taken by AIFA. In 2007, an AIFA regulation formally established the working group on counterfeit medicines. Its main goal was to analyze the problems related to the phenomenon of the counterfeiting of medicines, to identify possible gaps in the legal system, to define the procedures and the actors involved in this phenomenon, as well as to coordinate the authorities involved at different levels.

The main objectives for the working group envisaged by the 2007 regulation are reported below:

- evaluating the extent and typology of the phenomenon of counterfeit medicines in Italy;
- identifying procedures for gathering and analyzing data on the phenomenon of counterfeit medicines in Italy;
- defining an effective information flow between the national authorities involved at the national level;
- raising awareness for those officers working in the health system on: the problem of counterfeit medicines itself and the reporting-system to be used in case of incidents;
- formulating proposals on possible revisions of the legal system;
- improving international cooperation in order to exchange information on the issue of counterfeit medicines.

In 2008, a new act enlarged the board of the taskforce (officially named IMPACT Italia) to other relevant institutions, establishing cooperation with the High Commissioner for the fight against counterfeiting, a governmental institution created in 2005 and then suppressed in 2009. A new institution took the duties of the High Commissioner in 2009, namely the Anti-Counterfeiting Directorate of the Ministry for Economic Development, which is part of the taskforce and with which a fruitful cooperation was immediately started. According to the new regulation, the external composition of the taskforce has been partly modified, and the taskforce has been officially recognized as the national SPOC in the field of anti-counterfeiting of medicines. To this aim, a specific email account has been created in order to collect the warnings on suspected counterfeit medicines[10].

As far as the cooperation framework within the taskforce is concerned, the Italian medicines agency established different Memorandum of Understanding with the Ministry of Health and the police forces.

[10] The email address is IMPACT-Italia@aifa.gov.it

Activities of the taskforce[11]

The main objective of IMPACT Italia is the improvement of the information flow between the stakeholders interested in and by the phenomenon of counterfeit medicines. Since its establishment, the different activities implemented by the taskforce have been also focused on the development and sharing of technological knowledge on the phenomenon of counterfeit medicines.

Within this cooperation framework, several joint activities on investigations have been also carried out. Furthermore, the taskforce prepared guidelines for the training of field investigators and was involved in many training events. IMPACT Italia also developed a specific website in order to share intelligence and filter received signals and transfer them into the intelligence system.

These are some examples of the activities that the taskforce carried out in the recent years:

- Creation of a "quick check" procedure for investigators (which is part of the Permanent Forum for International Pharmaceutical Crime - PFIPC - investigators manual)
- Establishment of a "confidential" database containing brands of authorized medicines developed in cooperation with the private sector, namely with Farmindustria – association of branded pharmaceutical companies – and Assogenerici – association of generics pharmaceutical companies. The database is accessible to investigators in charge of making preliminary controls on suspicious packages. In the last 4 years, besides the branded medicines, also generic medicines and food supplements have been inserted in the database;
- Organization and delivery of specific training for specialized (NAS) and not-specialized police forces;

[11] Main source AIFA-EDQM (2011), p. 100 and IMPACT Italia activity report.

- Creation of training manuals for investigators and adaptation of the PFIPC manual with international case studies.
- Analysis of the investigative database of the Ministry of Interior;
- Launch of a sampling project on suspect online pharmacies and analysis of selected medicines sold online. Enlargement of this study from not-regulated sources (such as the Internet) to other types of products particularly dangerous for human health;
- Launch of an awareness raising campaign together with Farmindustria on the risks of buying medicines from not regulated sources;
- Improvement of the capacity and effectiveness of laboratories for the analysis of possible counterfeit medicines;
- Launch of a coordinate project among police forces, laboratories and AIFA on the risks of importing illegal pharmaceutical raw materials;
- Development of a procedure for mutual consulting and data exchange between law enforcement agencies and other technical bodies in counterfeiting cases;
- Development of a procedure and a reference point for consumers to report suspected cases.

Importance of the private sector

The participation and contribution of the private sector is extremely important for the effectiveness of the task force. However, the taskforce system is flexible enough to not require the private sector to be "on board" every time a seizure of a product suspected to be counterfeited occurs. In this regards, many resources have been invested in order to develop, in cooperation with specific police forces and universities, scientific methods for the laboratory analysis, in view of allowing them to better identify counterfeit medicines. The result of these efforts is that it is not always necessary for the private sector to provide assistance for the identification of a counterfeit version of their product and the national authorities may rely on the expertise of their own laboratories and specialists. However, there are cases in which counterfeits are extremely similar to originals and the intervention of the private sector is required. This flexibility in the support received from

the private sector is very important considering that it is difficult for industries to be involved in investigation cases, especially because they are mostly big multinational pharmaceutical companies and their security/investigation offices are often placed outside of Italy.

