

Executive Summary:

The inappropriate provision and consumption of non-prescribed medicines consists a public health problem of outmost importance for developed as well as for developing countries. The problem has been shown to be widespread in Mediterranean countries with enormous health risks. The OTC SOCIOMED project aimed at assessing the extent of inappropriate provision and consumption of non-prescribed medicines in certain Southern European countries and identifying factors that influence the provision and consumption of non-prescribed medicines in four primary care groups [general practitioners (GPs) - pharmacists (PHs) - patients -clients]. It further aimed to implement theory-guided interventions, addressing physicians' training needs and behavioural components playing an influential role in the inappropriate provision of non-prescribed medicines. The project was based on the multivariate model of Transcultural Health Care Utilisation (Slikkerveer, 1990), which identifies a series of actors affecting utilisation as well as the Theory of Planned Behaviour (TPB, Ajzen, 1991), which explains the psychosocial factors determining prescribing patterns and guidance compliance. The project was designed to last 24 months, in an integrated sequence of seven (7) work packages and involved 12 participating entities from 8 countries (Greece, Sweden, Netherlands, France, Cyprus, Czech Republic, Malta, Turkey). Work package 1 involved tasks related to project monitoring and coordination. Work package 2 described the consumption of non-prescribed medicines by patients and pharmacy clients and the provision of non-prescribed medicines by GPs and PHs. It further made regional and geographical comparisons in the consumption and provision of non-prescribed medicines (Northern-Central-Southern Europe, rural-urban settings). Work package 3 assessed GPs' and PHs' beliefs, attitudes and perceived behaviour control based on Theory of Planned Behaviour (TPB) and explored the role of TPB in explaining GPs' and PHs' intention to provide medicines in patients without well documented evidence. Work package 4 assessed patients' and clients' beliefs, attitudes and perceived behaviour control based on TPB and explore the role of TPB in explaining patients' and clients' intention to consume medicines. Work package 5 involved the design, implementation and evaluation of a multifaceted intervention addressing GPs' beliefs and attitudes towards medicines and aiming to test the feasibility of a pilot intervention as well as change GPs' intention to provide medicines to patients without well documented evidence. Work package 6 reviewed and evaluated the project results and interventions using a nominal group process. Finally, work package 7 involved the dissemination of the project's results through a variety of dissemination channels as well as developed a set of recommendations/practical guidelines, summarizing the knowledge gained from the project. These recommendations were distributed to a number of stakeholders identified through a mapping process, including public and private organizations/bodies involved in medical research and education, health care planning, drug industry distribution and monitoring.

Conclusively, the project identified modifiable determinants of the provision and consumption of non-prescribed medicines and delivered well-designed interventions promoting better use of non-prescribed medicines in Europe and especially in Southern European countries, where the problem of inappropriate provision of non-prescribed medicines seems to be predominant. The study further provided an operationalized structure to define and evaluate interventions targeting similar behaviours in various health care professions and disciplines. It introduced common evaluation standards and tools, translated in multiple European languages and tested in multiple European primary care environments, which could serve as an example for other districts and regions within Europe that share similar geographic and socio-cultural characteristics. In that respect, it could further enable comparisons among training interventions within Europe.

Project Context and Objectives:

The increasing availability of non-prescribed medicines involves many health risks, widely acknowledged in international literature. Most importantly, it may encourage patients to believe that there is a medicine solution for treating every ailment, it may lead to self-treatment when medical aid should have been sought (Bradley and Bond, 1996, Hughes et al., 2002) as well as it may delay or even 'mask' the diagnosis of serious illness, with increased risks of drug-to-drug interactions and adverse reactions (Hughes, 2003).

In Mediterranean countries, irrational consumption of non-prescribed medicines (OTC) is widespread (SCORE 2004, based on ESAC estimations). Besides irrational consumption of non-prescribed medicines, the patterns of provision are also inappropriate (Bottomley, 1976) and the need to identify these patterns is essential to improve standards of medicine provision (Figueiras et al., 2001, Antonakis et al., 2006). High risk prescribing has been noted to be more common in primary care patients where prescribed medicines are intended for long term use (Guthrie et al, 2011).

Although abuse of non-prescribed medicines is steadily rising (Lessenger et al, 2008) and concerns about inappropriate treatment and adverse drug reactions have been raised (Hughes et al, 1999), this subject does not appear to have received the attention it deserves in general practice/family practice research, particularly in Europe. Only few attempts have been made in Europe in order to depict the OTC subject in primary care population (Barat et al, 2000) although legislation constantly changes and concerns about safety have been extensively underlined (Ferner & Beard, 2008; Cohen et al, 2005) and national policies are in constant reform.

In Europe, particularly in the Southern European region, have neither a full national programme to promote better use of medicines nor a multidisciplinary national body under mandate to monitor medicine consumption or even to develop and coordinate the implementation of such a programme. This fact may have an impact on the cost of the health services and particularly that of medicine expenditure in a critical for Europe financial period. Thus, the need for developing measures and specific methodologies which will reduce the incidence of drug-related mishaps, and assist in maintaining good health of the individual and society, is widely acknowledged.

