



MIDIR PROJECT

Contract n° 036708

WP 2: Integration of concept in real risk management settings into various cultures

**Del. 2.2:
Experiences with the application of the risk
governance concept and tool for health risks
related to ecommerce in the Lazio Region and its
transferability to other member states**

Reference code: MIDIR – Del. 2.2



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Short Description:

Deliverable 2.2 presents a report on the Italian case study on health risks related to eCommerce

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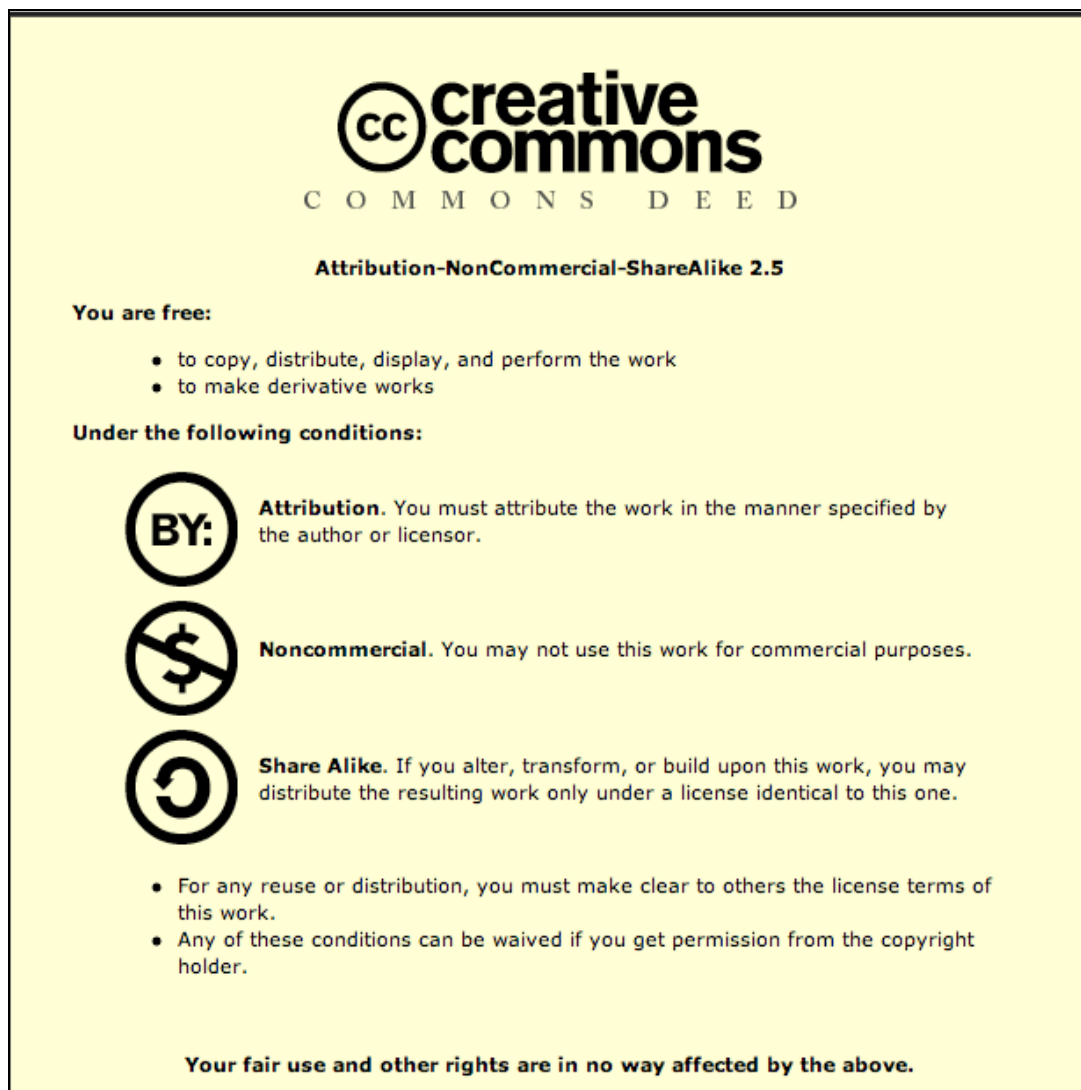


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1 Summary

The main objective of MIDIR project is to develop a resilience and risk governance concept based on existing research and an accompanying management tool. In this context, the material goal "resiliency" and the more procedural approach "risk governance" will be combined through an interdisciplinary approach that defines a reasonable path (risk governance) towards the material goal of creating resilient communities.

To test the indicator system in a real risk setting, a case study on risks related to health due to e-commerce in the Lazio Region, Italy (RL, IRPPS, IKU) was implemented. With the extremely rapid growth in use of the internet, established relationships between consumers and suppliers have been transformed. Whereas purchasing predominantly traditionally involved a direct physical and tangible relationship between buyer and seller, members of the public have become able to far more able to buy products from sellers who are remote and unknown in terms of their physical location, their authenticity and reliability.

In the emerging "health risk due to eCommerce" the MIDIR methodology was applied to the starting stage of the risk cycle: the risk assessment.

Stakeholder involvement was of major importance: after carrying out a preliminary analysis on the phenomenon, the MIDIR Team found out that there is a low availability of data concerning the purchase of online medicines and often this data is very fragmented. The main output of the preliminary analysis was that there is a gap between objective and perceived risk: although the objective risk related to online medicine purchasing is high, the users' real risk perception is low in Italy.

Due to the lack of data regarding the on-line medicines commerce and control institutions in this sector, it was necessary to select and involve the main local, regional and national stakeholders active in the health and pharmaceutical field in order to get a clearer picture on the current situation. This was the core activity of the Italian case study.

Nevertheless, in regards to the concept, it was decided that one case study is a representative example for an application of the methodology. The use of the internet as an interactive tool to purchase goods or accomplish commercial activities can be seen as a global phenomenon with no big differences in the client-customer relations.

Therefore the perception and estimation of this risk can be seen as relatively similar across Europe. Much more important as the impact of the different risk cultures are in this case the given differences between the several social groups of a society as well as existing distinctions between single individuals. These factors will be taken into account by a proper selection of stakeholders to be involved in the application in Lazio Region. The transferability of the method to other member states will be tested via an on-line questionnaire.

2 General Introduction

The case study on risks for health due to eCommerce was implemented by the Lazio Region, Italy, with the support of LAit Spa, LAzio Innovazione Tecnologica and IRPPS (CNR).

The main goal was testing the MIDIR Approach on a new and emerging risk with minimal information and low awareness but potentially a high risk. The concept has been tested in risk screening/problem framing and assessment.

Therefore the main objective of MIDIR is to develop, on the basis of existing research, a re-usable and scalable resilience and risk governance concept and to test it in real decision-making settings of existing risk management systems and cultures, by the example of an emerging risk with a high degree of ambiguity and uncertainty (risks related to health due to e-commerce). The process was managed, monitored and evaluated by an accompanying electronic tool. Concept and results of the test cases were disseminated to decision-makers of various levels and scientific experts due to focused networking, communication and dissemination activities. This way, the applicability of the concept within other risk cultures has been tested.

Building a bridge between different approaches in dealing with risks, developed by risk communities with a tendency to insularity (rarely interchanging with other approaches), has to be seen as a special challenge for the MIDIR project. Up to now **risk governance** is rarely used in disaster management strategies and **risk resilience** is not well integrated in approaches dealing with more man-made hazards.

The material goal "resiliency" (another similar used term, e.g. in climate change research, is adaptive capacity) can be seen as a widely accepted strategy within the natural disaster community. On the contrary, the more procedural approach "risk governance" has been created and adapted first in the area of new emerging, mostly man-made risks. The usage of both terms in the same context has to be seen as an innovative approach to combining an appropriate path (risk governance – including identification, assessment, management and communication of risk) towards the material goal of creating resilient communities, able to deal with the whole range of risks, nature-made as well as man-made ones. This is what MIDIR is aiming towards.

The specific goals of the project are:

1. To develop an overall framework for risk governance and resilience measurement and monitoring based on a review of current standards and state of the art;
2. To make measurable and tangible the culture of collaboration required by public sector organisations to collaborate in preparing for and meeting cross-sectoral risks;
3. To pilot an e-management resilience tool that can be used for resilience planning, monitoring and management across stakeholder organisations from European, national to local levels;

Based on results of 1. to 4. to provide worked examples based on two case studies, resulting in quantitative risk measures and Capability Maturity

Models to capture know-how in the domain, supported by a linked database of knowledge and case study experience;

Based on results of 1. to 4. to provide worked examples based on real risk management settings;

To provide a framework of questions whereby the completeness of risk awareness in a situation can be ensured or at least improved;

To disseminate the overall framework among decision-makers and science all over Europe by networking, events and the implementation of a communication and dissemination strategy.

The Italian case study will be described in five stages, as described in the following:

Stage 1: Case study preparatory stage

In the first part of the project a preliminary analysis of national scenario was carried out. The results of the research showed that in Italy there are no official tools and Institutions in charge of mapping spam website and emails, and also to quantify the number of people that purchase medicines on-line.

Then the project continued analysing the Regional scenario. The conclusion of this part was that most of the regional budget is used to cover health system expenses.

Stage 2: Identification of Stakeholders

The second step of the case study was dedicated to identify the European, Italian, regional and local stakeholders involved in the case. The real innovation of the research was to build up cooperation with them during the different steps of the project till the final event.

Stage 3: Interest and Risk Perception Analysis

During this part of the case study structured interviews to the ten stakeholders were carried out face to face individually and elaborated by Regione Lazio, IRPPS (CNR) and Lait.

Stage 4: Implementation of MIDIR concept

The next step was to organize the meeting with all the stakeholders. In that occasion different topics were discussed to compare the different points of view:

- the relevance of MIDIR within the policies of the Regional Ministry for Consumer Protection and Administrative Simplification;
- the presentation of the stakeholders involved in the case study and the presentation of interviews results;
- the presentation of MIDIR concept and Part A indicators.

Then during the meeting the stakeholders participated to select Part A and Part B indicators.

In the last part of the meeting the on-line questionnaire developed by IRPPS was presented. At the end the presentation of the Risk Community in SINAPSE.

Stage 5: Bottom-up risk perception analysis

To analyse the perception of health risks due to eCommerce by groups of citizens screened, a focus group was organized in Rome at the end of May 2008.

