**Scientific report for the Short Term Scientific Mission (STSM)**

COST Action IS1304: Expert Judgement Network: Bridging the Gap Between Scientific Uncertainty and Evidence-Based Decision Making

STSM participant: Dr Patricia Vella Bonanno, Superintendence of Public Health, Valletta, Malta

STSM host: Prof Alec Morton, University of Strathclyde Business School, Glasgow, UK

COST STSM Reference Number: COST-STSM-IS1304-32138

Period: 06.03.2016 to 16.03.2016

STSM type: regular (from Malta to the United Kingdom)

**Purpose of the STSM**

My main interest in expert judgement is from the perspective of how decision makers can apply tools and methodologies to support decision making in real life situations, particularly in the area of health. This interest developed and progressed through my work experience in various areas of health care including clinical practice, reimbursement, regulation and policy and my PhD, which was in the area of reimbursement and rational use of medicines.

This STSM followed from the meeting of the COST Action IS1304 which was held in Malta in October 2015. The theme of the COST Action meeting in Malta was the application of expert judgement in health care. Prof Alec Morton was Chairperson of the organising committee for this meeting and I was one of the members. I asked Prof Morton to be the host of this STSM due to his special interest in the area of decision making in healthcare, particularly with regards to health technology assessment and reimbursement decisions. Moreover Prof Morton is experienced and motivated to engage with decision makers in the field in order to achieve synergy between academics and practitioners, which is one of my main interests.

An idea which emerged from the meeting in Malta is the importance of the role of expert judgement in the policy and decisions required to secure early access to medicines. Early access initiatives often involve evaluation of new medicinal products before conclusive evidence about their effectiveness and benefit/risk is established, leading to conditional approval and possibly the transfer of additional risk to the post-authorisation phase. This concept is particularly applicable for certain disease conditions where there is unmet medical need, and will start being increasingly applied in practice. Early access to medicines has an impact on healthcare providers and payers and is an issue of great concern for them. This led to the proposal of organisation of a workshop for healthcare providers and payers from the NHS in Scotland. The aim was to identify and develop the role of expert judgement in the area of early access to medicines to support decision makers in their role and catalyse papers and/or grant proposals on this contemporary topic.

I was on the organising committee of this workshop and also delivered one of the presentations. This STSM enabled my participation at the workshop at Strathclyde and my contribution to the preparatory and follow-up work related to the workshop. It also supported other activities.

**Work carried out during the STSM**

***Workshop***

The main planned activity for the STSM was a workshop which was held at the 9th of March. This workshop was hosted by the University of Strathclyde Business School in joint collaboration with the Strathclyde Institute of Pharmacy and Biomedical Sciences. The workshop was entitled ‘The changing evidence base facing Health Systems and Health Technology Assessment (HTA) organisations – can a more informed identification and management of uncertainties and risk better support the planned introduction of new medicines?’.

The workshop organising team was constituted of Prof Alec Morton from the University of Strathclyde Business School, Prof Marion Bennie from the Strathclyde Institute of Pharmacy and Biomedical Sciences, Prof Brian Godman from the Strathclyde Institute of Pharmacy and Biomedical Sciences and the Karolinska Institutet in Stockholm and myself. The agenda and allocation of the topics of the presentations were done by the organising committee. The communication, invitations and arrangements with the participants of the workshop were done by Prof Bennie, who also holds a senior joint appointment with the NHS in Scotland. Prof Morton, Prof Godman and I delivered presentations.

My presentation was entitled ‘Managing the introduction of new medicines into national health services–supporting decision makers in their challenges’. I described the changing paradigm in the regulatory framework for medicines due to the increased adoption of initiatives for early access and the impact of this shift on the access and sustainability of new medicines within healthcare systems.

The role of the COST STSM to fund my visit to Strathclyde and thus be able to participate at this workshop was acknowledged. Prof Tim Bedford, COST MC Chair also participated at this workshop and explained the role of COST Action IS 1304.