A case referring to an identified counterfeit medicine – the s*orbitolo* case – can be used to better present the alert-response mechanism and the communication system existing between the public and the private sector in Italy.

On March 2012 a young woman died in Italy while performing a test used to verify food intolerances. The test was carried out by using a test substance and two other women were seriously affected by the use of the same substance during the same test. An investigation was immediately initiated and the doctor who performed the test stated to the prosecutor that he was using this type of test for the first time. Instead of using *glucose*, as it is usually done, he chose to buy online - on the famous auction site e-Bay - a test made up of *sorbitol*. According to the police, the real motive would be related to the price: the tests bought online had a price of about twenty euro less than the ones offered by pharmaceutical companies. After this case, e-Bay stopped all sales of *sorbitol* until the situation was clarified. The reasons for the death of the young woman still have to be verified. What is important to analyze in this case is the reaction system that was initiated by AIFA. The Italian pharmaceutical Agency launched the alarm and reacted promptly. It was immediately clear that the real problem was the *sorbitol*. The Police, the Ministry of Health and AIFA worked together to face the problem and seize the dangerous products. According to its role, AIFA acted as the repository and channel for information within the network of single points of contact. In this case the first signal came form the Police forces, it then passed to the Ministry of Health and reached AIFA. Industries were partially involved in this case because it was clear that the product was not a medicine. However, they provided some useful pieces of information.

For what concerns the circulation of information among the participants to the anti-counterfeiting stakeholders group, there are limits to this circulation at juridical level,

especially when the exchange of data refers to a case where the Court is involved. In all other cases, the limits in information sharing are up to the actors involved.

Anonymous signals are also considered by the ACS. On IMPACT Italia website, an interface for receiving anonymous signals has in fact been created. At the beginning the police forces disagreed with this proposal, due to the anonymity of the system. Finally the system was put in place and nowadays it works properly.

Another problem needed to be solved at the beginning of IMPACT Italia's works: numerous signals received concerned parallel trade. AIFA had thus to publish a specific document on parallel trade on its website to clarify the difference between illegal or counterfeit medicines and parallel traded ones.

The quick evolution of the ACS in Italy, led to the point in which the Italian medicines agency has become the entity in charge of recognizing real alerts. Moreover, the person responsible can start ex officio the investigation according to the signals received, since he/she has also an assessment duty.

With particular regard to the cooperation with the private sector within the taskforce, a protocol of enlargement is envisaged. In 2012 AIFA started to deliver services to the private sector, but this kind of cooperation still has to be developed. It is a stepwise process that will be probably finalized in the next years.

3.2.2 UK

Creation of the mechanism, main motives and preliminary steps

The strategy of the Medicines and Healthcare products Regulatory Agency (MHRA) in the fight against counterfeit medicines envisages the collaboration and support of public agencies and private stakeholders as a necessary element. Pharmaceutical companies and

distributors have a very important role to play in these regards, alongside medicines regulators, police and customs.

Historically, the relationship between public and private sector stakeholders wishing to work together to fight counterfeit medicines in the UK was re-active, rather than pro-active, since the private sector was addressing the MHRA with cases which the Agency would consider to investigate. Due to the role of the MHRA as a national medicines agency regulating the pharmaceutical sector, the relationship with individual private companies would always need to be managed carefully and transparently.

In this sense the role of the Pharmaceutical Security Institute (PSI) as an association has been particularly important in relation to being representative of a number of pharmaceutical manufacturers' security departments. The importance for the MHRA of engaging the security departments of the pharmaceutical manufacturers' sector can be found in the fact that, even if the Agency is responsible for ensuring that medicines and medical devices work and are acceptably safe, the companies have more information on:

- their own specific products
- supply chain history of specific batches
- reference samples of authentic products
- a thorough visual identification of suspect products in relation to covert and overt security features

Counterfeiters are sophisticated enough these days that visual examination alone can not recognize some fake medicines, while the producers have the ability to do that, particularly through examining known security features.

Both sides have a common need and mutual interest in forging co-operation, effective relationship and good communication practices. While the Agency has the mandate to safeguard public health by regulating and enforcing relevant legislation with regards to medical products, the pharmaceutical companies who own the intellectual property rights on the products, also have a responsibility to safeguard public health by protecting their

products and supply chains. In addition, distributors have a joint-responsibility to protect supply chains. For this reason, it is impractical and futile to work in isolation, hence the need for stakeholders to collaborate and share information which will assist in protecting the public from receiving counterfeit medicines while assisting with the apprehension and prosecution of suspects.

Having recognized the importance of this cooperation, in 2006 the MHRA proactively identified relevant stakeholders from UK industry, trade associations and law enforcement agencies and invited them to participate in an Anti-Counterfeit Stakeholders (ACS) meeting - which is held twice a year - to share information and intelligence gathered concerning counterfeit medicines and the threat posed to the UK supply chain[12].