3 Case study on health risks due to ecommerce

The case study on risks for health due to e-commerce was implemented by Lazio Region, Italy, in order to test the MIDIR Approach on a new and emerging risk with minimal information and low awareness but potentially a high risk. The concept has been tested in risk screening / problem framing and assessment. The process has been planned as follows:

- Interest and risk perception analysis carried out through interviews to ten stakeholders from the following bodies: The IMPACT – Italy Task Force (International Medical Products Anti-counterfeiting Taskforce) composed by: Italian Ministry of Health, Istituto Superiore di Sanità (ISS) – the leading technical and scientific public body of the Italian National Health Service, The Italian Medicine Agency (AIFA) and NAS Carabinieri, a special military branch of Carabinieri corps for the protection of health. The other involved stakeholders were Farindustria, the Italian Association of Pharmaceutical Manufacturers; the Italian Federation of General Practitioners (FIMMG); the Association of Pharmacists of Rome; The Roman Federation of Pharmacists (Federfarma Roma), the Agency for Regional Health Services (ASSR) and former students in the faculties of Pharmacy and Pharmaceutical Chemistry and Technology;
- On the basis of the interviews an analysis of the general framework of the specific risk situation was elaborated;
- A meeting with all the stakeholders involved was organized with the aim of identifying stakeholders needs and interests, selecting the Part A and Part B Indicators for the implementation of the MIDIR methodology;
- Discussion for the elaboration and development of a common brochure with the collaboration of all involved stakeholders (mainly the IMPACT-ITALY Task Force) for wide dissemination and an awareness raisings campaign within the Region and, possibly, around Italy.

In the case study it emerged that the pharmaceutical field and the respective risk setting involved parties with a different “impact” on the subject. It needs to be taken into consideration that some parties can be defined “stakeholders” because they regulate the market, while others need to be considered “observers”.

What also emerged from the case study of Lazio Region is that the health risks related to e-commerce could be potentially high but, in reality, it is not very visible in Italy yet because the Italian Health System (Sistema Sanitario Nazionale, SSN) guarantees health care to all citizens independently from their sex, residency, age, income, job and provides

most medicines for free or at a very low cost. As a consequence of this, Italian citizens are more protected by the Italian Health System compared to those countries where it is legal to buy medicines via the internet. In Italy on-line illegal purchasing is carried out directly by the single citizens who overcome and do not take into consideration the official and authorized distribution channels (industry, wholesale distribution and pharmacies) and is mainly for anabolic steroid and erectile dysfunction products.

Thus, the MIDIR methodology, if applied in the risk screening/problem framing and assessment phase (as in the Lazio Region case study) it could become even more effective because it was applied at the root of the problem and it will be able to manage and monitor the risk governance process from the beginning, attempting to avoid the possible worsening of the situation in the future.

3.1 Preliminary analysis of the Italian scenario

During this phase the MIDIR team structured the information about the case. They analysed different fields of interest to be able to evaluate the Italian scenario.

They were involved in:

- Mapping of spam websites that sell medicines on-line;
- Looking for ePharmacies;
- Quantifying the number of spam emails that advertise the on-line purchasing of medicines;
- Quantifying the number of on-line medicines purchases;
- Analysing different categories of people who usually buy medicines on-line;
- Selecting the national, regional and local stakeholders to be involved in the case study;
- Examining the national legislative framework concerning the on-line purchasing of medicines.

3.1.1 Results of the preparatory stage

Italian scenario

In Italy there are no official tools and Institutions in charge of mapping spam websites and emails and also to quantify the number of people that purchase medicines on-line. There is a low availability of data concerning on-line medicines purchasing and often they are very fragmented.

So far, in Italy there is not a specific legal framework that regulates the on-line selling and purchasing of medicines. Even if it is illegal to sell medicines online in Italy, people can buy them abroad in countries where it is legal. So, risk possibilities increase due to the lack of information and users' awareness about medicines quality and safety.

Regional Scenario

The last studies on health published by some consumer associations in Italy show that people are interested first in the service of first aid and in that of SSN doctors.

Analysing the regional budget the results show that is used to cover health system expenses such as:

- hospitals management;
- first aid stations management;
- medicines prescribed by GPs;
- clinical analysis;
- other health related services.

3.2 Identification of Stakeholders

3.2.1 Stakeholders identification process

Stakeholders involvement is one the most important aspects of a successful risk governance process (and therefore of the MIDIR Approach): the acceptability of a certain risk (and how to deal with it) is a normative question. In our European societies, governed according to law, such decisions should be based on a wide acceptance among affected persons. Stakeholder involvement raises the quality of the risk governance process and will, as mentioned above, validate the indicators or their measuring values.

3.2.2 Stakeholders identified

In general, it is of high relevance to select “appropriate” stakeholders (administration, experts, population etc.) Here, the following questions could be used:

- Who are the relevant stakeholders?
- Who are their interests and expectations?
- What kind of information is relevant for the stakeholders?
- What kind of dialogue process is suitable /applicable for stakeholder involvement?

This was done in both case studies used in connection with the MIDIR project.

The following were the identified stakeholders:

The IMPACT–Italy Task Force (International Medical Products Anti-counterfeiting Taskforce) composed by: Italian Ministry of Health, Istituto Superiore di Sanità (ISS) – the leading technical and scientific public body of the Italian National Health Service, The Italian Medicine Agency (AIFA) and NAS Carabinieri, a special military branch of Carabinieri corps for the protection of health. The order involved stakeholders were Farindustria, the Italian Association of Pharmaceutical Manufacturers; the Italian Federation of General Practitioners (FIMMG); the Association of Pharmacists of Rome; The Roman Federation of Pharmacists (Federfarma Roma), the Agency for Regional Health Services (ASSR) and former students in the faculties of Pharmacy and Pharmaceutical Chemistry and Technology.

3.2.3 Conclusion

Due to the lack of data regarding the on-line medicines commerce and control institutions in this sector, it was necessary to involve the identified stakeholders in order to overcome resistance and indifference. The stakeholders’ involvement became an integral part of the experimentation stage and an objective of the researchers.

There is a gap between objective and perceived risk. Although the objective risk related to online medicine purchasing is high, the users' real risk perception is low in Italy.

Public Administrations in Italy demonstrated that they do not have a proper strategy to face this risk situation. So, it is necessary to provide policy makers with effective and efficient means to understand the reasons for this gap.

The experimentation of MIDIR methodology, on this case study, becomes the effective strategy which will support Public Administrations.

3.3 Interest and Risk Perception Analysis

3.3.1 *First approach for the involvement of stakeholders*

The identified stakeholders were initially contacted by phone in order to establish an informal contact with them, to show the MIDIR team's real commitment in carrying out the experimentation and clearly explain and make them understand the crucial importance of their involvement in the case study. All of them found the project extremely interesting and immediately showed their interest in participating.

After the first contact by phone, Interviews to the ten stakeholders were carried out face to face individually and elaborated by Regione Lazio, IRPPS (CNR) and LAit.

The MIDIR team asked the same questions to each stakeholder involved.

3.3.2 *Interviews (structure, objectives, evaluation and results)*

The preparation of the interview structure permitted to discuss and decide which were the most important information to know about the arguments treated.

The following was the layout used:

INTERVIEW STRUCTURE:

Risk perception

Regarding the arguments:

- Which is the perception that people have about the specific risk?
- Which effects do you expect? What do you expect from the measures/activities?

Activities developed in the reference field

Regarding the roles of the organisation:

- Which role do you assign to your organisation in the risk governance process?
- Which role/responsibility do you assign to the other relevant stakeholders?"

Suggestions

With a view to the follow-up activities for the specific topic:

- What determines the further procedure / the information policy / the dialogue between stakeholders in your opinion?
- Which topics / questions should be handled and how?

The complete questionnaire (in Italian) is attached as Appendix 6.1.

EVALUATION OF INTERVIEWS

After all the interviews were carried out, they were evaluated and all relevant aspects were listed and analyzed.

The results of the interviews were the starting point for the selection of Part A and Part B Indicators (additional indicators for the specific risk).

Interviews with stakeholders showed that the risk of purchase of medicines via the internet carried out through non-official distribution channels can be considered as potentially high because of:

- fraud,
- forged drugs purchase,
- lack of quality checks,
- lack of origin guarantee,
- drug composition and conservation,
- the potential client is missing information by doctors and pharmacists about consumption,
- interactions with other drugs and counter-indications.

Stakeholders were interested in a dialogue among the involved parties as a chance to work on a risk reduction. They suggested an awareness campaign about the seriousness of the problem with specific communication for different target groups (e.g. at school, in sport centres etc).

3.4 Implementation of MIDIR concept

3.4.1 Meeting with all stakeholders

On April 21, 2008 in Rome, a meeting was organized to discuss the results of the first 3 stages of the case study, discuss the MIDIR concept and to decide the guidelines of the treated arguments.

The stakeholders who participated in the meeting were:

1. **Ministero della Salute** – Dott.ssa Maria Terracciano
2. **Istituto Superiore di Sanità, ISS** – Dott.ssa Luisa Valvo
3. **Agenzia Italiana del Farmaco, AIFA** - Dott. Domenico Di Giorgio
4. **Farindustria** – Dott.ssa Monica Vignetti, Dott.ssa Rita Pelaia
5. **Federfarma Roma** – Dott. Roberto Dominici
6. **Federazione Italiana Medici di Famiglia, FIMMG** – Dott. Alberto Chiriatti
7. **Laureati in Farmacia e Chimica e Tecnologia Farmaceutiche**: Dott. Claudio Vari, Dott.ssa Angela Rotundo, Dott. Carmine Cavour Caruso, Dott. Fabio Carpineta