The invited participants were health service providers and payers from the NHS in Scotland and came from the Scottish Medicines Consortium, NHS Health Boards in Scotland and NHS NSS procurement. There was active discussion during the workshop. Following the workshop, a summary of the key themes which evolved through the discussions and potential areas for further exploration and piloting were drawn up by the organising committee in agreement with the participants.

***Academic collaboration***

Meetings were held with academics and research students from the University of Strathclyde Business School as well as the Strathclyde Institute of Pharmacy and Biomedical Sciences. A number of these meetings were held jointly with researchers from both institutions. On Monday 14th March I participated and presented at the meeting of the Strathclyde Institute of Pharmacy and Biomedical Sciences Better Use of Medicines Research Group, which was also attended by Prof Morton and students from the Strathclyde Business School.

***Attendance as a public observer at a meeting of the Technology Appraisal Advisory Committee of the National Institute for Health Care Excellence (NICE)***

On the 15th of March I attended the meeting of the Technology Appraisal Advisory Committee A of the National Institute for Health and Care Excellence (NICE) at their offices in London, as a public observer. Attendance at these meetings is through online pre-booking and approval. During the meeting there were presentations and discussions regarding the ‘Appraisal of tramatenib in combination with dabrafenib for treating advanced (unresectable or metastatic) BRAF V600 mutation-positive melanoma’. It was interesting to get an insight into how NICE manages the presence of the public at their meetings. Although there is a level of public involvement, in reality the public present cannot in any way participate in the discussion. Moreover only certain presentations and limited levels of discussion are done in the presence of the public. The deliberation is done in private.

**Description of the main results obtained**

The participants at the workshop gave positive feedback about the workshop. They considered that the issue of early access and the themes which evolved during the discussion were very applicable to their practice and work. Through the workshop the participants gained knowledge about structured expert judgement and possible tools which can be used to support their decision making. Practitioners were eager to explore ways increase their accountability and to improve the framework for their practices. The workshop showed that there are various areas where there can be benefit through collaboration between academics and decision makers in healthcare and these may lead to opportunities for proposals for research projects and funding in the future.

Observation of how reimbursement meetings are carried out by NICE and how they manage aspects of transparency and the issue of confidentiality during their decision making process. This insight will be useful in case that Malta decides to adopt such practices for increased transparency during decision making in the future.

**Future collaboration with the host institution**

Following this STSM there is the possibility that I collaborate with the academics at Strathclyde Business School, on research in the area of health technology assessment and other health related topics. For example during my visit I had discussions regarding a current PhD dissertation on the use of structured expert judgement in early health technology assessment and the possibility of including a medicinal product as one of the case studies in this project. I can also be involved in joint research projects and proposals between the Strathclyde Business School and Strathclyde Institute of Pharmacy and Biomedical Sciences, particularly through an already existing collaboration through the Better Use of Medicines Research Group.

As a result of the workshop, a number of potential areas for further exploration and piloting between the practitioners from the NHS and Strathclyde Business School and Strathclyde Institute of Pharmacy and Biomedical Sciences were identified. Some of these areas could be linked to ongoing PhD dissertations for students. Moreover the workshop may lead to specific collaborative initiatives related to the areas relevant to the practitioners from the NHS in Scotland and the academic institutions. Initiatives piloted and adopted by the NHS in Scotland can possibly be rolled out to other European countries.

**Foreseen publications/articles resulting from the STSM**

Following my presentation and contribution during the discussion at the workshop, I was invited by Prof Brian Godman, who is the co-ordinator of Piperska to attend at their annual Piperska meeting scheduled from the the 30th of May to the 1st of June at Leiden, the Netherlands. Piperska is a group of interested health authorities, health insurance companies, ministries of health, the World Health Organisation and academics from different European countries. I have been asked to discuss early access initiatives and their impact from the perspective of health authorities (payers).