The ACS group was created with the objective of identifying "high risk" products through sharing information on: counterfeit medical products in the UK and overseas; reports of falsified medical products to the MHRA, police, customs and other regulators; unusual or suspicious market activity and information from industry concerning demand and supply. The identified "high risk" products form a Watchlist to enable the stakeholders to focus vigilance and resources where the risk is the highest.

One of the aims of the ACS is also inviting PSI and the other stakeholders to regularly present their UK/EU activities, providing information on what they have observed on particular criminality, suspicious behavior or medical product trading trends relating to counterfeit medical products.

Functioning of the mechanism

- ***ACS Membership, roles and responsibilities***

The Anti-Counterfeiting Stakeholders group includes trade associations for manufacturers (ABPI), wholesalers (BAPW), parallel traders (BAEPD), generics

[12] MHRA (2007), "Anti- Counterfeiting Strategy 2007-2010"

manufacturers (BGMA) and the Pharmaceutical Security Institute (PSI). UK Border Force (UKBF), HM Revenue and Customs (HMRC), Police, and the General Pharmaceutical Council (GPhC) are also represented.[13]

The MHRA organizes, hosts and chairs the ACS meetings every six months. One of the outcomes of these meetings, as discussed, is a Watchlist of 'high risk' medicines developed on the basis of the stakeholders' information. This list is reviewed every six months and shared with the ACS group.

According to the Falsified Medical Products strategy adopted by the MHRA, it is important to involve all the actors committed to the fight against counterfeit medical products, to the related organized crime activities and those working on IPRs, because they gather information on illegal trade and counterfeit goods from different perspectives and with different instruments. To fight medicines counterfeiting, it is important to look at the general role of organized crime in the production and trade of counterfeit goods in general, not just focusing only on medical products. Indeed, there are multi-commodity criminals interested in all IP issues. The UK IP Crime Group headed by the Serious and Organized Crimes Agency (SOCA) was created on the same principle and involves different organizations (see end of paragraph for further information).

- Legal, formal and/or informal background

The ACS group does not discuss nominal data or live investigation cases, therefore there is no requirement for a legal platform relating to the functioning of the group.

Meetings, contacts and flow of information

The Anti-Counterfeiting Stakeholders group meets twice a year. In general, maximum collaboration is sought, therefore there is no requirement for written roles: all participating actors work in the spirit of full co-operation.

[13] MHRA (2012), "Falsified Medical Products Strategy 2012-2015"

In order to make the ACS group mechanism working, it is fundamental to establish contact points both from the national medical products regulatory agency, law enforcement and the trade associations; to assure a continuous flow of data among the participants; and to set action points and deadlines. The information flow must be multi-directional and stakeholders must address the MHRA in case of counterfeit incidents.

The MHRA also introduced a Counterfeit Hotline which allows both health professionals and the general public to report suspicious incidents.

Additional Intellectual Property Group in the UK

Another example of existing good cooperation between the public and private sector in fighting different types of counterfeit products, can be found in the creation of the UK Intellectual Property Crime Group in 2004. It was founded by the Intellectual Property Office (IPO) - and is chaired by the (SOCA) - due to the need to bring together Government, enforcement agencies and industry groups. The group aims to ensure a collaborative approach in addressing key IP crime (counterfeiting and piracy) issues[14].

The Group manages a diverse subject that cuts across many public and private sectors. As well as ensuring that industry (IP right owners), law enforcement agencies and UK government agencies work together, the Group helps to find a common ground where there are conflicting interests and concerns. This Group creates a genuine partnership approach which is recognised as a model of best practice. The IP Crime Report is an example of how the Group works together to publish an annual report representing all their sectors and summarising the threat posed by IP crime as well as the activities undertaken to tackle this crime.

[14] Intellectual Property Office, "UK IP Crime Group", http://www.ipo.gov.uk/pro-policy/pro-crime/pro-crime-group.htm

The IP Crime Group meets 5 or 6 times every year, but in case of necessity an extraordinary session could be called.

3.3 Creation of the Good Communication Practice

The analysis of the GCP models already existing that was performed by UNICRI during the observation phase of the pilot, showed that Governments need to follow a clear coordination approach when creating their strategy against counterfeit medicines.

While the reasons for the need of a multidisciplinary approach have been explained in the introduction to this report, the analysis of the existing models of cooperation added an important element to this framework. This element is the recognition that coordination among the different actors representing the various sectors of the multidisciplinary approach is fundamental to ensure effectiveness to the cooperation mechanism.

The observation phase of the pilot was fundamental to ensure that the draft GCP that UNICRI was creating could benefit from the experience of the other existing ACS groups, which were clearly positioning themselves as models to be analyzed and followed. It was for this reason that UNICRI decided to draft the GCP using a research and testing approach that could avail itself of the support of the relevant stakeholders in Italy and the United Kingdom, two countries which had already experienced the challenging work of setting up a public-private cooperation mechanism to better fight against counterfeit medicines.