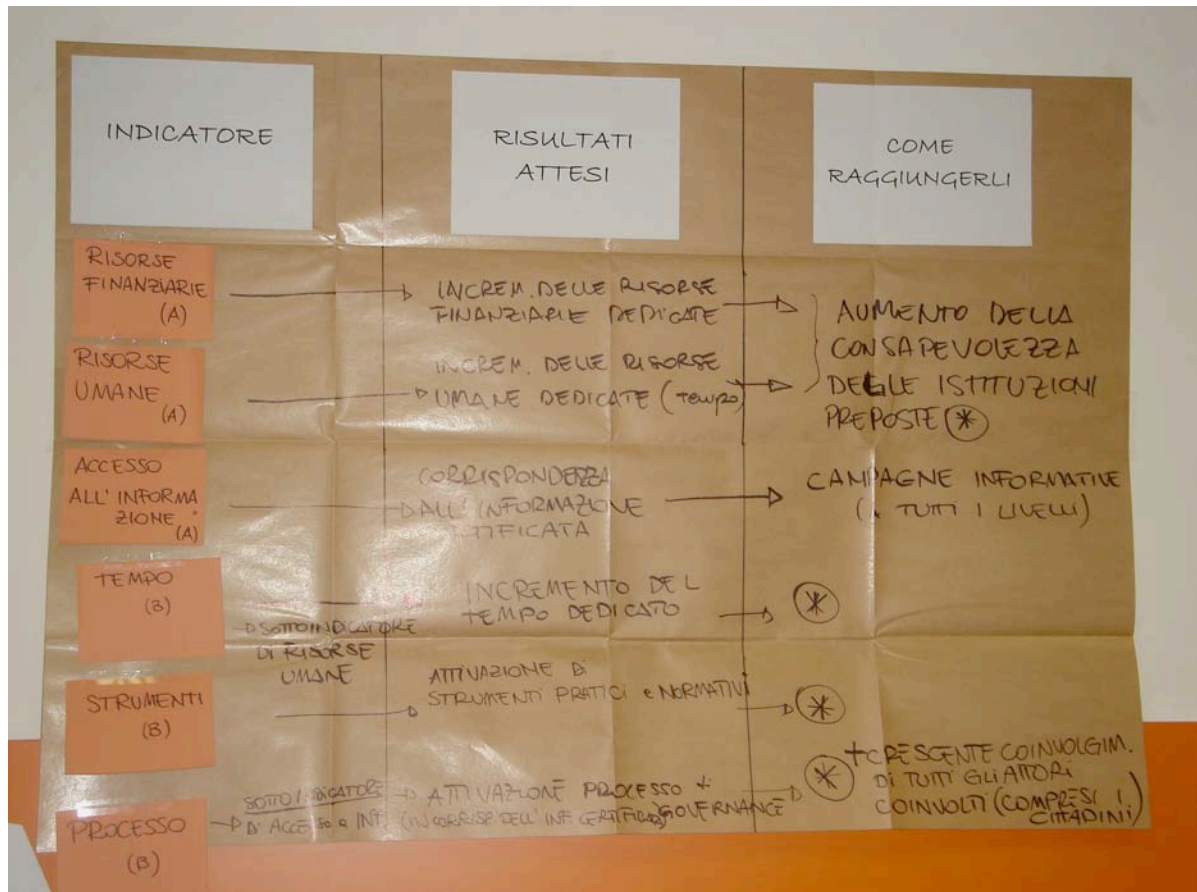
The following were the main topics discussed:

- The relevance of MIDIR within the policies of the Regional Ministry for Consumer Protection and Administrative Simplification;
- Presentation of the stakeholders involved in the case studies and presentation of interviews results;

- Presentation of MIDIR concept and Part A indicators;
- Selection of Part A and Part B indicators by stakeholders;
- Presentation of the on-line questionnaire developed by IRPPS;
- Presentation of the Risk Community in SINAPSE.

3.4.2 Selection of part "A" and part "B" indicators

During this unit the team's work was oriented to discuss the indicators involved in the risk perception about health risk due to ecommerce, the expected results and how to reach them.



The MIDIR Team facilitated the stakeholders in the selection of the indicators through the following questions:

1. Which are the most adequate indicators for the analyzed risk scenario?
2. Which are the expected results for each one of the Part "A" selected indicators?
3. Describe the process through which it is possible to reach the expected results.

These are the results of the discussion:

PART "A" INDICATORS

| PART "A" INDICATORS | EXPECTED RESULTS | HOW TO GET THERE |
|----------------------------|---|--|
| Financial resources | Increase in targeted financial resources | Increase of awareness in the institution in charge |
| Human resources | Increase in targeted human resources (also in term of time) | Increase of awareness in the institution in charge |
| Access to information | Correspondence with certified information | Awareness campaigns at all levels |

PART "B" INDICATORS

| PART "B" INDICATORS | EXPECTED RESULTS | HOW TO GET THERE |
|---|---|---|
| Time | Increase in dedicated time | Increase of awareness in the institution in charge |
| Tools | Activation of practical legislative tools | Increase of awareness in the institution in charge |
| Process (to be considered as a sub-indicator of "Access to information") | Activation of the process' governance (with respect to certified information) | Increase of awareness in the institution in charge and increasing involvement of interested parties |

3.5 Bottom up risk perception analysis: Focus Group**3.5.1 Introduction**

The choice of Focus groups technique allows interviewers to study people in a more natural setting than a one-to-one interview. In combination with participant observation they can be used for gaining access to various cultural and social groups, selecting sites to study, sampling of such sites, and raising unexpected issues for exploration. Focus groups have a high apparent validity - since the idea is easy to understand, the results are believable. They are frequently used in the social sciences and urban planning.

3.5.2 Methodology

The **focus group** is a form of qualitative research in which a group of people is asked about their attitude towards a product, service, concept, advertisement, idea or packaging. Questions are asked in an interactive group setting where participants are free to talk with other group members. There are usually 6 to 10 members in the group and the session usually lasts from 1 to 2 hours. A moderator guides the group through a discussion that probes attitudes about a client's proposed products or services. The

discussion is loosely structured and the moderator encourages the free flow of ideas. The moderator is typically given a list of objectives or an anticipated outline. He/she will generally have only a few specific questions prepared prior to the focus group. These questions will serve to initiate open-ended discussions.

The observer organizes the site and records the session, follows the discussion in silence observing non-verbal communication. At the end of the session the moderator and the observer discuss and compare their impressions.

Researchers examine more than the spoken words. They also try to interpret facial expressions, body language and group dynamics. Moderators may use straight questioning or various projective techniques, including fixed or free association, story-telling and role playing. Focus groups are often used to garner reaction to specific stimuli such as concepts, prototypes, advertising and video.

3.5.3 Focus Group Instrument Development

Focus group discussion guides were developed by the focus group researchers from recommendations of members of the MIDIR Project LAit Lazio Innovazione Tecnologica, Lazio Region and IRPPS.

The guides were then reviewed in order to select participants.

A short participant information form was developed by phone before inviting the participant to the focus group discussion.

Both the participant information form and the discussion guide were prepared on the basis of the results of stakeholders interviews and of the meeting of all the stakeholders and the selection of the indicators "Part A" and "Part B".

Site Selection

The meeting room of LAit in Rome was selected as the focus group site. The focus group was invited at 5.30 p.m., the discussion lasted approximately 2 hours and had a coffee break to make the situation informal and friendly.

Participant Recruitment

Participants were recruited by Dr Paola Enrico, LAit employee.

A screener form was developed to obtain a desired demographic profile representative of citizens that was male and female – 18 – 70 years – internet users.

Twenty people were initially screened to identify potential participants who met age, habits and educational level requirements. These individuals were then screened a second time and 10 were identified to obtain the desired subgroup mix.

Focus Group

One focus group was conducted at the site on May 27, 2008.

The group was deliberately arranged. Participants did not know each other. Experience in working with focus group indicates that people are less

reticent to share their opinions and experiences if they do not know each other. Also, they are more likely to share information about women-specific issues or family problems.

The focus group was conducted in Italian and lasted approximately 2 hours. The focus group discussion was tape recorded and later transcribed.

Demographics

9 people participated in the focus group. Of this number, 5 people were female and 4 were male. The focus group participants ranged in age from 18 to 70 years.

Table 1 delineates these ranges.

Table 1: Participants' Age

| Age Range | Percentage |
|----------------|------------|
| 18 to 29 years | 2 |
| 30 to 49 years | 4 |
| 50 to 70 years | 3 |

Employment

3 people were retired, but involved in some social or working project, 1 person was unemployed, 2 people were employees in private companies, 3 people were freelance.

Marital Status and Number of Children

5 of the participants were married, 3 people were single, 1 person was divorced. The number of children that the participants had ranged from none to seven children.

Internet use

All the participants use internet, most of them since 10 or 15 years. They use email to communicate and google or other to explore internet.

Language preferences

| Language preferences | percentage |
|----------------------|------------|
| Only Italian | 100% |
| English | 60% |
| Other languages | 30% |

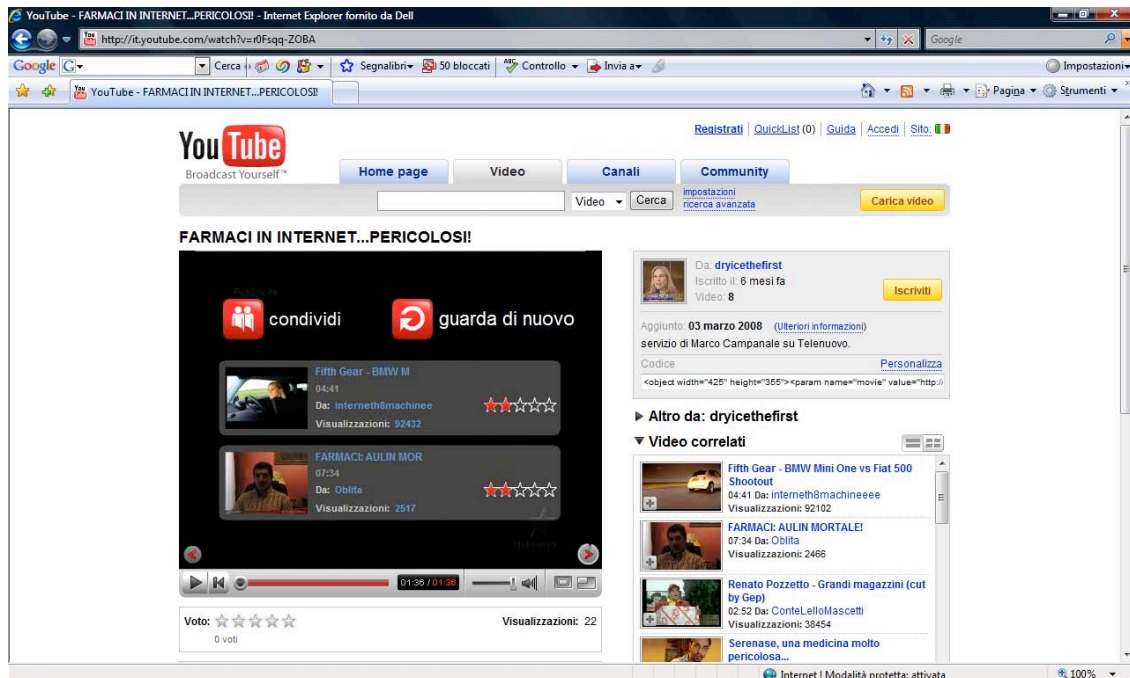
3.5.4 Focus Group Discussion Guide

DISCUSSION QUESTIONS

- 1. Purchase health medicines via the internet: opportunities and threats?**
- 2. Who are the potential risk consumers – fraud and forgery?**
- 3. Pharmaceutical market deregulation?**
- 4. Which type of medicines are suitable to eCommerce?**
- 5. Authorities: which role and what are the suggestions?**

1. Purchase health medicines via the internet: opportunities and threats

The first argument of discussion was introduced by the vision of a video via the internet in YOU TUBE (Interview of Francesca Martini, Regional Minister in Veneto in 2001).



The majority of the group discussed the video and most of them defined impossible or very difficult to purchase medicines via the internet. They told it will be very dangerous because of the risks for the quality of the products. They told that no rules exist about purchase of medicines on-line and this was perceived with uncertainty and risky.

