Council of the European Union

Brussels, 6 July 2015
(OR. en)

9869/15

LIMITE

PHARM 29
SAN 183
MI 398
COMPET 311

NOTE

From:	Presidency
To:	Delegations
Subject:	Innovation for the benefit of patients: Follow-up to the Council´s conclusions – *Discussion*

In view of the meeting of the Working Party on Public Health at Senior Level on 15 July 2015, delegations will find attached a document prepared by the Presidency in cooperation with BE, NL, MT and SK delegations on the above-mentioned subject.

Discussion Paper
(BE, LU, NL, MT, SK)

A LONG TERM AGENDA FOR BETTER ACCESS TO INNOVATIVE AND AFFORDABLE MEDICINES

1. General context: the need for a long term agenda

At its meeting on 17 February 2015, the Working Party on Public Health at Senior Level (WPPHSL) approved the proposal of the Latvian and next four Presidencies (LU, NL, SK and MT) to establish a long term agenda for improving innovation for the benefit of patients as a follow up to the **Council conclusions on innovation for the benefit of patients** adopted on 1st December 2014[1].

At the same meeting, Belgium presented a non paper setting out possible actions to be taken by the Member States on a voluntary basis with the support of the European Commission, which could be part of such long term agenda.

It has been stressed that any future discussion and possible actions shall be without prejudice to the Member States' competences for their health policy and for the organization and delivery of health services and medical care and the allocation of resources to them, shall take place within existing fora and that the participation of Member States shall be voluntary.

It was agreed that the incoming Presidencies would continue the work in more detail and define specific items for discussion at the forthcoming meetings.

[1] see: doc 5511/2015, OJ C438, 6.12.2014, p.12

Meanwhile, an important **report on access to new medicines in Europe** was published in March 2015 by **WHO** Europe, providing an overview of policy initiatives and opportunities for collaboration and research[2].

This report underlines that "the balance between ensuring long term sustainability of health care systems with appropriate access for patients and fair reimbursement for innovation is one of the biggest challenges for systems in Europe and worldwide."

From this report several issues emerge, such as the need for :

- collaborative and transparent policy making and prioritization;
- a common vision on what constitutes a fair reward for innovation while preserving access;
- closer collaboration between European health systems focusing on the entire continuum of care including prevention and treatment.

Furthermore, one cannot ignore the growing attention of the **European Parliament** to measures needed for ensuring availability and affordability of medicines in the European Union as reflected by recent debates and parliamentary questions, just as by the launch of the Interest Group on Patient Access to Healthcare on 27 January 2015.

Finally, important initiatives are taken at European level, namely the creation of a Commission Expert Group on Safe and Timely access to Medicines (**STAMP**)[3] and the further development of the network on Health Technology Assessment (**HTA-Net**)[4] bodies using the instrument of joint action.

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2 « Access to new medicines in Europe : technical review of policy initiatives and opportunities for collaboration and research »: http://www.euro.who.int/en/health-topics/Health-systems/medicines/publications2/2015/access-to-new-medicines-in-europe-technical-review-of-policy-initiatives-and-opportunities-for-collaboration-and-research

3 For a description of the scope and mandate of the group, please see: http://ec.europa.eu/health/files/committee/stamp/stamp_stamp_agenda_point_2_mandate_en.pdf

4 For a description of the scope and mandate of the group, as well as its strategy, please see: http://ec.europa.eu/health/technology_assessment/policy/network/index_en.htm

2. Future action and deliverables steered by the WPPHSL

In its conclusions on innovation for the benefit of patients of 1st December 2014 (see point 30), the Council mandated the WPPHSL to work further on innovations.

However, prior to defining an **agenda** for incoming Presidencies, it is necessary to **take stock of what already exists** in terms of current initiatives, structures and cooperation in this field and of **what needs to be done** in order to **address possible gaps**.

Subsequently a **long term agenda** could be established, defining future actions and deliverables and designate the (existing) fora that will execute the actions and deliverables. Initially this would cover the duration of the current WPPHSL work programme (2015-2017). Further on, the achievements along this agenda could serve as a basis for future discussions on the longer term developments in the field of pharmaceuticals and their consequences for the respective national systems and EU regulatory framework.

The WPPHSL shall monitor the implementation of this agenda, create synergies between the different fora discussing issues related to access to medicines, and where appropriate steer actions of these fora including relevant Council preparatory working structures. The fora that are currently discussing issues related to access to medicines are: the working party on pharmaceuticals and medical devices, the pharmaceutical committee, the Commission expert group STAMP, the HTA Network and the Network of Competent Authorities on Pricing and Reimbursement[5] (NCAPR).

3. Topics and activities

The following issues and activities could be addressed by the upcoming trio Presidencies and where necessary steered by means of strategic discussions by the WPPHSL, without prejudice to Member States' competences:

- The development of common perspectives on the challenges associated with access to innovative medicines, including aspects such as cooperation on assessing the economic value of personalised medicine and its cost-effectiveness as compared to standard of care, both on European level and on Member States level;

[5] The Network of Competent Authorities responsible for Pricing & Reimbursement (NCAPR) is a platform set by the Member States during the Slovenian Presidency (2008) aiming at the exchange of information and best practices on pricing and reimbursement topics. Each rotating Presidency is responsible for the organisation of these meetings with the European Commission acting as a facilitator providing financial and administrative support.