By analyzing what the National Authorities of Italy and of the United Kingdom had achieved in the recent years, and especially how they achieved it, UNICRI was able to gather the maximum of information during the observation test of the pilot in view of closely cooperating with the National Authorities of Romania for the practical phase and the creation of the ACS group in this country.

During the observation phase, UNICRI focused its attention on specific elements of the mechanisms. This research phase of the pilot was aimed, in particular, at assessing how the cooperation mechanism had been created in practice in these countries and how it worked. The ultimate aim of this phase was the identification of specific good practices within the cooperation models that made possible the creation and running of the public-private cooperation scheme.

Preliminary studies conducted since the very beginning of the SAVEmed project, had allowed UNICRI to create a basic scheme, listing several factors that had to be taken into account or that had to be further researched for the preparation of the Good Comunication Practice. These elements allowed UNICRI to elaborate a first draft indicating the steps to be taken for the creation of the GCP that was submitted for inputs and approval of the involved experts during the first roundtable organized in Turin in March 2012. During the first ten months of activity, and especially in the period between the first and second roundtables organized in Turin (March – November 2012), UNICRI was very attentive in ensuring that this draft was a veritable living document, since it had to be adapted to the results of the observation phase that was being conducted during the pilot in both Italy and the United Kingdom.

The elements that were contained in the draft of the GCP set the basis for UNICRI's work with regards to both the observation and practical phases. The specifications to these elements had to be taken from the practical experience that UNICRI was gathering thanks to the observation phase and, once defined in accordance with the National Authorities of Romania, allowed for the possibility to base the practical phase of the pilot on solid and tested grounds.

Three main areas of interest were identified in the draft GCP and the observation phase had to provide UNICRI with information to better specify these areas and transform them into a strategy aimed at practically creating the ACS group in Romania. The first area of interest was aimed at analyzing the way in which the two models had been established, in view of identifying a path that could be followed also in the case of Romania. Specific

elements to be discussed were: the motivations at the basis of the cooperation mechanisms' creation, the stakeholder(s) that promoted the mechanism, and if a legal background had mandated its creation.

The analysis of both the Italian and UK experiences allowed UNICRI to highlight how the systems were created in these two countries. The motivations at the basis of the ACS implementation are very clear and common in both Italy and the UK: the need to pass from a reactive to a proactive strategy in order to fight counterfeit medicines, increasing the effectiveness of the anti-counterfeit medicines strategy. The Italian example differs from the UK one. The Italian ACS was primarily created among public stakeholders and then, in a later stage, enlarged to private industries' participation. The group set up by AIFA progressively extended its composition, first by allowing an increased number of public administration to participate and finally (also in view of its role as SPOC) to the private sector. On the other hand, the MHRA immediately tried to bring at the same table public and private stakeholders. In this regard, the MHRA found in PSI a very important player, since this private association allowed the UK DRA to rely on one single contact that was able to channel the information from the MHRA to the private industries it represented and from the private industries to the MHRA. Apart from this, the need to improve and increase communication and cooperation among different actors was common to both experiences, confirming that what UNICRI was proposing was an important step to enhance the fight against counterfeit medicines. Both experiences also relied on the fact that an increased cooperation was mutually beneficial for both the public and private sector.

In both cases there was no legal requirement from the Government to set up such a cooperation scheme. However, while in the UK there is no legal platform regulating the system and the stakeholders to be involved in the ACS were progressively identified and invited to the group by the MHRA, in Italy AIFA set up some regulations during the years. While also in Italy activities started in an informal manner and were regulated mainly on the basis of soft law indications, in 2007 AIFA formally established the working group on counterfeit medicines and in 2008 a new AIFA Act enlarged the board

of the taskforce to other participants and changed the name of the group into IMPACT Italia. Furthermore, AIFA signed two Memoranda of Understanding with other Institutions in Italy to ensure the effectiveness of the ACS group's work.

It is interesting to highlight that, in both the Italian and UK cases, the creation of the cooperation mechanism was an evolution of the respective anti-counterfeiting strategies, which progressively understood the important role that the private sector could play to step up the effectiveness of their anti-counterfeiting actions. Furthermore, in both cases the initiative for the establishment of such cooperation came from the DRA, who started acting as promoter and coordinator of its respective group.

The second area of interest was aimed at gathering information concerning how the mechanisms worked in practice, with specific reference to information as: which National Authorities and which representatives of the private sector were involved, if respective roles and responsibilities were identified, and if a chart or statute of the group indicating its tasks was created.