"The purchase of medicines without guarantees permit to be free, to be independent, but risky" (female, 43 years)

"There isn't control on medicine quality?" (female, 49 years)

"Purchase medicines via the internet is mad, health is too important for me, it's very unwise" (male, 29 years)

"If someone is so stupid to purchase medicine via the internet has to die...." (male, 70 years)

"I'm not sure to buy medicines without guarantees or the consultancy of the pharmacist" (female, 57 years)

The discussion continued talking about opportunities of the internet: autonomy and anonymous client buying, good prices.

"I was born in a village in Calabria where people are ashamed to buy particular medicines, Viagra or pill for example. Probably for this reason the purchase via the internet from these villages is spread" (female, 29 years)

"Via the internet medicines are economic, this probably people value for their budget" (female, 49 years)

2. Who are the potential risk consumers – fraud and forgery

The group indicated three different type of risk consumers : children, senior and sick because they are vulnerable. To explain their opinions the participants told personal experiences.

"Children are the most vulnerable, because if they are not controlled, they risk to face dangerous realities. We must consider poor families...." (female, 29 years)

"My daughter is 12 years old, she uses msn since one month but my nephews (6 and 10 years old) who live in Milan, are totally free to use internet" (female, 43 years)

"..... we begin to use internet late compared to new generation, we were fifteen or eighteen years old..." (male, 31 years)

Most participants agreed that elder people risk more as very young people or children because they are not well users of internet.

"..Senior can buy via the internet because it's easy and economic" (female 57 years)

" ...people sixty years old could be interested to buy viagra and cialis..." (female 57 years)

The moderator asked the group which type of medicines interest young people.

The group answered:

- New drugs;
- Stimulating Medicines;
- Medicines to loose weight.

3. Pharmaceutical market deregulation

The moderator asked the group about their opinions on the recent law for the deregulation of medicines sale.

Most participants explained that while the pharmaceutical industries agree with the government, on the contrary the pharmacists consider the possibility to buy medicines on-line something impossible to control.

They also think that the sale in the supermarket should only be possible if a pharmacist is present.

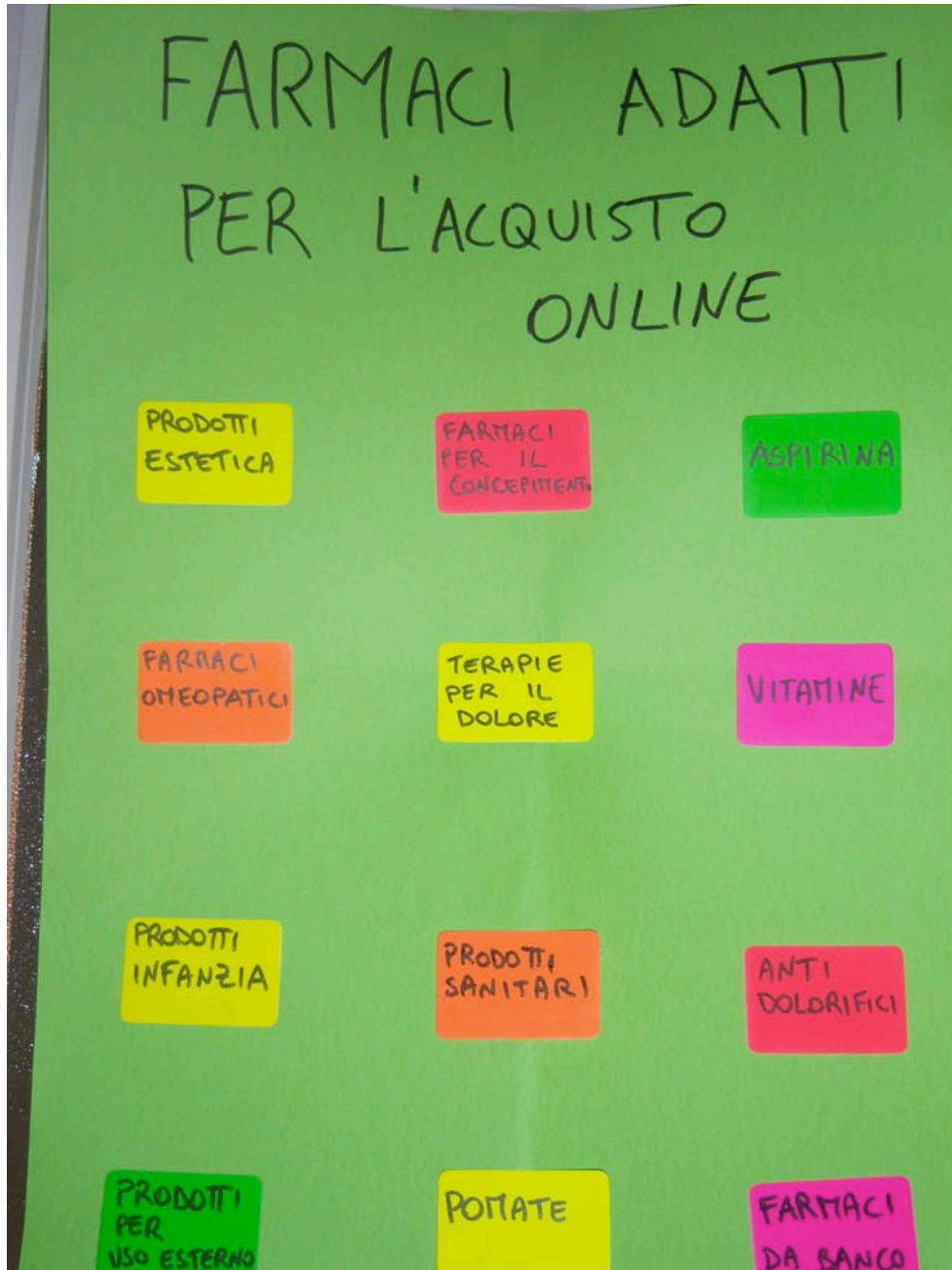
4. Which type of medicines are suitable to eCommerce

Every participant decided which type of medicines would be suitable to eCommerce and wrote their decision on a post-it. Afterwards they discussed their proposals in two small groups.

Suitable medicines to be sold on-line, as suggested by the group, were:

- Aspirin;
- Vitamins;
- Medicines for pain;
- Children products.

- Health products;
- Aesthetic products;
- Homoeopathy medicines;
- Creams;
- Medicines to conceive;
- Contraceptives.



" some products can be sold via the internet but the risk of fraud is high..." (one group)

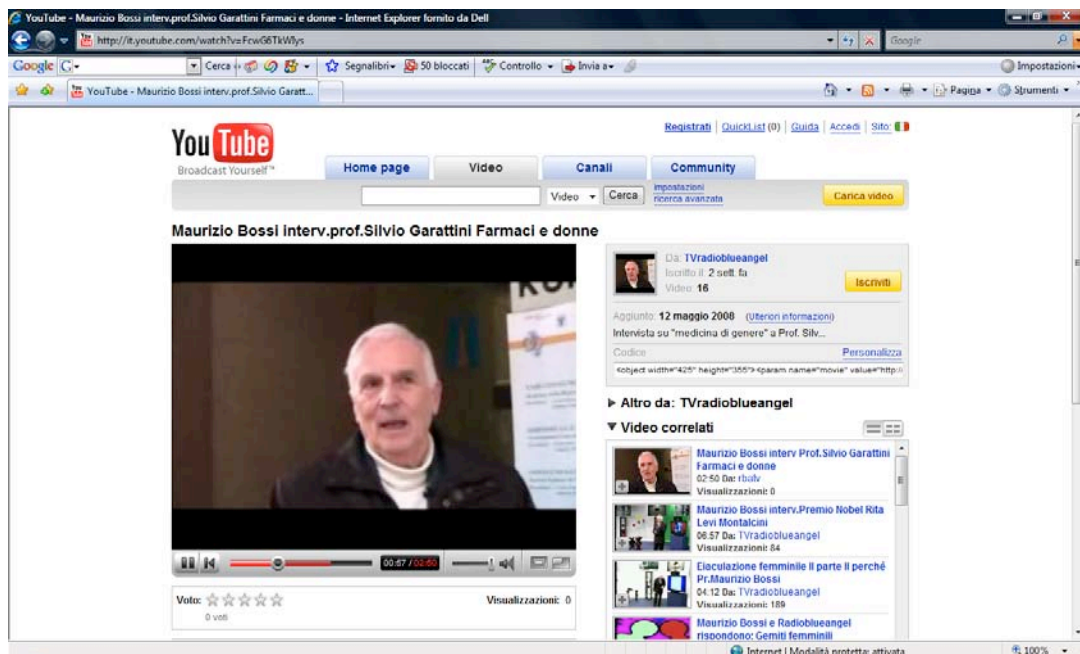
"Today I can't buy anything, but if a pharmacy with the doctor will be on-line, probably everything could be sold via the internet"
(female 49 years)

"The guarantee of the seller is necessary" (one group)

Most of the group reported that even the traditional pharmacy has lacks: they give you medicines without prescriptions and other cases that although people need a medicine the pharmacist say no.

Medicines and women

One more video was shown to the group. Sivio Garattini was interviewed about medicines and women. He said "medicines have different effects on men and women. Women use more medicines." The group agreed with the opinion expressed in the video and told to the others information about the habits in their family. Who use medicines, who buys them. The result of the discussion is that women buy medicine in the family, they take care of themselves, instead men are afraid about sickness.



