EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Tourism, CSR, Consumer Goods and International Regulatory Agreements
Unit F5 Food and Healthcare Industries, Biotechnology

Access to Medicines in Europe

Meeting of the project group on promoting good governance for non – prescription drugs

Friday, 25 November, 2011 - Brussels

Draft Minutes

1. PARTICIPANTS

[redacted] (Germany), [redacted] (France), [redacted] (Lithuania), [redacted], [redacted], [redacted] (UK), [redacted] (PGEU), [redacted] (BCEU), [redacted] (CPME), [redacted] (EPF), [redacted] (AIM), Hubertus, Cranz, [redacted] [redacted] [redacted] (AESGP), [redacted] (EMINet).

Apologies: Portugal, Denmark.

2. INTRODUCTION

The co- Chairs (DG Enterprise & Industry and the UK) welcomed the participants to the first face to face meeting of the project group on promoting good governance for non prescription drugs, launched in the framework of the Platform on access to medicines in Europe of the process of corporate responsibility in the field of pharmaceuticals.

The co-Chairs highlighted that the project is timely in light of the evolving role of self-care in healthcare and the empowerment of patients, as well as the international nature of pharmaceutical trade.

Co-Chairs explained that participation in the projects is on voluntary basis and so is the co-chairing – in line with the approach that is being followed in all five projects that run in parallel in the Platform on access to medicines in Europe. A big part of the coordination of the project will be organised via e-mails, if necessary conference calls and face to face meetings with an optimum perspective to conclude by the end of 2012 but without excluding the possibility to extend this time framework a little if needed. Although this group starts slightly later than the others under the platform everybody is committed to facilitating its progress.

The objectives of the group are to enhance collaboration and exchange of best practices between interested stakeholders and reach practical outcomes linked with the Terms of Reference. To conclude the process and based on the experience, members will be invited to propose a list of best practices and recommendations for adoption by the Steering group.

Specific objectives of the meeting of the 25th November:

-Discuss and agree the draft Terms of Reference of the group

-Agree on an outline work plan and discuss priorities in the context of the operation of the existing regulatory framework.

The group agreed that it would be important to start by developing a sound understanding of the landscape and the issues for non-prescription medicines in Europe.

3. PRESENTATION OF THE TERMS OF REFERENCE

The first draft text of the Terms of Reference was presented to the group. This had been prepared taking into account the comments from the teleconference of October, 2011. There was a detailed examination of the text and there were proposals for amendments. There was an agreement that the text would be redrafted based on the discussions and circulated to members for comment and approval.

Some of the main comments /proposals of the discussion were:

- A short introduction will be added underlying the connection with the Process of Corporate Responsibility in the field of pharmaceuticals.

- An addition in the preamble will clarify that the primary aim of the project group was improving and enhancing the governance of non-prescription medicines in the context of operation of the current legislative framework. The group noted that the focus is on non-prescription medicines and not food supplements and other products not regulated under the pharmaceuticals regime.

- The text should be focused on clear deliverables of the project.

- The text should include exploring the "situation on the ground", i.e. the great diversity among the member states.

- There was a discussion on terminology and the different perception of some terms, such as "appropriate uptake" and whether the term "consumers" or "patients" should be used. EMINet proposed the development of a working glossary.

- Patients' attitudes and expectations, and their perception of non-prescription medicines played an important role impacting on disparities in national approaches, and creating enablers or barriers to switches..

- Consider different traditions and cultures that could affect risk analysis as well as other parameters.

- Consider the cross border dimension, the possibility for a patient to obtain a medicinal product on different terms between Member States (with / without prescription, without / without reimbursement).

- the issue of Pricing & Reimbursement aspects of non prescription medicinal products issue should on balance be included within scope, as though it is complex it is fundamental for improving the access to non-prescription products - the group will try to at least note the most important of the issues and to understand any links between reimbursement status and reclassification.

4. EXCHANGE OF EXPERIENCES

In the framework of exchange of ideas / experiences / best practices co-Chairs invited all members of the group, competent authorities and the other stakeholders to present their own perspective of the situation.

At the first meeting the following presentations were made and are attached:

European Patients Forum (EPF) – Value of self care – the group noted some interesting initiatives (eg web education tools) which would be worthy of further exploration

Pharmaceutical Group of the European Union (PGEU) – Innovation in Pharmacies – the group considered that the best use of pharmacy resource was worthy of further discussion

Association of the European Self Medication Industry (AESGP) – Historical perspectives on reclassifications - the group agreed that the experiences offered useful opportunities to learn from both successful and unsuccessful reclassifications

EMINet[1] – Possible ways of cooperation with the group on data collection and research in light of the work done to date and ongoing EMINet strategy..

5. NEXT STEPS

All of the documents considered, Terms of Reference and Minutes would be shared after adoption via the CIRCA library system. The same applies for all the presentations. Additionally:

- Amended text of the Terms of Reference will be sent to group members for adoption through a written procedure preferably by 9/12 in order to present them at the Steering Group meeting of the 13/12 in Poland.

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[1] The EMINet project – European Medicines Information Network on Pricing and Reimbursement of pharmaceuticals – was launched in December 2008 and is co-funded by the European Commission (DG Enterprise and Industry). It aims to support EU Member States, EEA-EFTA countries and the Commission by providing information, technical expertise and analysis on pharmaceutical pricing and reimbursement policies and related topics.

EMINet is established by three partners:

1. Gesundheit Österreich GmbH, Österreichisches Bundesinstitut für Gesundheitswesen -GÖG/ÖBIG- located in Vienna/Austria (acting as Leader)
2. Andalusian School of Public Health, Escuela Andaluza de Salud Pública, -EASP- located in Granada/Spain
3. LSE Health and Social Care (LSEHSC) - a research centre in the Department of Social Policy at the London School of Economics and Political Science - located in London/United Kingdom

- Next face to face meeting of the group is likely to be held in April 2012.

- The Commission will establish what data is available on patient attitude and data gathering (for example Eurobarometer, draft EMINet papers), with input from group members as appropriate.

- The UK will provide futher information on an initiative to be launched around April 2012 (GP practices and measurable improvements)

- Between now and next meeting EMINet will prepare a draft Glossary

- Denmark will give a presentation at the next meeting on their national experiences

- AESGP will provide input on innovative approaches by the industry and identify case histories of successful and unsuccessful reclassifications.