The current collaborative project utilized a theory-specific approach with the aim to identify and understand the behaviour of four different primary care groups (GPs, PHs, PATs, CLs) towards the provision and consumption of prescribed and non-prescribed medicines in selected European countries (Greece, France, Turkey, Cyprus, Czech Republic, Malta, Sweden). It was based on the multivariate model of Transcultural Health Care Utilisation (Slikkerveer, 1990). This model identified a series of actors affecting utilisation, which were divided into five 'blocks', including system variables and variables at the individual level, such as predisposing, enabling and perceived-morbidity factors.

It further used the popular conceptual framework of the Theory of Planned Behaviour (TPB, Ajzen, 1991) to identify and explain the psychosocial factors, which determine prescribing patterns and guidance compliance. The project was implemented in a series of 7 work packages (WPs). All the work packages were creatively designed in a distinct order to try and reach the goals of the OTC Project. In this schematic presentation it is made clear that WP5 that aimed to implement a pilot intervention was designed on the basis of both conceptual frameworks utilized in three work packages (WP2, WP3, WP4) while WP6 on the evaluation and assessment retrieved evidence and information

from all WP3, WP4 and WP5. The objectives of the project work packages (WPs) are described in detail below in line with the Technical Annex of the project.

Work Package 1

1. To establish a clear and effective management and communication system for the duration of the project. That includes ensuring the smooth and efficient running of the project towards its goals, managing the coordination and decision making with other projects and relevant parties, and ensuring the high quality and best exploitation of the project results. This WP also aimed at ensuring continuous monitoring of the project activities and achieving communication between the different project actors and the EU.
2. Project coordination, quality management and progress monitoring of the consortium.
3. To organise and host the Electronic Data Platform (EDP) including the project documentation.
4. To monitor progress against milestones and deliverables and keep an overview of finances

Work Package 2

1. To describe the consumption of non-prescribed medicines by patients and clients.
2. To describe the provision of non-prescribed medicines by GPs and PHs.
3. To explore the type of non-prescribed medicines provided by GPs and PHs and consumed by patients and clients.
4. To examine how patient/client characteristics influence the consumption of specific types of non-prescribed medicines.
5. To make regional and geographical comparisons of the provision and consumption of non-prescribed medicines (Northern-Central-Southern Europe, rural-urban settings).

Work Package 3

1. To assess GPs' and PHs' beliefs, attitudes and perceived behaviour control based on the TPB.
2. To explore to what extent TPB could explain the intention to provide medicines in patients without well documented evidence.
3. To discuss whether restructuring normative beliefs can result in GPs' behaviour change.
4. To explore potential pathways of effective collaboration between GPs and PHs.
5. To organise a workshop of experts to exchange experiences, gather ideas, compare practices and identify external factors that affect the feasibility and acceptability of an intervention which will support evidence-based provision of medicines.
6. To discuss and explore effective interventions to change identified beliefs as antecedents to prescribing behaviour.

Work Package 4

1. To assess the patients'/clients' beliefs, attitudes and perceived behaviour control based on the TPB.
2. To explore to what extent TPB could explain the consumption of medicines by patients/clients.
3. To discuss whether restructuring normative beliefs can result in patients'/clients' behaviour change. and to explore external factors affecting the patients'/clients' demand of non-prescribed medicines.
4. To discuss and explore effective interventions to change the beliefs that influence irrational consumption of non-prescribed medicines by patients/clients.
5. To investigate into the role of the PHs in the provision of non-prescribed medicines.

Work Package 5

1. To implement the interventions that were developed in WP3 and WP4, that aimed to change the beliefs and attitudes, of GPs' intention to provide medicines, and patients'/clients' intention to consume medicines irrationally.
2. To evaluate these interventions by assessing their impact on behavioural intention.
3. An additional objective that it was not included in the Technical Annex included the design and implementation of a systematic review of interventions that was carried out in the framework of this FP7 project.

Work Package 6

1. To evaluate the projects accountability, progress-to-date and means of possible improvement.
2. To review and analyse experience gained from the project's implementation.
3. To assess and rank the appropriateness and effectiveness of different interventions.
4. To discuss effective ways on how to best disseminate the results of the project, as widely as possible throughout Europe and particularly in Southern European countries, so as to attract new users and communities and increase awareness among general practitioners/family physicians, health care managers, policy makers, governmental bodies and local authorities.
5. To propose an exploitation plan to take full benefits of the project's results.
6. To discuss materials needed for the next WP and prepare a plan for the dissemination of results and their respective analysis.

Work Package 7

1. To design materials and a net-based communication platform and increase skills and knowledge of new users and communities.
2. To disseminate the results of the project widely in Europe and increase awareness among audiences such as health care professionals, public health officials, health care managers,

policy makers, governmental bodies, local authorities, pharmacists, the pharmaceutical industry and the general community.