"...Women take care of themselves because they need to be well"
(female, 43 years)

"..women tolerate pain more than men" (female, 43 years)

" I'm afraid about sickness so I use many medicines" (male, 31 years)

"In my family my wife buy medicines, we use them following the prescriptions of the doctor" (male, 70 years)

5. Authorities : which role and which are the proposal

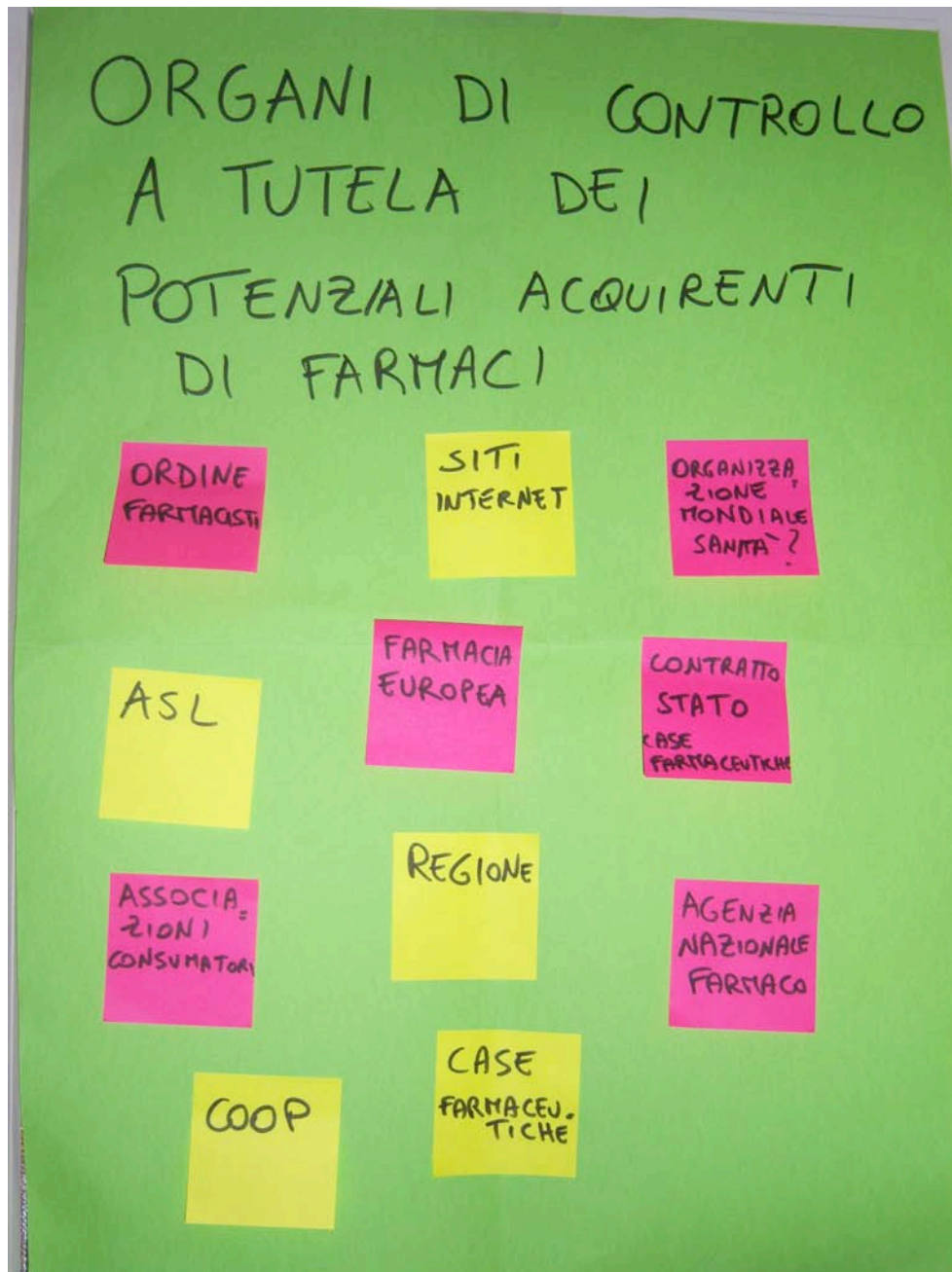
In the last part of the focus group discussion the moderator proposed to discuss which role and who would be the authorities that could control the medicine market via the internet.

"...Agenzia nazionale del farmaco, in general as guarantee,... who sell medicines to the website, ...Coop or others ,... web site etc"
(male, 42 years)

"... Who control the ecommerce medicines market, Ordine dei Farmacisti" (female, 49 years))

" For me the Region must be the controller" (female, 57 years)

" It's necessary to create consumer association that like in Tourism and commerce register all the sales and conserve memory" (female, 49 years)



"World Health Organisation must control the medicines and their component" (male, 42 years)

"It's also possible that pharmaceutical industries control each other the medicines..." (female, 57 years)

" a European market of medicine must be controlled by the creation of a European Pharmacy" (female, 43 years)

"the same medicine in France costs less, so for me the government must control the pharmaceutical industries " (male, 43 years)

In the conclusions one of the participant explained that the most important thing would be to be informed and have access to information. Knowledge is the basis for trust and certainty.

It will be necessary to know specialized websites to purchase medicines on-line.

The trust in the authorities is very low.

The traditional Pharmacy is considered the most safety way to buy medicines today, however they do not exclude the possibility to use the internet if the products are cheap.

4 Transferability of the MIDIR methodology to European level

The methodology elaborated in the MIDIR project was tested in the real decision-making settings of existing risk management systems, by the example of two emerging risks with a high degree of uncertainty and ambiguity:

- risks related to criminals under hospital treatment order in Germany;
- risks due to illegal e-commerce of drugs in Italy.

As described in section 3, the main goal of the Italian case study was to assess the MIDIR approach on a new and emerging risk with minimal information and low awareness, that is the risk for health due to illegal e-commerce of drugs.

Section 3.3 described the interviews carried out to the Italian stakeholders and illustrated the six indicators of the MIDIR methodology chosen to monitor and evaluate the risk governance process in the field of e-commerce of drugs.

In the following sections we will illustrate the involvement of European stakeholders of pharmaceutical field, in order to test and verify the transferability (to European level) of the proposed MIDIR methodology applied to the field of e-commerce of drugs, with particular reference to the six indicators chosen by Italian stakeholders.

The transferability assessment has been carry out in three steps:

- First step: identification of stakeholders among experts of different associations of pharmaceutical field;
- Second step: implementation of a questionnaire to the European stakeholders;
- Third step: analysis of answers of stakeholders.

4.1 Identification of European stakeholders

We carried out an analysis of the European scenario to identify stakeholders to involve in the transferability task. Experts and representatives of the following fields have been contacted:

- Pharmaceutical Group leaders;
- National or Local Health Authorities;
- European Medicines Agency;

- Pharmaceutical Information and Pharmacovigilance association;
- International Medical Products Anti-counterfeiting Taskforce;
- European Association of Hospital Pharmacists;
- Pharmaceutical Association of European countries;
- Chamber of Pharmacists of European countries;
- Order of Pharmacists of European countries.

Therefore, a steering committee was founded, consisting of organizations shown in Table 1.

Table 1: Stakeholders involved in the European steering committee.

| Name | Organisation | Country |
|------------------------------|--|----------------|
| Roberto Frontini | EAHP - European Association of Hospital Pharmacists | Germany |
| Hervé de la Bardonnie | ANEPF – National Association for Studies on Pharmacy in France | France |
| Nikoleta Chojnacka | Ministry of Health | Poland |
| Rob Darracott | CEO - Company Chemists' Association. | United Kingdom |
| Emil Hristov | Bulgarian Drug Agency | Bulgaria |

The steering committee contributed:

- to test and assess the MIDIR indicator system for the management of risk due to illegal e commerce of drugs, and
- to develop ideas to improve the MIDIR methodology in the specific risk setting.

In the first involvement of the steering committee we explained the main objectives of the project and the methodological aspects of the MIDIR Risk Governance Approach. Successively, the steering committee was involved in the filling of a questionnaire, whose structure will be described in detail in the following section.

4.2 Implementation of a European questionnaire

The structure of the questionnaire is composed of three sections:

- A) Test and evaluation of the subset of indicators selected by Italian stakeholders involved in the case study on risks due to illegal e-commerce of drugs;

- B) Indicators selection: it allows stakeholders to give a feedback on the whole Indicator system, (composed of twelve PART A indicators), in order to complete and improve the standard set of six indicators, previously analysed and assessed;
- C) Proposals of new indicators: in this section, the suggestion or proposal of new indicators, that are not part of the MIDIR indicator system, can be given.

The content of each section is described in more detail below.

- A) The section on the *Evaluation process* is composed of twelve questions. In particular, we asked stakeholders to evaluate the part A KPIs (Access to information, Financial Resources and Human Resources) and the three part B KPIs (Time Resources, Equipment/Tools and Process) chosen by stakeholders of the Italian case study. To allow stakeholders to answer to the questions, two tables are used, which summarize the description of all PART A Key Performance Indicators and the three proposed Part B Key Performance Indicators. Table 2 shown the twelve MIDIR Part A Key Performance Indicators, in which the three indicators chosen by stakeholders of the Italian case study are highlighted.

Table 2: MIDIR Part A Key Performance Indicators

| KEYWORD | KEY-QUESTION | OBJECTIVES | POSSIBLE ASSESSMENT BASIS |
|-------------------|--|--|---|
| PRINCIPLES | What are the guiding principles? | The main aspect of this indicator is the question how it should be dealt with the existing risks. Is it clear and defined what the action is aiming at (e.g. resilience)? Is the vision shared by all involved groups? Is there an alignment of principles? This can be formulated by a guiding principle. The indicator is positive, if guiding principles are defined and a consistent system of objectives exists | <p>Red = no guiding principles</p> <p>Orange = discussion process about guiding principle started</p> <p>Yellow = all guiding principles are defined</p> <p>Green = discussion concerning the „target system“ started</p> <p>Blue = principles through a consistent system of objectives – which is continuous reviewed and if applicable adjusted – are implemented</p> |
| TRUST | How far is attention paid to relevance of an atmosphere of mutual respect and trust? | The indicator shows if the necessary steps to build an atmosphere of trust and mutual respect have been considered. Key words: competence, fairness, efficiency. | <p>Red = not to broach the issue of trust</p> <p>Yellow = trust is discussed on a case by-case basis</p> <p>Blue = trust is systematically reflected and if applicable trust-building measurements are made</p> |

| | | | |
|---------------------------------|--|--|---|
| OBJECTIVES | What are the concrete protection goals for subjects of the protection? | The indicator is positive, if an agreement concerning protection goals for the relevant subjects of protection compared with a defined risk exist (through a "target system"). | <p>Red = subjects of protection and protection goals are not defined</p> <p>Orange = process of discussion concerning the subjects of protection and protection goals is initiated</p> <p>Yellow = subjects of protection and protection goals are defined</p> <p>Green = obligation for protection goals is regulated</p> <p>Blue = protection goals are continuous reviewed and if applicable adjusted</p> |
| ACCOUNTABILITY PRINCIPLE | How far is accountability defined at each level (process, each risk)? | Indicator shows how far the responsibilities are clearly defined ("clear responsibility of stewardship"). This is important for a good as well as successful risk governance process. | <p>Red = responsibilities are not defined</p> <p>Orange = Process of discussion concerning the definition of responsibilities started</p> <p>Yellow = responsibilities are defined</p> <p>Green = responsibilities are implemented</p> <p>Blue = responsibilities are continuously reviewed and if applicable adjusted</p> |
| JUSTIFICATION | How far is the activity concerning the management of existing risks justified? | The indicator shows how far governmental action is justified. The questions behind are: Why is there a need of governmental action concerning risks? Why shall the individual accept constraints concerning his own decisions? | <p>Red = no justification</p> <p>Orange = discussion about the justification started</p> <p>Yellow = justification exists</p> <p>Green = justification as a part of obligatory arrangements</p> <p>Blue = existing justification is continuously reviewed and if applicable adjusted</p> |
| REPRESENTATION | How far are all relevant social groups (and their representatives, stakeholder respectively) and their expectations known? | The main aspect of this indicator is the question, if all social groups and their expectations are known. This will avoid that no group is passed over. Stakeholder that were not considered may interfere the risk governance process and this could lead to conflicts. | <p>Red = neither social groups nor their expectations are known</p> <p>Orange = process of the "Stakeholder-Identification" (e.g. through an Interest-Analysis) started</p> <p>Yellow = social groups are known</p> <p>Green = stakeholders' expectations are known (Interest-Analysis is finished)</p> <p>Blue = continuous monitoring of the expectations is implemented</p> |