To summarize: in Italy, the following stakeholders take part in the ACS: AIFA, the Italian official medicines control laboratory, the Carabinieri NAS, the Italian Customs Agency, the Ministry of Health, the Anti-Counterfeiting Directorate of the Ministry for Economic Development, associations of pharmaceutical manufacturers (Farmindustria, Assogenerici), pharmacists (Federfarma), associations of generics' producers and of parallel importers.

In the UK, the Anti-Counterfeiting Stakeholders group includes, apart from the MHRA: the UK Border Force (UKBF), HM Revenue and Customs (HMRC), Police, the General Pharmaceutical Council (GPhC), trade associations for manufacturers (ABPI), wholesalers (BAPW), parallel traders (BAEPD), generics manufacturers (BGMA) and the Pharmaceutical Security Institute (PSI).

For what concerns the tasks of the ACS, in the case of Italy, and even if no real chart or statute was established, an AIFA regulation officially establishing the working group indicated also its tasks. In the case of the United Kingdom, a progressive informal mechanism was created among the public and private sector without an official document at its core. Furthermore, both cooperation systems do not officially indicate the members' roles and responsibility. In the case of Italy, the only element in this regard is contained in the already mentioned AIFA regulation and establishes the coordinating role of AIFA with respect to the working group. In the UK, the MHRA has the same role but this is not established in any document. It was the very same creation process of the ACS – being born from the MHRA initiative - and its progressive evolution that made very clear the MHRA prominent role.

The third area of interest for the creation of the GCP was the practical functioning of the ACS, covering aspects ranging from the number of regular meetings per year to how the information was flowing among the group.

Both the UK and Italian working groups have regular meetings twice a year. However, in the case of Italy the AIFA regulation establishes also a secretariat of the working group. The latter has the specific task of identifying the operational modalities of the ACS and meets every two months.

The most important element to be analyzed in this area of interest was the nature and circulation of information among the ACS participants. Both cooperation mechanisms showed a certain degree of flexibility in this regard. In Italy, in particular, AIFA acts as collector of warning signals coming from different sources (both from other ACS members or external, even anonymous ones). It then elaborates the signals and asks the support of other ACS members in order to obtain more information and coordinate the response to the problem. In order to render the flow of information more effective, each ACS member has established a single point of contact responsible for this task. As we have seen in the part dedicated to the Italian cooperation scheme, the private sector is fully inserted into this mechanism but, given the expertise developed by AIFA, its

presence is not required in every case. The system has a strong and effective reactive component (as demonstrated by the *sorbitolo* case previously described) but it also progressively implemented proactive elements. Even if the flow of information is bi-directional, restrictions apply in case of confidential or sensitive information and it is the role of the ACS coordinator to judge, on a case by case basis, what type of information can be shared with which ACS member.

Similar considerations apply also to the UK ACS coordinated by the MHRA. Also in this case each member of the working group established a single point of contact responsible to ensure maximum and fast information flow. Intelligence and information is shared among the ACS members during the regular meetings as a proactive way of addressing the counterfeit medicines problem and the private sector (mainly through PSI) is called to contribute in case of need. The reactive element is also present and, in this case, MHRA takes the lead and coordinates the information gathering and the investigation. The private sector can also be called to contribute in this case. A specificity of the UK system is that the MHRA has direct investigation powers and can consequently initiate and lead investigations on counterfeit medicines incidents. In this case, once the private sector passes the MHRA information which is relevant to a case, this information enters the MHRA's exclusive competence and it is up to the Agency to decide if, and to which extent, informing the private sector of the investigation's development.

Both the Italian and UK ACS implemented specific activities among the group members aimed at analyzing the problem of counterfeit medicines, react to incidents and prevent illicit activities. The UK ACS, for instance, created a Watchlist of 'high risk' medicines that was developed on the basis of the stakeholders' information and that is reviewed every six months and shared with the ACS group. In Italy, IMPACT Italia created a "confidential" database containing brands of authorized medicines developed in cooperation with the private sector. The database is accessible to investigators in charge of making the preliminary controls on suspicious packages. IMPACT Italia also created a web interface in its website aimed at allowing users the possibility to communicate warning signals to the ACS coordinator.

3.4 Practical test of the Good Communication Practice in Romania

The identified good practices in Italy and in the United Kingdom formed the analytical basis upon which the test phase was performed in Romania.

Since both Italy and Romania are civil law countries, the Romanian National Authorities decided to follow mainly the Italian approach, mixing the creation of an informal cooperation network with MoUs between the participating Governmental Agencies. This approach was formally decided and approved during the second roundtable that was organized in Turin in November 2012.

In order to facilitate the Romanian Authorities´ activities, soon after the first roundtable held in Turin in March 2012, UNICRI sent them a description in English of the functioning of both the UK and Italian cooperation mechanisms. Furthermore, the MoUs created by the Italian National Authorities linking AIFA to the other participants of the ACS group, were translated into English and sent to the Romanian Authorities.

