STAMP 1/002

Scope, objectives and functioning of the Commission Expert Group on Safe and Timely Access to Medicines for Patients ("STAMP")

DRAFT

Introduction

The balance between evidence-based marketing authorisation and timely access of patients to innovative medicines is a constant challenge in the field for pharmaceuticals. Patient access to innovative medicines is a complex issue influenced by many different factors, including pricing and reimbursement which are national competence of the Member States.

Over the years, flexibility has been built in the existing authorisation system to facilitate early access of patients to medicines with mechanisms, such as the accelerated assessment procedure, conditional authorisations, and authorisation under exceptional circumstances on the basis of less complete data, to address unmet medical needs.
In addition, the pharmaceutical legislation provides the possibility to make medicines available to patients before a marketing authorisation is granted, on grounds of compassionate use and treatment on a 'named-patient basis'.

Despite the measures already in place, the issue of earlier access to innovative and affordable medicines for patients continues to be raised. Several initiatives have sprung in recent years in relation to this issue.

The European Medicines Agency (EMA) initiated in March 2014 a pilot project on adaptive licensing (AL). Adaptive licensing is defined as a prospectively planned process, starting with the early authorisation of a medicine in a restricted patient population, followed by iterative phases of evidence gathering and adaptations of the marketing authorisation to expand access to the medicine to broader patient populations[1]. There are also developments in the field of personalised medicine, a medical approach ensuring the right treatment to the right patient[2].

Some Member States have developed initiatives to allow patients with life threatening or seriously debilitating conditions to get access to medicines that do not yet have a marketing authorisation. More recently, the need to support innovation with better use of the existing regulatory tools for marketing authorisation procedures was highlighted in

[1] EMA's communication on adaptive licensing following the initial experience of the Adaptive Licensing Pilot project:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000601.jsp&mid=WC0b01ac05807d58ce

[2] http://ec.europa.eu/health/files/latest_news/2013-10_personalised_medicine_en.pdf

the Informal Health Council in Milan on 22 September 2014 and in the Council conclusions on innovation for the benefit of patients[3].

Responding to these developments, the Commission initiated in March 2014 a reflection process with the Member States to discuss the link between the pharmaceuticals regulatory framework and timely access of patients to medicines. The Commission asked the high level experts from the Member States in the Pharmaceutical Committee to give their views on several issues including:

- whether current approaches to marketing authorisation meet the objective to ensure timely access of patients to innovative medicines;
- ways to improve the situation within the current legal framework; and
- the perceived merits and weaknesses of an adaptive licensing approach from the regulatory/policy point of view.

On the basis of the feedback received by the Member States and on advice by the Pharmaceutical Committee, a Commission expert group on **"Safe and Timely Access of Medicines to Patients" (STAMP)** was created.

Scope:

The STAMP expert group is set up to provide advice and expertise to the Commission services in relation to the implementation of the EU Pharmaceutical legislation, as well as programmes and policies in this field. The STAMP will exchange views and information about the experience of Member States, examine national initiatives and identify ways to use more effectively the existing EU regulatory tools with the aim to further improve safe and timely access and availability of medicines for patients.

Objectives and tasks:

Within the aforementioned scope, the main objective of the STAMP is to assist the Commission services to identify ways to further improve safe and timely access and availability of medicines for patients, including specific categories of medicines (e.g. orphan medicinal products, antibiotics etc.) or medicines for specific therapeutic areas.

To attain this objective the STAMP will:

- Examine the link between the pharmaceutical regulatory framework and the timely access and availability of medicines for patients.
- Exchange views on the problems identified with the implementation of the EU pharmaceutical legislation and the reasons for those problems.
- Analyse adaptive approaches to marketing authorisation, in particular EMA's pilot project on adaptive licensing, from the policy and regulatory point of view.
- Exchange views on Member States' experiences and national initiatives.
- Identify ways, where possible, to use more effectively existing EU regulatory tools.

[3] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/145978.pdf

- Explore, where possible, ways to increase information-sharing and cooperation among Member States.

The tasks identified as well as priorities and timelines will be included in a work programme to be set up and adopted after the first meeting of the STAMP. The work programme will be reviewed, if necessary in the light of the progress of discussions.

Limitations

Whilst the role of the expert group is to provide advice and expertise to the Commission services with regard to the implementation and better use of the existing EU pharmaceutical legislation, this group is not mandated to provide advice with the aim to revise the basic acts Directive 2001/83 and Regulation 726/2004.

Although Health technology assessment as well as pricing and reimbursement policies are important aspects influencing the patient access to and availability of new medicines, they will not be the primary focus of the STAMP. On the other hand, for the benefit of a more holistic approach synergies will be created with other groups and European activities dealing with these issues, such as the HTA network, the Network of Competent Authorities on Pricing and Reimbursement (CAPR), the Process on Corporate Responsibility in the field of Pharmaceuticals, EMA pilots on scientific advice involving HTA Bodies, the SEED Consortium and the Council Working Party on Public Health at Senior Level.

Activity Report

The STAMP may decide to produce reports or reflection papers for the specific issues identified and discussion during its meetings.

Meetings documents and summary records will be published on the dedicated webpage under the following link:
http://ec.europa.eu/health/documents/pharmaceutical-committee/stamp/index_en.htm

Members

Member States' authorities, the European Medicines Agency and EEA countries will be invited.

The representatives will be appointed by the Member States on the basis of their expertise on the topics to be discussed. Member States may nominate individuals as permanent representatives or appoint appropriate representatives on an ad hoc basis depending on the meeting agenda.

The Commission services may invite experts with specific competence in a subject on the agenda to make a presentation or take part in the work of the group on an ad hoc basis.

Meeting frequency and duration of the activity

The maximum number of face-to-face meetings will be four per year. Further consultation may be carried out by e-mail in order to keep up dynamic discussions in between meetings. The STAMP is a temporary working group which will continue its activity for the period of time needed to complete its tasks.