| | | | |
|--|---|--|--|
| ACCESS TO INFORMATION | How far is information for all stakeholders accessible? | Although a permanent information flow could be organised e.g. by the internet it is very important to actively inform stakeholders by regular meetings and discussions because they guarantee the communication flow in both directions. The higher the share of involved stakeholders is, the better the indicator performs. It is required that all relevant stakeholders are involved because the share alone does not show if the most relevant stakeholders in the end are really involved. | <p>Red = risk information is not available/accessible</p> <p>Orange = discussion about the intermediation concerning the risk information started</p> <p>Yellow = guidelines for information-policy are available</p> <p>Green = guidelines for information-policy are applied</p> <p>Blue = continuous quality control (understandability and availability of information)</p> |
| TOLERANCE PROCESS & OUTCOME | How far do the stakeholders tolerate/accept the risk governance process and its outcomes? | Tolerance in the process and outcome can be described as a result of creating an atmosphere of trust and mutual respect. | <p>Red = tolerance/acceptance of the process & outcome are ignored</p> <p>Orange = discussion about the establishment of tolerance/acceptance started</p> <p>Yellow = criteria concerning the measurement of tolerance/acceptance defined</p> <p>Green = measurement of tolerance/acceptance is part of the process</p> <p>Blue = deficiency of tolerance/acceptance leads to the revision of the process and/or its results.</p> |
| DIALOGUE | To what extent is a constructive dialogue with the relevant stakeholders available or conducted? | Compilation of the dialogue-quality with the stakeholder. The following dialogue-concepts are possible: information (rising of the level of information), consultation (receive important suggestions), cooperation (collective elaboration of topics and proposals), collaboration (collective creation and decision-making) | <p>Red = no discourse available</p> <p>Orange = discussion about the initiation and elaboration of discourse processes has started</p> <p>Yellow = Interests and expectations concerning the discourse processes are known</p> <p>Green = Dialogue concepts are accepted by the participants</p> <p>Blue = discourse processes are an integral part of a risk governance process and are consequently reviewed</p> |
| FINANCIAL RESOURCES | To what extent do the available financial resources meet the requirements of the defined Risk Governance Process? | The concepts and ideas for a successful risk governance process and the available financial resources concerning the realisation of measures have to be concerted. | <p>Red = Costs and benefits of the risk governance process are not monetized</p> <p>Orange = Calculation of costs and benefits is initiated</p> <p>Yellow = relationship of costs and benefits is transparent</p> <p>Green = financing is possible</p> <p>Blue = sufficient funds are available, the requirements are continuously reviewed and if applicable adjusted</p> |

| | | | |
|------------------------|--|--|--|
| HUMAN RESOURCES | To what extent do the human resources (technical qualification and number of people) meet the requirements of the defined Risk Governance Process? | The concepts and ideas for a successful risk governance process and the available human resources concerning the realisation of measures have to be concerted. | <p>Red = no consideration concerning human-resource allocation available</p> <p>Orange = conception of a required human-resource allocation is initiated</p> <p>Yellow = quantity and competences are defined (staff appointment scheme)</p> <p>Green = selection procedure is working</p> <p>Blue = adequate personnel resources are available, are continuously reviewed and if applicable adjusted</p> |
| ROLE | How far has the role of experts been defined? | Often there is the problem that experts are asked (e.g. in committees) although a political answer is needed. Experts cannot answer questions about the acceptable risk because this is a question the society has to answer. Thus the role of experts shall be to give expertise but not to make decisions of political character. It is important that the role of experts is not just defined but how it is defined | <p>Red = experts' role not defined</p> <p>Orange = definition of the problems/questions and requirements concerning (external) expertise, e.g. science advisor, communication consultant, evaluator</p> <p>Yellow = possible experts known (names)</p> <p>Green = experts' role and concrete persons meet the acceptance of the process participants</p> <p>Blue = expertise is integrated into ongoing processes, incl. Performance review</p> |

Table 3 shown the three Part B Key Performance Indicators defined by Italian stakeholders.

Table 3: Part B Key Performance Indicators

| KEYWORD | KEY-QUESTION | OBJECTIVES | POSSIBLE ASSESSMENT BASIS |
|-----------------------|--|--|---|
| TIME RESOURCES | How far is there calendar time to meet the governance process defined? | The concepts and ideas for a successful risk governance process according to temporal constraints concerning the realisation of measures have to be concerted. | <p>Red = no consideration concerning calendar time available</p> <p>Orange = calculation of a calendar time is initiated</p> <p>Yellow = the calendar time is defined</p> <p>Green = a study for evaluating the feasibility of the calendar time with relation to the personnel and financial resources is working</p> <p>Blue = adequate temporal allocation of resources is available, temporal constraints are continuously reviewed and if applicable adjusted</p> |

| | | | |
|------------------------|---|--|--|
| EQUIPMENT/TOOLS | How far do the equipment resources available meet the needs of the governance process defined? | The concepts and ideas for a successful risk governance process and the available equipment resources concerning the realisation of measures have to be concerted. | <p>Red = no consideration concerning equipment resources allocation available</p> <p>Orange = conception of required equipment resources allocation is initiated</p> <p>Yellow = all required equipment resources/tools are defined</p> <p>Green = supply procedure is working</p> <p>Blue = adequate equipment resources are available, are continuously reviewed and if applicable adjusted</p> |
| PROCESS | How far is there a risk governance process – e.g. objective/indicator – measurement – review – analysis – action plan – learn – repeat – improve? | The indicator shows if the necessary steps of the risk governance process have been defined and accomplished | <p>Red = phases of the risk governance process are not defined</p> <p>Orange = process concerning the definition of risk governance phases started</p> <p>Yellow = phases of the risk governance process are defined</p> <p>Green = phases of the risk governance process are applied</p> <p>Blue = risk governance phases are continuously reviewed and if necessary adjusted</p> |

The questions about the relevance of the indicators in the monitoring of risks due to illegal e-commerce of drugs, are composed of seven possible answers: Strongly relevant, Moderately relevant, Slightly relevant, Undecided, Slightly irrelevant, Moderately irrelevant and Strongly irrelevant. The appropriateness of the key-question, objectives and possible assessment basis, used to describe the six indicators, are measured by seven other values: Strongly adequate, Moderately adequate, Slightly adequate, Undecided, Slightly inadequate, Moderately inadequate, Strongly inadequate.

- B) The section on *Indicators selection* contains the list of twelve indicators that stakeholders can choose, if necessary, in order to complete and improve the standard set of six indicators, previously analysed and assessed.
- C) In the section on *Proposals of new indicators*, stakeholders can freely suggest further indicators, that are relevant to monitor the risks due to illegal e-commerce of drugs and that are not part of the twelve PART A indicators. Moreover, they can define the appropriate objectives, key-question, and possible assessment basis for the new proposed indicators.

The complete questionnaire can be found in Appendix 6.2

4.3 Analysis of European questionnaires

Stakeholders involved in assessment of the MIDIR methodology, in particular in evaluation of the indicators applied to the case study on risks due to illegal e-commerce of drugs, evaluated as relevant or adequate the proposed indicators and related key questions, objectives and possible measuring value.

The following table shows in detail the answers given by single stakeholders.

Table 4 – Answers given by European stakeholders

| | Value 0 | Value 1 | Value 2 | Value 3 | Value 4 | Value 5 | Value 6 |
|----------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|--------------------|
| Question n.1 | | | | | | 2 | 3 |
| Question n.2 | | | | | 1 | 2 | 2 |
| Question n.3 | | | | | | 1 | 4 |
| Question n.4 | | | | | | 3 | 2 |
| Question n.5 | | | | | | 1 | 4 |
| Question n.6 | | | | | 1 | 2 | 2 |
| Question n.7 | | | | | | 4 | 1 |
| Question n.8 | | | | | 1 | 2 | 2 |
| Question n.9 | | | | | 1 | 1 | 3 |
| Question n.10 | | | | | 1 | 1 | 3 |
| Question n.11 | | | | | 1 | 1 | 3 |
| Question n.12 | | | | | 1 | 2 | 2 |

Value 0 = Undecided

Value 1 = Strongly irrelevant / inadequate

Value 2 = Moderately irrelevant / inadequate

Value 3 = Slightly irrelevant / inadequate

Value 4 = Slightly relevant / adequate

Value 5 = Moderately relevant / adequate

Value 6 = Strongly relevant / adequate

(see appendix for whole questionnaire).

Following the structure of the questionnaire, in the section on the **evaluation process** stakeholders gave a positive feedback about the relevance of the three part A indicators. In particular, most of stakeholders evaluated the indicator "*Access to information*" as strongly relevant. The related key-question, objectives and possible assessment basis have been evaluated as strongly and moderately adequate. The indicator "*Financial Resources*" has been evaluated strongly relevant by most of involved stakeholders, while the related key-question, objectives and possible assessment basis have been evaluated as moderately and strongly

adequate. Moreover, the indicator "*Human Resources*" has been evaluated strongly relevant by most of involved stakeholders, strongly and moderately adequate the related key-question, objectives and possible assessment basis.

Concerning the three Part B indicators, stakeholders gave a positive evaluation. In particular, the indicator "*Time Resources*" has been evaluated by European stakeholders as moderately relevant, while the related key-question, objectives and possible assessment basis have been evaluated as strongly and moderately adequate. Finally, the indicators "*Equipment/tools*" and "*Process*" have been evaluated as strongly relevant, and the related key-question, objectives and possible assessment basis as strongly adequate.

The second section on **indicator selection** allowed stakeholders to suggest other indicators from the PART A indicators, in addition to the six proposed indicators. In particular, all stakeholders suggested to add the indicator Principle, whereas two stakeholders suggested the indicator Accountability principle. They focussed on the importance of exactly defining the rules of actions and to give clearly defined responsibilities to the actors involved in the governance process. Finally, other suggested indicators are: Trust, Tolerance process & outcome, Dialogue, Objectives and Role.

In the third section on **Proposals of new indicators**, stakeholders didn't suggest further indicators.

The evaluation of the transferability to European level leads to the conclusion that the elaborated methodology is appropriate for a successful risk governance process and is well-applicable to monitor risks due to illegal e-commerce of drugs.

5 General conclusions

The issue addressed in the case study on health risks due to eCommerce is very peculiar. The protection of citizens' health has always been a very delicate matter, it involves many different interests and many stakeholders are involved in this subject.