Project Results:

Work package 1

A kick-off meeting was conducted on the first month of the project in Crete, Greece, where the work plan was discussed and the intellectual property rights and obligations of each partner were agreed. Communication tools were set-up at the first three months of the project for internal planning and progress monitoring, among which an electronic mailing lists, file server and an Electronic Data Platform (EDP, <http://www.otcsociomed.uoc.gr>). The EDP also functioned as shared data storage for the consortium. The EDP involves a web page available to the public including general information about the OTC SOCIOMED Project (e.g. aims and objectives, work package description, methodology, impact, contact details) as well as a private area, password-protected, accessible only to the members of the project through login, where confidential information regarding the project was shared (e.g. minutes from meetings, progress reporting documents etc).

Overall, this WP ensured regular reporting to the EU and submission of the deliverables and of all contractual reports (periodic progress reports, annual review reports, workshop reports, final report, etc). It further ensured that all participants shared a common understanding of the key missions and objectives of the project, clearly understood their roles in achieving the objectives and the specific steps needed to achieve them. In addition, quality criteria for the designated milestones and deliverables as well as decision-making systems and procedures were also established.

Work package 2

A detailed description of the methodology and the results of WP2 can be found in the Deliverable 2.1. A total of 1270 providers (585 GPs and 685 PHs) and 1788 consumers (932 PATs and 855 CLs) from Greece, Cyprus, Malta, Turkey and Czech Republic were enrolled in the study. Data from France were not included in the analysis due to technical problems. Turkey enrolled 785 respondents (98.0% of the targeted 800 respondents), Czech Republic enrolled 739 respondents (92.0% of the target), Greece enrolled 673 respondents (84.1% of the target), Malta enrolled 481 respondents (60.0% of the target) and finally Cyprus enrolled 380 respondents (48.0% of the target).

Overall, the study found that 2,459 medicines were consumed by the 932 PATs in all countries, subdivided in 819 (33.3%) non-prescribed medicines and 1,640 (66.7%) prescribed medicines, 2,455 medicines were consumed by the 853 CLs in all countries, subdivided in 1,278 (52.1%) non-prescribed medicines and 1,177 (47.9%) prescribed medicines, 2,864 medicines were provided by the 565 GPs in all countries, subdivided in 956 non-prescribed medicines and 1,908 prescribed medicines and 3,524 medicines were provided by the 701 PHs in all countries, subdivided in 1,468 non-prescribed medicines and 2,056 prescribed medicines.

This WP achieved to identify the various categories of factors included in the conceptual model of health and illness related behaviour (Slikkerveer, 1995) that play a potential role in PATs and CLs' medicine consuming behaviour as well as GPs' and PHs' medicine providing behaviour, as illustrated clearly in the Deliverable2.1 prepared by the WP2 leader Prof. Slikkerveer in collaboration with members of the LEAD programme and the UNPAD team.

A remarkable overall conclusion was that in both the GPs and the PHs, the intervening determinants show a strong dominance over all other independent categories of determinants - including the

psycho-social determinants - which open up a new focal point for behaviour change in the arena of the classical doctor-patient relations and interactions. Another remarkable conclusion is that in both the PATs and CLs by contrast the independent socio-demographic and psycho-social determinants show a strong dominance over all other intervening categories of determinants - including the intervening GP- and PH-specific determinants - opens up a new focal point for behaviour change at the individual and community level. Determinants by category of providers and consumers are described below.

Determinants of GPs' medicine provision (all countries)

Some of the major results of the mutual relationships analysis among various categories of behavioural determinants of medicine provision and the GPs' reported patterns of provision of non-prescribed and prescribed medicines are presented below:

1. Comparison of the outcome patterns of provision of non-prescribed and prescribed medicines by GPs show a marked dominance of two-third of prescribed medicines (66.6%) over one-third of non-prescribed medicines (33.4%), indicating a strong GPs' preference in the provision of prescribed medicines.
2. The impact of the intervening determinants of the interaction between the GPs and their PATs is remarkably high with the largest number of determinants (10) and the highest values of significance (7 most strongly significant).
3. Similarly, the impact of the intervening determinants of the regulations and promotions of medicines is remarkably high where both determinants have the highest values of most strongly significance.
4. As expected, the role of the 6 psycho-social determinants is substantial as independent determinants of the GPs, albeit that only 2 determinants have the highest value of most strongly significance.
5. The impact of the determinants of the health service organization is interesting, where both determinants have values of weakly significant and very strong significant;
6. The impact of the independent socio-economic determinants is less profound as only 1 determinant of the annual income of the GPs has a value of weakly significant.

Determinants of PHs' medicine provision (all countries)

Some major results of the mutual relationships analysis among various categories of behavioural determinants of medicine provision and the PHs' reported patterns of provision of non-prescribed and prescribed medicines are presented below:

- 1) Comparison of the outcome patterns of provision of non-prescribed and prescribed medicines by PHs shows a less marked dominance of prescribed medicines (59.3%) over non-prescribed medicines (41.7%), indicating a trend towards a more balanced distribution of both types of medicines, i.e. more than two-fifth of non-prescribed medicines and nearly three-fifth of prescribed medicines.
- 2) The impact of the intervening determinants of the interaction between the PHs and their CLs is remarkably high with the largest number of determinants (11) and the highest values of significance (8 most strongly significant).