The creation of an ACS group dedicated to the fight against counterfeit medicines in Romania was also facilitated by the fact that a similar group was already in place. It is the IPR working group, which is focused on the fight against counterfeit products in general and that brings together representatives of both the public and private sector. Reference to an already existing cooperation mechanism in the country, created the possibility to refer also to an already existing national model which was headed by the Romanian Public Ministry. This National Administration was already cooperating with UNICRI in the SAVEmed project, creating a link and a continuity of action between the existing cooperation mechanism and the one dedicated to counterfeit medicines that was in the process of being created during the project.

One of the crucial elements was the identification of a focal point within the participating National Administration which could guide the process and become the reference point for the functioning of the ACS. During the second roundtable in Turin, a considerable

part of the discussion focused on this element. Given the proactive role played so far by the Romanian Public Ministry, and also considering that the already existing IPR working group is headed by the same National Authority, this Administration was identified as the leader of the project in Romania. Thus, the configuration of the ACS group in this country marks a first significant difference with regards to the Italian and UK models, where the ACS groups are in both cases headed by the respective National Drug Regulatory Authority. However, and considering both the proactive role that the Romanian Public Ministry had throughout the entire duration of the SAVEmed project and that this National Authority already leads the existing IPR Working Group, this approach was welcomed and opens for the possibility of a cooperation mechanisms which will be developed in a slightly different way from the others.

Following this phase, the Romanian Public Ministry produced noticeable efforts in ensuring the involvement of several National Administrations in the ACS working group. Some of them had already agreed to participate in the project since they were involved during both the roundtables that UNICRI organized in Turin. This was the case, for instance, of the Romanian Police and the Romania National Drug Regulatory Agency. The private sector had already agreed to participate during both roundtable thanks to the participation and commitment of the National Association of Pharmaceutical Producers.

The Public Ministry engaged in several talks with other National Administrations that had not participated in the roundtables but that, thanks to the experience gathered during the organization and heading of the IPR Working Group, were deemed important for the proper functioning and effectiveness of the ACS group.

Results probably exceeded expectations in this regard, thanks to the excellent work of the Romanian Public Ministry and the support of the Romanian Police and the National Medicines Agency. On 31 May 2013, the Public Ministry organized a high level meeting on the cooperation mechanism to be created within the framework of the SAVEmed project. Apart from the Public Ministry, the following National Administrations participated: the General Inspectorate of the Romanian Police, the General Inspectorate

of Border Police, the National Customs Authority, the National Medicines Agency, and the Romanian Intelligence Service. During this meeting, the Public Ministry agreed with the other National Administrations on a way forward leading to the establishment of a national cooperation mechanism against counterfeit medicines, putting into practice what was discussed and presented during the SAVEmed project.

From the formal point of view, and with respect to the UK and Italian models, the Romanian cooperation mechanism presents a more formal element. In this regard, the meeting of 31 May 2013 established that a general protocol establishing the working group had to be created by the Public Ministry and then signed by all the other participating National Authorities. After this step, and in order to establish a clear cooperation under the leading role of the Public Ministry, the latter needed to create and sign a single MoU with each other involved National Administration. This practice was identified to guarantee the proper functioning of the anti-counterfeit medicines working group. After this phase, the group's participation would be enlarged to the representatives of the private sector with a separate act. During the same meeting, and following the successful experience of the SPOC system, it was agreed that every National Administration participating in the working group will have to indentify a single point of contact to facilitate the flow of information among participants. Furthermore, a dedicated webpage with restricted access will have to be created, protected by a username/password access.

During a mission that UNICRI organized in June 2013 to support the Public Ministry action in this regard, it was immediately clear that the work done by the Romanian National Authorities was excellent, especially considering the number and relevance of the National Administrations that were involved in the cooperation mechanism.

The Romanian anti-counterfeiting stakeholders´ group was officially launched on 18 March 2014, during a presentation event that UNICRI organized in Bucharest for this purpose. The following Ministries and National Administrations take part in the working group: the Public Ministry, the Internal Affairs Ministry, the National Tax Administration

Agency, the National Medicines and Medical Devices Agency, the Romanian Intelligence Service, the National Veterinary and Sanitary Authority for Food Safety, the Romanian Association of International Medicines Manufacturers, the Romanian Generic Medicines Manufacturers Association.

4. GUIDELINES

The results obtained during the research and pilot phases allowed UNICRI to outline a series of recommendations and lessons learned to be used as a guidelines and reference points supporting those countries that want to create a communication mechanism on counterfeit medicines involving both public and private stakeholders.