Therefore, the preliminary analysis of the national scenario and the identification of the stakeholders was quite a complicate phase of the case study and represented a very important part in the entire process.

In addition, there are so many information available and often they are fragmented, especially when we are dealing with the on-line dimension.

Moreover, the on-line purchasing of medicines is quite an emerging phenomenon in Italy. For this reason, besides the above mentioned initial hindrances, the MIDIR project and, specifically the subject addressed, aroused a very strong interest among the involved stakeholders, because they really understood the relevance to be involved in such an important process in its very early stage of development.

From the involvement of stakeholders belonging to the pharmaceutical field in the case study "health risks due to eCommerce" some important aspects emerged.

Depending on the role that stakeholders play in the risk governance process and the kind of risk taken into consideration, some indicators can turn out to be self-referential. In order to have a completely objective selection of the indicators, all interested parties should be involved. That could not be the case of this case study because it would have been impossible to involve the entire range of interested parties and to implement the MIDIR concept together with all of them. Therefore, the MIDIR team had to reduce the selection of stakeholders to the pharmaceutical/health sector in the first part of the case study. In the second part the MIDIR team collected information from a group of citizens through a focus group, in order to have a balanced feedback, both from stakeholders and from common people.

The selection of stakeholders and their involvement in the implementation of the MIDIR methodology needs to take into account the role of each stakeholder, assigning him a different "weight". The involved stakeholders suggested to define some parties as "stakeholders", because they regulate the market, while others need to be considered as "observers".

They also expressed the need for a dialogue among all interested parties as a chance to front the illegal online selling of drug items from the very beginning of the process.

The results of the Italian case study were transferred to European level in order to test and assess the applicability and relevance of the MIDIR methodology in the specific risk setting (illegal e-commerce of drugs) and European scenario. Stakeholders involved in this evaluation phase highlighted the adequateness of the MIDIR indicator system and regarded the methodology as valid and applicable in the management of risks due to illegal e-commerce of drugs, focusing on the importance of combining the methodology with the definition of accurate rules of actions and responsibilities for the actors involved in the governance process.

One of the main positive output of this case study and its transferability to European level was represented by the opportunity of all the involved stakeholders to start to establish a dialogue among them and the Public Administration, to raise awareness among citizens through communication activities and to begin to address the problem from its very early stages, performing an effective risk governance process thanks to the implementation of the MIDIR concept.

6 Appendices

Text of the Interview to stakeholders (in Italian)**INTERVISTA AGLI STAKEHOLDER**

Stakeholder intervistato:

Organizzazione:

Luogo dell'intervista:

Data:

Intervistatore/i:

Note:

A) PRESENTAZIONE

A.1) Ci può dare una breve descrizione della sua organizzazione?

B) PERCEZIONE DEL FENOMENO

B.1) Cosa ne pensa della vendita di farmaci on-line?

B.2) Secondo Lei esistono rischi? Quali sono?

B.3) Secondo Lei esistono dei vantaggi? Quali sono?

C) ATTIVITA' SVOLTE SUL TEMA

- C.1) Avete lavorato nello specifico su questo tema?
- C.2) La sua Organizzazione ha un ruolo attivo sul tema specifico? Se sì, quale?
- C.3) Che tipo di strategie avete adottato?
- C.4) Che tipo di risultati avete ottenuto?
- C.5) Quali altre Organizzazioni ritiene siano coinvolte sul tema? In che modo?

D) SUGGERIMENTI E PROPOSTE DI SVILUPPO

- D.1) Vi sentite di suggerire proposte per diminuire i rischi legati al fenomeno?
- D.2) Vi sentite di suggerire proposte per massimizzare i vantaggi legati al fenomeno?

E) COINVOLGIMENTO NEL PROGETTO

- E.1) Vede nel confronto tra più soggetti interessati un'opportunità per affrontare il tema della vendita dei farmaci on-line?
- E.2) Stiamo predisponendo uno o più incontri con esperti del settore per discutere del fenomeno, sarebbe disposto/a a partecipare?

6.1 MIDIR – European Questionnaire

An evaluation of the transferability of the MIDIR methodology applied to risks due to illegal e-commerce of drugs

MIDIR – European Questionnaire

An evaluation of the transferability of the MIDIR methodology applied to risks due to illegal e-commerce of drugs

The project "Multidimensional Integrated Risk Governance" (MIDIR) is a Coordinated Action in the Sixth Framework Programme of the European Commission, Area "Science & Society", Priority "Integrative approaches to risk governance". Its main aim was to develop a resilience and risk governance concept based on existing research and an accompanying management, monitoring and evaluation tool.

The MIDIR approach provides the "MIDIR Indicator System", identified in a scientific analysis of a wide range of projects and initiatives in the field of risk governance. It consists of twelve Key Performance Indicators that are the basis for an efficient mapping of activities, performance and results with regard to a specific risk. The system is divided into so called "Part A Indicators" that are generally valid for every risk setting, and "Part B Indicators" that are context related aspects, to be defined individually according to the characteristics of a specific risk setting.

Table 1: The twelve identified MIDIR Part A Key Performance Indicators.

| KEYWORD | KEY-QUESTION | OBJECTIVES | POSSIBLE ASSESSMENT BASIS |
|----------------|--|---|--|
| PRINCIPLES | What are the guiding principles? | The main aspect of this indicator is the question how it should be dealt with the existing risks. Is it clear and defined what the action is aiming at (e.g. resilience)? Is the vision shared by all involved groups? Is there an alignment of principles? This can be formulated by a guiding principle. The indicator is positive, if guiding principles are defined and a consistent system of objectives exists. | Red = no guiding principles Orange = discussion process about guiding principle started Yellow = all guiding principles are defined Green = discussion concerning the „target system“ started Blue = principles through a consistent system of objectives – which is continuous reviewed and if applicable adjusted – are implemented |
| TRUST | How far is attention paid to relevance of an atmosphere of mutual respect and trust? | The indicator shows if the necessary steps to build an atmosphere of trust and mutual respect have been considered. Key words: competence, fairness, efficiency. | Red = not to broach the issue of trust Yellow = trust is discussed on a case by-case basis Blue = trust is systematically reflected and if applicable trust-building measurements are made |
| OBJECTIVES | What are the concrete protection goals for subjects of the protection? | The indicator is positive, if an agreement concerning protection goals for the relevant subjects of protection compared with a defined risk exist (through a "target system"). | Red = subjects of protection and protection goals are not defined Orange = process of discussion concerning the subjects of protection and protection goals is initiated Yellow = subjects of protection and protection goals are defined Green = obligation for protection goals is regulated Blue = protection goals are continuous reviewed and if applicable adjusted |
| ACCOUNTABILITY | How far is accountability | Indicator shows how far the | Red = responsibilities are not defined |

| | | | |
|--|--|--|---|
| PRINCIPLE | defined at each level (process, each risk)? | responsibilities are clearly defined ("clear responsibility of stewardship"). This is important for a good as well as successful risk governance process. | Orange = Process of discussion concerning the definition of responsibilities started Yellow = responsibilities are defined Green = responsibilities are implemented Blue = responsibilities are continuously reviewed and if applicable adjusted |
| JUSTIFICATION | How far is the activity concerning the management of existing risks justified? | The indicator shows how far governmental action is justified. The questions behind are: Why is there a need of governmental action concerning risks? Why shall the individual accept constraints concerning his own decisions? | Red = no justification Orange = discussion about the justification started Yellow = justification exists Green = justification as a part of obligatory arrangements Blue = existing justification is continuously reviewed and if applicable adjusted |
| REPRESENTATION | How far are all relevant social groups (and their representatives, stakeholder respectively) and their expectations known? | The main aspect of this indicator is the question, if all social groups and their expectations are known. This will avoid that no group is passed over. Stakeholder that were not considered may interfere the risk governance process and this could lead to conflicts. | Red = neither social groups nor their expectations are known Orange = process of the "Stakeholder-Identification" (e.g. through an Interest-Analysis) started Yellow = social groups are known Green = stakeholders' expectations are known (Interest-Analysis is finished) Blue = continuous monitoring of the expectations is implemented |
| ACCESS TO INFORMATION | How far is information for all stakeholders accessible? | Although a permanent information flow could be organised e.g. by the internet it is very important to actively inform stakeholders by regular meetings and discussions because they guarantee the communication flow in both directions. The higher the share of involved stakeholders is, the better the indicator performs. It is required that all relevant stakeholders are involved because the share alone does not show if the most relevant stakeholders in the end are really involved. | Red = risk information is not available/accessible Orange = discussion about the intermediation concerning the risk information started Yellow = guidelines for information-policy are available Green = guidelines for information-policy are applied Blue = continuous quality control (understandability and availability of information) |
| TOLERANCE PROCESS & OUTCOME | How far do the stakeholders tolerate/accept the risk governance process and its outcomes? | Tolerance in the process and outcome can be described as a result of creating an atmosphere of trust and mutual respect. | Red = tolerance/acceptance of the process & outcome are ignored Orange = discussion about the establishment of tolerance/acceptance started Yellow = criteria concerning the measurement of tolerance/acceptance defined Green = measurement of tolerance/acceptance is part of the process Blue = deficiency of tolerance/acceptance leads to the revision of the process and/or its results. |
| DIALOGUE | To what extent is a constructive dialogue with the relevant stakeholders available or conducted? | Compilation of the dialogue-quality with the stakeholder. The following dialogue-concepts are possible: information (rising of the level of information), consultation (receive important suggestions), cooperation (collective elaboration of topics and proposals), collaboration (collective creation and decision-making) | Red = no discourse available Orange = discussion about the initiation and elaboration of discourse processes has started Yellow = Interests and expectations concerning the discourse processes are known Green = Dialogue concepts are accepted by the participants Blue = discourse processes are an integral part of a risk governance process and are consequently reviewed |
| FINANCIAL RESOURCES | To what extent do the available financial | The concepts and ideas for a successful risk governance | Red = Costs and benefits of the risk governance process are not monetized |

| | | | |
|------------------------|--|--|--|
| | resources meet the requirements of the defined Risk Governance Process? | process and the available financial resources concerning the realisation of measures have to be concerted. | <p>Orange = Calculation of costs and benefits is initiated</p> <p>Yellow = relationship of costs and benefits is transparent</p> <p>Green = financing is possible</p> <p>Blue = sufficient funds are available, the requirements are continuously reviewed and if applicable adjusted</p> |
| HUMAN RESOURCES | To what extent do the human resources (technical qualification and number of people) meet the requirements of the defined Risk Governance Process? | The concepts and ideas for a successful risk governance process and the available human resources concerning the realisation of measures have to be concerted. | <p>Red = no consideration concerning human-resource allocation available</p> <p>Orange = conception of a required human-resource allocation is initiated</p> <p>Yellow = quantity and competences are defined (staff appointment scheme)</p> <p>Green = selection procedure is working</p> <p>Blue = adequate personnel resources are available, are continuously reviewed and if applicable adjusted</p> |
| ROLE | How far has the role of experts been defined? | Often there is the problem that experts are asked (e.g. in committees) although a political answer is needed. Experts cannot answer questions about the acceptable risk because this is a question the society has to answer. Thus the role of experts shall be to give expertise but not to make decisions of political character. It is important that the role of experts is not just defined but how it is defined | <p>Red = experts' role not defined</p> <p>Orange = definition of the problems/questions and requirements concerning (external) expertise, e.g. science advisor, communication consultant, evaluator</p> <p>Yellow = possible experts known (names)</p> <p>Green = experts' role and concrete persons meet the acceptance of the process participants</p> <p>Blue = expertise is integrated into ongoing processes, incl. Performance review</p> |

The twelve identified MIDIR Part A Key Performance Indicators are used as a basis for the elaboration or generation of Part B Indicators since basic features of Part A as e.g. "stakeholder involvement" have to be considered as well when defining context related indicators in Part B. Consequently both parts are interdependent and implemented simultaneously and strictly connected to each other. The practical application of the process was the focus of the two case studies:

- risks related to criminals under hospital treatment order (Germany) and
- risks related to health due to e-commerce (Italy).