- 3) Similarly, the impact of the intervening determinants of the regulations and promotions of medicines is remarkably high where both determinants have high values of strong and very strongly significance.
- 4) The impact of the 3 psycho-social determinants as independent determinants of the PHs is less than expected as 2 determinants have values of weakly significance and 1 determinant of strong significance.
- 5) The impact of the determinants of the health service organization is interesting, where 1 determinant has a value of weakly significant influence.
- 6) The impact of the independent socio-economic determinants is less profound as only 1 determinant has a value of weakly significant influence.

The overall conclusion that in the mutual relation analysis of providing behaviour of PHs the intervening determinants show a strong dominance over all other independent categories of determinants - including the psycho-social determinants - opens up a new focal point for behaviour change in the arena of the classical doctor-patient relations and interactions.

Determinants of PATs' medicine consumption (all countries)

Some major results of the mutual relationships analysis among various categories of behavioural determinants of medicine consumption and the PATs' reported patterns of consumption of non-prescribed and prescribed medicines are presented in below:

1. Comparison of the outcome patterns of consuming of non-prescribed and prescribed medicines by PATs shows a marked dominance of prescribed medicines (66.7%) over non-prescribed medicines (33.3%), indicating a preference for prescribed medicines, i.e. more than two-fifth of non-prescribed medicines and nearly three-fifth of prescribed medicines.
2. The impact of the intervening determinants of the interaction between the PATs and their GPs is less profound with a reduced number of determinants (5), albeit with 4 determinants with the highest values of most strongly significant, and 1 with the value of strongly significant.
3. The impact of the intervening determinants of the regulations and promotions of medicines is remarkably high where both determinants have a value of very strongly significant.
4. The impact of the 4 psycho-social determinants as independent determinants of the PATs is substantial as 3 determinants have values of most strongly significant and 1 determinant of very strongly significant
5. The impact of the determinant of the health service organization is interesting, where 1 determinant has a value of most strongly significant.
6. The impact of the determinants of the perceived morbidity of the PAT is remarkably high, where 2 determinants have values of most strongly significant, and 1 determinant has a value of strongly significant; 7 The impact of the independent socio-economic determinants is high as 1 determinant has a value of most strongly significant.

Determinants of CLs' medicine consumption (all countries)

Some major results of the mutual relationships analysis among various categories of behavioural determinants of medicine consumption and the CLs' reported patterns of consumption of non-prescribed and prescribed medicines are presented below:

1. Comparison of the outcome patterns of consuming of non-prescribed and prescribed medicines by CLs shows a less marked dominance of prescribed medicines (47.9%) over non-prescribed medicines (52.1%), indicating a trend towards a more balanced distribution of both types of medicines, i.e. even more than half of non-prescribed medicines and nearly half of prescribed medicines.
2. The impact of the intervening determinants of the interaction between the CLs and their PHs is less profound with a reduced number of determinants (2), where both determinants have values of respectively strongly significant, and weakly significant.
3. The impact of the independent psycho-social determinants of the CLs is substantial as 1 determinant has a value of most strongly significant, 1 determinant has a value of strongly significant, and 2 determinant have a value of weakly significant.
4. The impact of the determinants of the perceived morbidity of the CL is remarkably high, where 2 determinants have values of most strongly significant.
5. No impact of the independent determinants of socio-economic status of the CL, of the health service organization and of the intervening determinant of regulations and promotions of medicines have been found in relation to the reported patterns of consuming behaviour of non-prescribed and prescribed medicines by CLs.

Work package 3

A total of 698 GPs and 667 PHs from Greece, France, Cyprus, Malta, Turkey, Czech Republic and Sweden were enrolled in the study. There was a great variation across the countries in terms of number of GPs recruited (N=41 to 122) as well as number of PHs (N=16 to 190). About three quarter of the GPs' questionnaires were eligible for analysis (542/698; 78%) whereas it was two thirds for PHs (449/667; 67%). In summary, positive attitude towards medicines was found to affect both the GPs' and the PHs' intention to provide medicines. In addition, social pressure (Subjective Norm) was found to have an impact on GPs' and PHs' intention to provide medicines in the participating Mediterranean countries only. Gender on the other hand affected only the GPs' intention to provide medicines, while it had no significant impact on PH's intention to provide medicines.

Factors that affect the provision of medicines in general practitioners (GPs)

GPs' attitude towards medicines was significantly associated with their intention to provide medicines in Czech Republic, Malta and Turkey. In Czech Republic, GPs' positive attitude towards medicines had a much stronger impact on their intention to provide medicines than in Malta (Odds Ratio was 5.3 in Czech Republic whilst in Malta the Odds Ratio was 3). Interestingly enough, GPs' positive attitude towards medicines in Turkey was found to have a negative association with their generalized intention towards provision of medicines, indicating that there could be some other factor/process that influences their intention and generates this inverse correlation (Odds Ratio was approximately 0.3).

We also should underline that in Greece and Sweden no strong correlation was found between the GPs' attitude towards medicines and their intention to provide medicines.