Before presenting the guidelines, it has to be noted that, apart from the practical realization of any formal element that may be necessary for the establishment of a cooperation mechanism between different stakeholders, the most noticeable component is the importance to properly channel the crucial importance of cooperation among participants. In this regards it is important that the involved stakeholders do not perceive the institution of a cooperation mechanism as a new burden to their work. On the contrary, they have to be convinced of the beneficial effects that such a mechanism may have for the fight against counterfeit medicines and for improving the effectiveness of their work. In this regards, building trust among participants is of paramount importance, especially when it comes to the involvement of the private sector. Trust will allow the members of the cooperation mechanism to rely on its established relations and communication methods, being sure that every counterpart is sharing the same goal and same objective.

Considering the above, the guidelines will assume the form of practical suggestions that may guide stakeholders in this process, giving particular consideration not only to the formal establishment of the group but also to its preparatory phase.

4.1 Preparatory phase

- **Assess the current situation in the country regarding counterfeit medicines**

  This phase should be aimed at collecting information on the existence of the problem in the country. This element will help in presenting the actual country´s situation to the other National Authorities and stakeholders to be involved in the good cooperation mechanism. It is fundamental that the information collected allow for presenting the importance of the establishment of such a cooperation mechanism in a way that is clear to the other stakeholders, showing the presence of the phenomenon in the country.

- **Prepare a needs assessment**

  This phase should complement the previous one by identifying and presenting the gaps that exist at the national level regarding the response put in place by National Administrations against counterfeit medicines. Lack of cooperation and barriers in the communication flow among stakeholders, if any, should be particularly highlighted, since it is on these aspects that the good communication mechanism can have the most beneficial results. The important contribution that can be brought by the private sector should also be highlighted in this phase.

- **Identify the other stakeholders to be involved and establish contact points**

  The results of this phase depend very much from the internal administrative structure of each different country. The stakeholder or National Agency which is trying to create the good cooperation mechanism should identify which are the other National Administrations and stakeholders to be involved. Once this part is successfully carried out, it will be important to identify the key people to be contacted and involved within each single National Administration/stakeholder. Openness to discussion and motivation to fight counterfeit medicines should be taken into consideration when identifying the key people to involve.

- **Involve them in the process since the very beginning**

  It is extremely important that the identified National Administrations and stakeholders are part of the process since the very beginning. This will give them a sense of ownership of the action which will be shared by all participants. The decision to create a good communication mechanism has to be the result of a dialogue and sharing of ideas and approaches between all the people involved at this stage of the process. The impression that one National Administration is deciding what to do and is imposing the decision to the others must be avoided. This is a common strategy, and stakeholders must implement together.

- **Organize one or more meetings to discuss the problem of counterfeit medicines and present the elaborated needs assessment**

  The organization of presentations and meetings is a fundamental element of the preparatory phase. The National Administration that is providing the input for the creation of the good communication mechanism will find extremely beneficial to sensitize the other identified participants, to organize roundtables and meetings for discussing the problem and begin the dialogue which may lead to the establishment of the good communication mechanism. Presenting the results of the country's needs assessment will support the start of the discussion and the search for potential solutions. The discussion will have to be guided and the importance of creating communication channels between stakeholders (or enhancing existing ones) will have to play a key role. There is no indication regarding the number of meetings, presentations or roundtables to be organized as this will greatly vary from country to country.

- **Make the discussion active and accept suggestion from the involved stakeholders**

  It is important that during the discussion phase, all participants will have the possibility to express their ideas. Each participant should feel part of the process and know that his/her contribution has the possibility to influence the outcome of the

process. National Administrations guiding the establishment of the good communication practice must be ready to modify their initial vision of the mechanism implementation, as this may be a key element in ensuring cooperation from all the stakeholders that have to be involved.

- **Make reference to existing experiences and models, showing results obtained and the importance of establishing cooperation**

  Experience drawn from other countries who managed to implement such cooperation mechanisms may support the discussion and the decision making phase, demonstrating that the establishment of cooperation mechanisms between various stakeholders is possible and successful. Internationally accepted baseline standards, as the SPOC system of the Council of Europe, are also a good starting point to show the effectiveness of rapid and consistent information flow.

- **Involvement of the private sector**

  As we extensively explained in this report, involving the private sector is a key element of the entire approach. National Administrations leading the creation of a good communication mechanism should identify the key people to involve as soon as possible. It is also highly advisable to refer to associations of pharmaceutical manufacturers since key people in these associations usually have the trust of manufacturers and may present them in the right way the establishment of such initiatives. They are also in a privileged position to support the group after its establishment and may act as reference points linking the private and public sector. It is up to the National Administrations to decide the moment in which to officially involve the private sector. Depending on the attitude of the various public and private stakeholders, this may happen in the preparatory phase or after the official launch of the group. This element should also be part of the initial discussion in order to ensure a result that is satisfactory for all the parties involved.