The Italian case study tested the application of the Indicator System using the case of risks related to on-line selling of drugs.

Several meetings, involving Italian experts of pharmaceutical field, have been organized. During the meetings stakeholders selected three PART A indicators among the twelve of Table 1 (Financial resources, Human resources and Access to information) and defined three PART B indicators, shown in Table 2:

Table 2: The three Part B Key Performance Indicators defined by Italian stakeholders

| KEYWORD | KEY-QUESTION | OBJECTIVES | POSSIBLE ASSESSMENT BASIS |
|------------------------|---|--|--|
| TIME RESOURCES | How far is there calendar time to meet the governance process defined? | The concepts and ideas for a successful risk governance process according to temporal constraints concerning the realisation of measures have to be concerted. | Red = no consideration concerning calendar time available Orange = calculation of a calendar time is initiated Yellow = the calendar time is defined Green = a study for evaluating the feasibility of the calendar time with relation to the personnel and financial resources is working Blue = adequate temporal allocation of resources is available, temporal constraints are continuously reviewed and if applicable adjusted |
| EQUIPMENT/TOOLS | How far do the equipment resources available meet the needs of the governance process defined? | The concepts and ideas for a successful risk governance process and the available equipment resources concerning the realisation of measures have to be concerted. | Red = no consideration concerning equipment resources allocation available Orange = conception of required equipment resources allocation is initiated Yellow = all required equipment resources/tools are defined Green = supply procedure is working Blue = adequate equipment resources are available, are continuously reviewed and if applicable adjusted |
| PROCESS | How far is there a risk governance process – e.g. objective/indicator - measurement - review - analysis - action plan - learn - repeat – improve? | The indicator shows if the necessary steps of the risk governance process have been defined and accomplished | Red = phases of the risk governance process are not defined Orange = process concerning the definition of risk governance phases started Yellow = phases of the risk governance process are defined Green = phases of the risk governance process are applied Blue = risk governance phases are continuously reviewed and if necessary adjusted |

Italian stakeholders selected and defined these six indicators, as they are more appropriate to deal with risks related to on-line selling of drugs.

Moreover, during the meetings stakeholders emphasized the following relevant aspects:

1. Lack of stakeholders' objectiveness in evaluating different indicators
2. Assignment of different weights to stakeholders
3. Need of dialogue among involved actors.

1. Depending on the role that stakeholders have in the risk governance process and the kind of risk under consideration, some indicators (and this can happen also for both PART A and PART B indicators) can turn out to be self-referential. In fact, stakeholders, as potential actors in the risk governance process, can have a subjective view of some indicators. In other words, a conflict of interest may occur between stakeholders and some indicators. In fact, if a stakeholder is involved in the risk governance activities monitored by the indicator he will tend to give a positive evaluation for that indicator. For instance, if the stakeholder is involved in an awareness campaign about the seriousness of the health problems linked to the administration of drugs purchased via the non-authorized web distribution channels, he will tend to give a positive value to the indicators which measure the stakeholder involvement in the risk governance process.

2. The risk analyzed in the Italian case study involved a widespread number of parties and groups of interest, ranging from authorities of the pharmaceutical and health fields that have a regulatory and active role in the governance process, to associations for the protection of consumers' interests. The selection of stakeholders and their involvement in the implementation of the MIDIR methodology have to take into account the role of each stakeholder, assigning him a different weight. The steering committee suggested to define some parties "stakeholders", because they regulate the market, while others need to be considered "observers".

3. Italian stakeholders suggested the confrontation and dialogue among involved actors as a chance to front the illegal online selling of drug items. They suggested the involvement of multidisciplinary experts and an awareness campaign about risk gravity, communication by brochure, poster, Tv and radio spot, school information and a specific communication for different targets.

Below you can find the questionnaire to evaluate the MIDIR methodology applied to risks due to illegal e-commerce of drugs at European context.

Thank you for helping us with our survey by marking the column that states your opinion. Please be assured, that all answers given will be treated confidentially.

1. Looking at the indicator “Access to information” (provided in Table 1), it has the aim of assess the access for all stakeholders to the relevant risk governance information. In your opinion, is it relevant for monitoring the risk due to illegal e-commerce of drugs?

- ☐ Strongly relevant
- ☐ Moderately relevant
- ☐ Slightly relevant
- ☐ Undecided
- ☐ Slightly irrelevant
- ☐ Moderately irrelevant
- ☐ Strongly irrelevant

Comments:

2. Are the key-question, objectives and possible assessment basis (provided in Table 1) adequate to describe the indicator “Access to information”?

- ☐ Strongly adequate
- ☐ Moderately adequate
- ☐ Slightly adequate
- ☐ Undecided
- ☐ Slightly inadequate
- ☐ Moderately inadequate
- ☐ Strongly inadequate

Comments:

3. Looking at the indicator “Financial Resources” (provided in Table 1), it has the aim of assess the allocation of sufficient financial resources for a successful risk governance process. In your opinion, is it relevant for monitoring the risk due to illegal e-commerce of drugs?

- ☐ Strongly relevant
- ☐ Moderately relevant
- ☐ Slightly relevant
- ☐ Undecided
- ☐ Slightly irrelevant
- ☐ Moderately irrelevant
- ☐ Strongly irrelevant

Comments:

4. Are the key-question, objectives and possible assessment basis (provided in Table 1) adequate to describe the indicator “Financial Resources”?

- ☐ Strongly adequate
- ☐ Moderately adequate
- ☐ Slightly adequate
- ☐ Undecided
- ☐ Slightly inadequate
- ☐ Moderately inadequate
- ☐ Strongly inadequate

Comments:

5. Looking at the indicator “Human Resources” (provided in Table 1), it has the aim of assess the allocation of adequate personnel resources for a successful risk governance process. In your opinion, is it relevant for monitoring the risk due to illegal e-commerce of drugs?

- ☐ Strongly relevant
- ☐ Moderately relevant
- ☐ Slightly relevant
- ☐ Undecided
- ☐ Slightly irrelevant
- ☐ Moderately irrelevant
- ☐ Strongly irrelevant

Comments:

6. Are the key-question, objectives and possible assessment basis (provided in Table 1) adequate to describe the indicator “Human Resources”?

- ☐ Strongly adequate
- ☐ Moderately adequate
- ☐ Slightly adequate
- ☐ Undecided
- ☐ Slightly inadequate
- ☐ Moderately inadequate
- ☐ Strongly inadequate

Comments:

7. Looking at the indicator “Time Resources” (provided in Table 2), it has the aim of assess the temporal allocation of resources for a successful risk governance process. In your opinion, is it relevant for monitoring the risk due to illegal e-commerce of drugs?

- ☐ Strongly relevant
- ☐ Moderately relevant
- ☐ Slightly relevant
- ☐ Undecided
- ☐ Slightly irrelevant
- ☐ Moderately irrelevant
- ☐ Strongly irrelevant

Comments:

8. Are the key-question, objectives and possible assessment basis (provided in Table 2) adequate to describe the indicator “Time Resources”?

- ☐ Strongly adequate
- ☐ Moderately adequate
- ☐ Slightly adequate
- ☐ Undecided
- ☐ Slightly inadequate
- ☐ Moderately inadequate
- ☐ Strongly inadequate

Comments:

9. Looking at the indicator “Equipment/tools” (provided in Table 2), it has the aim of assess the allocation of adequate equipment/tools for a successful risk governance process. In your opinion, is it relevant for monitoring the risk due to illegal e-commerce of drugs?

- ☐ Strongly relevant
- ☐ Moderately relevant
- ☐ Slightly relevant
- ☐ Undecided
- ☐ Slightly irrelevant
- ☐ Moderately irrelevant
- ☐ Strongly irrelevant

Comments:

10. Are the key-question, objectives and possible assessment basis (provided in Table 2) adequate to describe the indicator “Equipment/tools”?

- ☐ Strongly adequate
- ☐ Moderately adequate
- ☐ Slightly adequate
- ☐ Undecided
- ☐ Slightly inadequate
- ☐ Moderately inadequate
- ☐ Strongly inadequate

Comments:

11. Looking at the indicator “Process” (provided in Table 2), it has the aim of assess if the necessary steps of the risk governance process have been defined and accomplished. In your opinion, is it relevant for monitoring the risk due to illegal e-commerce of drugs?

- ☐ Strongly relevant
- ☐ Moderately relevant
- ☐ Slightly relevant
- ☐ Undecided
- ☐ Slightly irrelevant
- ☐ Moderately irrelevant
- ☐ Strongly irrelevant

Comments:

12. Are the key-question, objectives and possible assessment basis (provided in Table 2) adequate to describe the indicator “Process”?

- ☐ Strongly adequate
- ☐ Moderately adequate
- ☐ Slightly adequate
- ☐ Undecided
- ☐ Slightly inadequate
- ☐ Moderately inadequate
- ☐ Strongly inadequate

Comments:

13. In addition to the six analysed indicators, do you suggest to select other indicators from the PART A indicators (shown in grey in Table 1)?

☐

Yes

☐

No

Which indicator(s)?

☐

Principle

☐

Trust

☐

Objectives

☐

Accountability principle

☐

Justification

☐

Representation

☐

Tolerance process & outcome

☐

Dialogue

☐

Role

Comments:

14. Do you suggest to add further indicators, which are in your opinion relevant to monitor the risks due to illegal e-commerce of drugs and that are not part of the proposed indicators?

☐

Yes

☐

No

☐

Indicator 1:

Key-question:

Objectives:

Possible assessment basis:.....

☐

Indicator 2:

Key-question:

Objectives:

Possible assessment basis:.....

Comments:

Thank you!