Subjective Norms were found to play a vital role in the GPs' intention to provide medicines as well. In particular, GPs' intention to provide medicines was found to be affected by the social pressure in Greece, Malta and Turkey, whilst GPs' intention was not affected by social pressure in the remaining countries. It is worth mentioning that in Malta there was a stronger association between the GPs' intention to provide medicines and social pressure than in Turkey and Greece (the odds ratio was approximately 6.0 in Malta whilst it was approximately 2.5 in Greece and Turkey). It is worth mentioning that social pressure was found to affect GPs' intention to provide medicines only in the Mediterranean Countries.

GPs' Perceived Behavior Control was found to affect their intention to provide medicines in Czech Republic and Malta, whilst GPs in the remaining countries were not affected.

The gender of the GPs was also found to affect their intention to provide medicines. Significant correlations were found in Czech Republic, Greece and Malta. By looking at the odds ratio we can conclude that female GPs in these countries expected to prescribe/recommend more medicines in patients without well documented evidence than their male colleagues, whereas in the remaining countries the gender did not seem to affect GPs' intention to provide medicines.

Finally, the age of the GPs was found to affect their intention to provide medicines in Malta, Sweden and Turkey. Younger GPs in Malta and Sweden expected to prescribe medicines without well documented evidence more than their older colleagues, whilst in Turkey younger GPs presented higher odds of having generalized intentions in favor of prescribing medicines in comparison with their older colleagues.

Factors that affect the provision of medicines in pharmacists (PHs)

PHs' positive attitude towards medicines was found to have a strong impact on their intention to provide medicines in Czech Republic, Greece and Malta. Among these countries, PHs' attitude towards medicines was found to have a stronger impact on their intention to provide medicines in Czech Republic in comparison with Greece and Malta (The odds ratio in Czech Republic was approximately 5.5 whereas in Greece was 3.8 and in Malta 3.2). In Turkey, PHs with a positive attitude towards medicines were 72% less likely to expect to recommend medicines in comparison with PHs without a positive attitude towards medicines (OR 0.28, 95% CI from 0.13 to 0.60).

Subjective Norms were found to play a vital role in PHs' intention to provide medicines in Greece. To be more specific, PHs under social pressure in Greece expected to recommend more medicines without well documented evidence comparing to PHs not being under social pressure.

PHs' Perceived Behavior Control was found to have a greater impact on their intention to provide medicines in Czech Republic. In addition, gender did not seem to affect PHs' intention to provide medicines in any country.

Finally, the age of the PHs was found to affect their intention to provide medicines only in Greece, where younger PHs expected to disperse/recommend more medicines and without well documented evidence comparing to their older colleagues. Detailed information on the factors affecting the intention of PHs to provide prescribed and non prescribed medicines can be found in the Deliverables 3.1 and 4.2.

Work package 4

In total, 1,838 consumers (patients and clients) from Greece, France, Cyprus, Malta, Turkey, Czech Republic and Sweden were enrolled in the study. Overall, the proportion of complete data was 80%, and ranged from 44% to 100%. In summary, high consumption of non-prescribed medicines was found in Cyprus, Czech Republic, Greece and Malta. Gender differences were found in the consumption of non-prescribed medicines in Cyprus, Czech Republic and Malta. Positive attitude towards medicines was found in consumers of Czech Republic, Greece, Malta and Turkey.

Factors that affect medicine consumption

The highest percentage of consumers of prescribed medicines was observed in Cyprus, Malta and France where above 90% of the respondents (patients and clients) reported having consumed at least one prescribed medicine during the last 6 months. The highest percentage of consumers of non-prescribed medicines were found in Cyprus, Czech Republic, Malta and Greece where above 80% of the respondents reported having consumed at least one non-prescribed medicine during the last 6 months. One can also observe that in France, Sweden and Turkey the percentage of prescribed medicines consumers was higher than the respective non-prescribed. On the contrary, in Malta, Cyprus, Greece the percentages were almost equal and in Czech Republic, the percentage of consumers of non-prescribed medicines was higher than the consumers of prescribed medicines. Besides these, gender variations in the number of both prescribed and non-prescribed medicines consumed were found with women tending to consume on average more medicines than men. Overall, consumers' attitude towards medicines was found to be positive in all participating countries. In other words, this highlights that fact the consumers' attitude towards medicines leans towards a more favourable intention towards medicine consumption. The most favourable attitudes towards medicines were observed in the consumers of Czech Republic, Greece, Malta and Turkey. Consumers' Subjective Norms were also found to be somewhat positive in all the participating countries except from Cyprus. Consumers' Subjective Norms were found to have an impact on their intention to consume medicines in France, Malta and Turkey. Consumers' Perceived Behaviour Control was found to be positive in all the participating countries except from Malta. Consumers in Cyprus, France and Turkey presented higher scores of Perceived Behaviour Control expressing their self-confidence about medicines consumption. Besides these, consumers' intention to consume medicines was found to differ amongst the participating countries. Consumers' Generalized Intention 1, which expressed consumers' will to consume medicines in the near future was found to be positive in all the participating countries except from Turkey. Consumers' Generalized Intention 2, which expressed consumers' expectation to consume medicines if they need to do so, was found to be positive in all the participating countries. Finally, consumers' intention to consume non-prescribed medicines was found to be positive in Cyprus, Czech Republic and Sweden, whilst it was found to be negative France, Greece, Malta and Turkey.