- **Agree on a common strategy and way forward**

The final result of the preliminary phase should be the creation of an agreed and shared strategy aimed at improving communications among public and private stakeholders involved in the fight against counterfeit medicines through the establishment of a dedicated good communication mechanism or an anti-counterfeiting stakeholders´ group. The different steps to be performed by each participating stakeholder in this respect as well as a tentative implementation timeline should also be agreed among participants.

- **Agree on the identification of a leading agency which will act as reference point guiding the process**

  During the meetings/roundtables, the various stakeholders should agree and identify a leader of the project, which will guide the rest of the group throughout the preliminary and implementation phase. Even if in many cases the national DRA took the lead in this respect, there is no indication regarding which National Administration should be entitled to do it in principle. In the pilot application tested by the SAVEmed project in Romania, for instance, the Public Ministry took the lead and successfully created and launched the good cooperation mechanism.

- **Build trust**

  This is a fundamental element overarching the entire preliminary phase. The National Administration guiding the process should be able to build trust among all participants, not only towards its own lead but especially among participants themselves. The mechanism needs trust in order to work properly and it is probably the existence of this element that will decide if the efforts implemented so far by the leading National Administration will be successful or not.

- **Evaluate if external support from another country or an International Organization may facilitate the creation of the mechanism**

  This is an optional element of the preparatory process. In some cases, obtaining assistance from International Organizations or other countries that already created a

good cooperation mechanism (or both) may be a good element to convince the other stakeholders of the need to create such a mechanism and on the concrete possibility to be successful in this regard.

4.2 Implementation phase

- **Evaluate the need of taking formal steps for the establishment of the cooperation mechanism**

  According the specific legislative framework of each country, the leading National Agency will decide if formal steps are needed to set up the cooperation mechanism. A reference document of the group or a statute indicating the number of participants, roles and responsibilities, as well as other basic information will possibly be created at this stage, if needed. This is not a requirement, as the group may function very well without a formal element, as demonstrated by the case of the mechanism established in the UK by the MHRA

- **Consider the need or importance of creating MoUs with the various participants**

  This is another optional step. In the case of Italy and Romania, the establishment of MoUs with various participants facilitated the creation and functioning of the group. Such MoUs were not necessary in the case of the UK. Each country specific situation will have to be taken into consideration by the leading National Authority in this respect.

- **Remember that flexibility could be one of your most powerful allies**

  Very often, the solution to the points mentioned above will come with experience and after having evaluated how the mechanism may work in practice. Flexibility at the beginning of the mechanism implementation, especially for what concerns any decision regarding the need to create formal steps, could allow the mechanism to start

its activities, leaving the decision regarding the formal framework that will have to be used for a later stage.

- **Establish single points of contact within the various stakeholders involved**

  This is one of the most important elements to ensure the correct flow of information. A single person should possibly be in charge for ensuring the communication flow in each participating stakeholders and one email address should be dedicated to this purpose.

- **Ensure that the mechanism provides for regular meetings of the group and for the possibility to call a meeting in case of urgency**

  This element ensures that the cooperation mechanism is ¨kept alive¨ and that participants feel part of it. Both in the case of Italy and the UK, the cooperation mechanism has regular meetings (called twice a year). They also provide to call a meeting in case of urgency. These elements should be an integral part of the cooperation mechanism to be created also in other countries.

- **Establish a leader of the group**

  The leader could be the same National Agency who took the lead during the preparatory phase and provided inputs for the establishment of the mechanism. However, participants may agree and choose a different group leader. Its functions should at least include the organization of the regular meetings, the overview of the information flow, and the general overview of the mechanism functioning.

- **Define clear rules for the flowing of information among participants**

  Deciding which kind of information is shared among the group is extremely important in order to ensure that all participants are confident with how the cooperation mechanism works. From the practical point of view, and especially for what concerns the relations linking public stakeholders with the private sector, the

representative of the latter should operate as a filter to ensure that the National Authorities receive the data needed for their investigations on counterfeit medicines while producers are comfortable that no data which is sensitive for their business will be used in an improper manner.

- **Create a rapid alert/response mechanism**

  The group leader should supervise the creation of this element. What is important is that the alert/response mechanism ensures that, once a warning signal is received by any participant of the cooperation mechanism, the information rapidly flows among the relevant other participating National Authorities, ensuring a rapid and effective response.

- **Your group is a resource, involve them also in other activities**

  The information collected during the SAVEmed project allowed us to appreciate how the cooperation mechanisms established in Italy and the UK evolved. These groups are today also acting as catalysts for supporting the realization of a series of different activities which proved to be very useful for ensuring that proper attention is given to the problem of counterfeit medicines. These activities range from the organization of training courses to the implementation of awareness campaigns. The cooperation established with participants to the mechanism is consequently a valuable tool to implement several actions which may have a positive impact for the fight against counterfeit medicines. It is up to the group itself to step up its activities and become a reference point for all national actions in this field.