Work package 5

The intervention/feasibility study was implemented in five countries (Greece, France, Malta, Turkey, Cyprus). The study drew on the TPB model, which has been identified as a successful model for behaviour change in general practice (Conner, 1995). Key findings of previous work packages (WP2, WP3, WP4) of the OTC SOCIOMED project guided the design, content and methods of this feasibility/intervention study. The main components of the multifaceted intervention were the

following: (a) Delivery of a one-day educational course, (b) Poster with key messages on rational prescribing demonstrated at the participants workplace over a 4-week period, (c) reminders of rational prescribing as text or email alert messages sent to the participants over the four-week period. A pre and post-intervention design was used with a control group. Four different instruments were used at pre-intervention and post-intervention level to detect changes in the participants' intention to provide medicines, their prescribing practices and their overall satisfaction, in both the intervention and the control group. In total, 104 GPs participated and 84 (80.7%) of them provided complete data.

One-day training outcomes

A total of 42 GPs provided data before the implementation of the educational course in all the participating countries. Data from France were not included in the analysis due to missing post-intervention comparative data. According to the results, GPs from all the countries involved in the intervention, reported high expectations from the educational course, in terms of its usefulness, applicability in clinical practice and its potential influence on behavioural change. Among the study participants, Maltese GPs displayed the lowest expectations from the educational course while Cyprians and Turkish GPs displayed the highest ones. The level of information provided to the participants prior to the educational course was the element that received the worst evaluation in all the participating countries. As regards to their evaluation of the educational course, the highest overall satisfaction was reported by the Turkish GPs and the lowest one by the Maltese GPs. The level of behavioural change achieved as a result of the educational course and the extent of the seminar's applicability were some of the elements that received more moderate evaluation comparing to others. The quality of the seminar received the worst evaluation in Cyprus.

Acceptability of the multifaceted intervention

The intervention met moderate to high acceptability in the participating countries. GPs in Cyprus, Greece and France found the structure of the intervention 'fairly good', in Malta 'somehow good' and in Turkey 'very good'. The content of the intervention was considered to be 'fairly good' in Cyprus, France, Greece and Turkey and 'somehow good' in Malta. The intervention material was assessed to be 'fairly good' in Cyprus and France, 'very good' in Turkey whilst in Greece and Malta the score was neutral.

Based on the results of the one-day training, the seminar as a whole was considered to be 'very interesting' in Cyprus and Turkey and 'fairly interesting' in Greece and Malta. In addition, the quality of speakers was considered 'high' in Cyprus, Greece and Turkey and 'good' in Malta. The seminar as a whole was considered to be more applicable in Cyprus, Greece and Turkey than in Malta.

Practicality of the multifaceted intervention

The intervention was found to be practical for general practice in most participating countries. GPs in Cyprus and Turkey stated that the intervention changed their view of non-prescribed medicines at a 'high degree', whilst in Greece and Malta the intervention changed GPs' view of non-prescribed medicines 'somehow'. Furthermore, GPs in France were 'undecided' about whether this intervention changed their views of non-prescribed medicines.

Based on the results of the one-day training, GPs in Cyprus, Greece and Turkey found the seminar 'very helpful' for their future work, while in Malta GPs found the seminar 'somehow helpful' for their future work). Finally, highest acceptance of the seminar was reported by GPs in Cyprus, Greece and Turkey and lowest acceptance was reported by GPs in Malta.

Predicted Efficacy of the multifaceted intervention

Although testing of efficacy was necessarily in this pilot/feasibility study, certain trends have emerged based on the responses to the three study questionnaires. As the country sample sizes were small, outcomes were assessed by focusing on the magnitude of the differences between intervention and control groups, and to a much lesser extent on the statistical significance.

Overall, changes in GPs' intention to provide medicines tended to be positive in the intervention group whilst no changes were found in the control group. This pattern was seen across all 5 countries. Statistically significant differences were observed in Cyprus (generalized intention p -value=0.01, intention statement 2 p -value = 0.017, ie GPs in the intervention group expected to prescribe medicines to patients without well documented evidence in 10% less patients) and in Malta (GPs in the intervention group expected to prescribe medicines to patients without well documented evidence to 10% fewer patients than in the control group (p -Value = 0.021).

There was no apparent change in the number of prescribed medicines (before - after the intervention) in Cyprus and Greece. In France there was a small increase in the number of prescribed medicines at post intervention level, which may be due to coincidence with the season of vaccination. In Malta and Turkey, a small decrease in the number of prescribed medicines was observed in both the intervention and the control group, without this change being statistically significant.

There was a change towards a more rational prescription found in the intervention group comparing to the control group. For instance in Cyprus, after the intervention, 60% of the GPs (in intervention group) stated that they would not prescribe medicines already purchased from the pharmacy without prescription while that percentage was zero prior to the intervention. In Greece the percentage of the GPs who would not prescribe a medicine already bought from the pharmacy was also 60% after the intervention whilst it was 20% at baseline.

A positive change was also found regarding prescribing of medicines to third persons (relatives, friends etc.). To be more specific, in Cyprus 80% of GPs stated that they would not prescribe a medicine to a third person while that percentage was 40% before the intervention. In Greece, 60% of the GPs stated that they would not prescribe a medicine to a third person after the intervention, while that percentage was 40% before the intervention.

In Cyprus and Greece there was an increase of 20% at the number of GPs stating that they would always discuss the prescribed medicines with patients suffering from chronic disease (baseline percentage was 40% in Cyprus and 60% in Greece).

Finally, in Cyprus 80% of GPs stated that they would not prescribe medicines suggested by another physician after the intervention, while the baseline percentage of GPs was initially zero. In Greece, 100% of GPs said that in such occasion they would contact the physician who suggested this medicine to their patient while the baseline percentage of GPs stating this response was 60%.

Work package 6

The project's evaluation phase has produced a number of statements conveying key messages to GPs serving the participating Southern European countries, policy makers and other stakeholders. These statements along with the methodology that was employed to develop them can be found in detail in the Deliverable 6.1. The statements were divided into three sections as follows: (a) Determinants of

provision of non-prescribed medicines, (b) Issues of interventions, and (c) Proposals for health policy issues. A Nominal Group Process (Expert Panel Technique) was then used to prioritize and gain group consensus on the statements that were most important in achieving the study goal as well as on the outcomes that emerged in common in the participating countries as a result of the project. The Nominal Group Process involved two stages. The first stage was implemented via e-mail and the second stage involved a consensus meeting held in Athens within the framework of a National Conference on Health Management and Health Economics. Within the two individual stages, all the country representatives were asked to express their level of agreement with each of the evaluation statements. The statements were rephrased based on the first evaluation stage and were re-evaluated in their new form during the second evaluation stage. The statements with higher mean agreement were those that best reflected the project outcomes in the participating countries and those that could be translated into policy recommendations. These statements reflect the latest trends in the provision and consumption of non-prescribed medicines based on the results of the systematic review that was carried out in the framework of WP5, on the multi-country surveys that were carried out in WP2, WP3 and WP4 and on the multi-centre pilot intervention that was implemented in WP5. This evaluation outcome was strengthened by a widely used theoretical model of quality assessment as well as by a sound methodological framework, which was based on collective and evidenced-based decision-making by country representatives and experts instead of individual decision-making.

Work package 7

A set of recommendations / practical guidelines based on the TPB results and summarizing the knowledge gained from WP2-WP5 was developed based on the 'realist' approach and it is extensively illustrated in the Deliverable 7.1. The sources of information employed for the purposes of the review involved the following: (a) The project deliverables (Del. 2.1, Del. 3.1, Del. 4.1, Del. 4.2, Del. 5.1, Del. 6.1), (b) The progress reports to the European Commission, (c) A systematic review about the effectiveness of interventions for rational prescribing and the use of "Over the Counter Drugs" (OTCs) in general practice and Primary Health Care that has been designed and was carried out exclusively for the purpose of WP5. In addition, a set of propositions/suggestions for interventions addressing issues of clinical practice, health policy and health research were developed based on the WP2 results and can be found in the Deliverable 7.1. The information used for the development of the propositions/suggestions for interventions involved the following: a) the bivariate analyses for the joint data of 5 countries for each of the categories of respondents (GP, PH, PAT & CL), b) the mutual relation analyses for the joint data of 5 countries for each of the categories of respondents (GP, PH, PAT & CL) and, c) the multivariate analyses for the joint data of 5 countries for each of the categories of respondents (GP, PH, PAT & CL).

Informative material resulting from the OTC SOCIOMED project along with the final set of recommendations/ practical guidelines was distributed via e-mail to all the stakeholders engaged in medicine distribution, monitoring and evaluation, identified through a mapping process. The aim of this action was to inform all stakeholders about the knowledge gained through the project and ensure the transfer of knowledge into everyday clinical and pharmaceutical practice as well as the introduction of key and missing issues in the agenda of policy makers. This further aimed to provide a shared basis of knowledge and experience regarding the medicine provision and consumption as well as guidance towards planning and implementing improvements in professional practice.

Potential Impact:

The impact of the study could be explored on various levels. Firstly, the theoretical exploitation of the behavior of all health actors that are involved in the provision and consumption of non-prescribed and prescribed medicines. It has been creatively achieved by the implementation of two conceptual frameworks that offered a very analytical description of the determinants of consuming and providing behaviour of medicines of the GPs, PHs, PATs and CLs. Analytical reports with various categories of factors have been delivered to the participating countries for a potential and future implementation of this theory-based evidence into their local settings. Secondly, certain pilot interventions have been tested in local settings and a proposed intervention frame has been evaluated as feasible, relevant and practical in the busy health care environment. The study further provides an operationalized structure to define and evaluate interventions targeting similar behaviours in health professions and other disciplines. It introduces common evaluation standards and tools translated in multiple European languages, appropriate in measuring the effectiveness of current interventions and their applicability in other settings. Researchers now, have at their hands an educational intervention tool with relevant methodologies and instruments for a future large scale implementation, to alter the existing situation at the regional and national level and reducing the cost of pharmaceutical expenditures due to non radical decisions of all groups of health actors. Thirdly, the prepared and disseminated set of recommendations and proposed practical guidelines prepared from this project could have an important impact on policy makers, health actors, stakeholders, researchers and academicians. Most importantly, the current study provides evidence to policy makers on future policy actions targeting physicians' skills and prescribing behaviour in primary health care. It can additionally provide guidance on how to manage physicians' behavioural change and how to prevent irrational prescribing of medicines at primary care settings, through borrowing theoretical constructs from behavioural sciences. These constructs could be fertilized in undergraduate, postgraduate and continuous medical education to improve medical practice. This study is further expected to enable in the long run multi-country, multi-stakeholder consultations in medicine provision and consumption. Lastly, this collaborative effort combined capacity building from academic departments, colleges of GPs and primary care networks by using a theory guided approach for observational studies and designed and implemented an intervention and concluded with a list of an interesting compilation of recommendations and proposed practical guidelines.

Shortly summarizing the above, this FP7 project has a clear impact on:

1. The theory exploitation and implementation,
2. The development of tools and instruments suitable to clinical practice and research,
3. The design and evaluation of a pilot intervention that can guide future research,
4. The health policy within settings where financial and economical crisis is calling for urgent intervention in reducing unnecessary cost denoted to pharmaceutical expenditures.
5. Research capacity building apart from tools and methods left a strong multidisciplinary network to provide additional research within the European setting.

Main dissemination activities and exploitation of results:

The OTC SOCIOMED website (<http://www.otcsociomed.uoc.gr>), through which general information on the project was made available to the public, played a major role in the dissemination of the project activities and results. It was launched in February 2010 and continuously populated and updated with content during the lifetime of the project. Practically every public result of the project was available at the website including the project posters, publications, workshop programs, conference presentations and other events. In addition to the public website, the OTC SOCIOMED website served also as a collaborative tool for data sharing during the course of the project and featured a password protected area with restricted access to OTC SOCIOMED members. The website remain operational under the website of the coordinating centre.

Peer-reviewed scientific publications were also part of the OTC SOCIOMED dissemination activities. One paper was submitted for publication to a peer-review scientific journal (Evaluation and The Health Professions) and two scientific papers are currently in manuscript planned to be submitted in the next month (one is planned to be submitted to Family Practice in the first week of August 2012 and the second one reporting on the results of the feasibility study will be submitted to the journal of BMC Family Practice). The OTC SOCIOMED study results were presented in five national and European conferences addressing various audiences in the areas of medicine, pharmacy, health policy, health economics, and others.

OTC SOCIOMED workshops were held in various European countries (e.g. Greece, Turkey, Austria) as part of major scientific events (e.g. Annual Greek Congress on Health Economics, Annual Conference of the Turkish Association of Family Physicians, WONCA European Annual Conference, etc). A total of five workshops were organized to discuss the project results from different perspectives according to the audience of the conference. The agenda and the slides of the workshop presentations are available at the OTC SOCIOMED website.

Exhibitions at large scientific events were also used to disseminate the project's results. OTC SOCIOMED stands were prepared for WONCA Europe Annual Conferences in Warsaw 2011 and in Vienna 2012, a major event of the European network of family physicians with great numbers of attendees of biomedical disciplines from all over the world, where dissemination activities have been hosted in the WONCA Europe booth. These stands included posters of the project and relevant information on its implementation. Executive summaries of the project were also communicated to the Executive Board of WONCA Europe at different time periods including the last council meeting in Vienna in order to discuss the findings as part of their forthcoming activities and introduce the OTC SOCIOMED topic in their future agenda.

A set of recommendations for policy implementation were developed on the evidence generated by the OTC SOCIOMED project and was distributed via e-mail to all the stakeholders identified through the mapping process. This action, which is ongoing, aimed to inform all stakeholders about the knowledge gained through the project and ensure the transfer of knowledge into everyday clinical and pharmaceutical practice as well as the introduction of key and missing issues in the agenda of policy makers. The recommendations provided important information to different stakeholders such as professional groups (e.g. Cyprus Medical Association for Primary Care) and networks of health professionals (e.g. World Organization of Family Doctors - WONCA; European GP Research Network - EGPRN), academic and research organizations (e.g. Department of General Practice, Charles University Prague, Czech Republic), Quality Assessment Organizations (e.g. European Network for Health Technology Assessment -EUnetHTA), International Agencies for Medicines (e.g.

World Health Organization), Authorization and Regulatory Agencies for Medicines (e.g. Greek National Organization for Medicine) and drug industry (e.g. Association of the European Self-Medication Industry - AESGP→) in order to develop and implement health policies and legislation to support comprehensive care. The recommendations conveyed key messages and guidance for the design and implementation of national medicines programmes to improve medicines use as well as national level interventions. Relevant material with the practical guidelines/recommendations, published papers and abstracts are planned to be uploaded on the websites of both WONCA World and WONCA Europe.

In summary, this project achieved to discuss its main findings in different symposia and conferences and most importantly it managed to raise this challenging subject in many stakeholders in the health and other relevant sectors. The OTC SOCIOMED results are expected to receive a prompt attention by certain European, regional and national policies.

List of Websites:

<http://www.otcsociomed.uoc.gr>