- the development and testing of a methodology for a so called 'horizon scanning exercise'. This will allow Member States to signal potentially successful treatments at an early stage that could pose a budgetary risk or otherwise could create policy dilemmas for Member States. This can be of great value in relation to pricing and reimbursement strategies of Member States (cf. HepC treatment Sofosbuvir/Sovaldi in 2014) (see: point 35 and 40 of the Council Conclusions);
- the exchange of views on how to make effective use of the existing EU regulatory tools of accelerated assessment, conditional marketing authorization and authorization in exceptional circumstances, including the outcomes of the EMA pilot on "adaptive pathways", and on the effectiveness and impact of these tools while ensuring a high level of patient safety, (see: point 31 of the Council Conclusions);
- to provide a comprehensive and in-depth evaluation of the functioning of the pharmaceutical legislation in relation to several aspects (e.g. response to unmet medical needs, timely access to patients, the functioning of incentives, effect on innovation, etc). Such an evaluation would be essential to obtain an independent view on the "fitness for purpose" of the legislation. This study is already planned under point 4.3.11 of the 2015 Work Programme of the Third Health Programme[6] (in accordance with thematic priority 3.6 in Annex I to the Programme Regulation No 282/2014).
- the analysis of the (financial) impact on national budgets of specific financial incentives in relevant EU market access regulations (e.g. data protection, supplementary protection certificates)[7];
- the development of an instrument for information exchange, via the NCAPR, on drug use, market structure and circumstances, post marketing knowledge and other relevant information to support Member States in drug pricing and reimbursement decisions (see: point 27, 29 and 40 of the Council Conclusions);

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6 COM (2015) 3594 final, 2.6.2015. Point 4.3.11.

7 Article 9(3) of Regulation (EC) No 141/2000 on orphan medicinal products requires that the Commission publishes, on a regular basis, a detailed inventory of all incentives made available by the Commission and the Member States to support research into the development and availability of orphan medicinal products. That inventory should be updated regularly.

- the development of joint approaches on pricing and access schemes, for those MS who wish to participate on a voluntary basis, that would enable:
  - fitting payment schemes in adaptive processes;
  - voluntary joint negotiation processes;
  - evaluation of voluntary joint negotiation processes (see: point 36 of the Council Conclusions);

whilst recognizing that pricing remains a Member State competence (see: point 35 a and 36 of the Council Conclusions);

- the elaboration of appropriate research and information tools that aim to provide a better understanding of how pharmaceutical markets work, including how pharmaceuticals pricing may be applied to maximise benefits for patients and Member States' health systems, and, where relevant, to minimise possible unintended negative effects on patient access and health (see: point 27, 32 and 41 of the Council Conclusions);
- the elaboration of appropriate monitoring instruments relating to medicines shortages, due to parallel export or other reasons, and the evaluation of the access to valuable innovative medicines in the context of resilient and sustainable healthcare systems in Europe.

4. Working Arrangements

Each **incoming Presidency** will focus on one of the above mentioned topics and will prioritize it during its term-in-office, in coordination with future Presidencies, so as to ensure that all topics are properly addressed in the foreseeable future. Progress and results on the individual activities of this agenda will be reported to the WPPHSL by the rotating Presidency.

The attached **roadmap** in Annex I provides for a first indicative agenda setting for the period 2015-2017.

The activities listed in annex I, should be **implemented** by the relevant parties, making the best use of the work and where possible creating synergies with existing Council working parties, expert committees and other working structures, and looking for close consultation with competent authorities and stakeholders, including representatives of patients, industry and other parties involved.

The Commission shall **support** the implementation of the activities listed in Annex I, and in particular as follows:

- support the cooperation among Member States to implement the HTA strategy,
- support the exchange of information between Member States on prices, pricing policies and economic factors determining the availability of medicinal products as well as, where appropriate, medical devices, with particular attention being paid to orphan medicinal products and small markets,
- identify the need for and support of research and information tools that aim to provide a better understanding of how the pharmaceutical markets work, including how pricing and reimbursement may be applied to maximise benefits for patients and Member States' health systems,
- continue discussions with the Member States within the STAMP and the pharmaceutical Committee on ways to optimize the use of existing regulatory tools within the EU pharmaceutical legislation.

A **mapping, taking stock** of the various initiatives, activities and different fora has been provided by the Commission (see annex II), including an overview of studies, reports, analyses and other activities that are undertaken by the Commission in the coming years in relation to access to innovative medicines. Based on this exercise, the Commission is invited to contribute to the reflection on how the work of these fora can be further integrated and coordinated.

The activities listed above, as well as further analysis and debate on future developments regarding innovations for the benefit of patients, shall provide input for the elaboration of a **longer-term, integrated approach** in this field, covering relevant aspects in the pharmaceutical field, including accessibility and affordability of innovative medicines. Such a long-term view is to be elaborated by the **Council Working Party on Public Health at Senior Level in cooperation with the Commission,** with due respect to the existing division of competences in this field.

Annexes:

1)Roadmap 2015-2017

2)Mapping of activities

Annex I

Roadmap 2015 – 2017

Activity	**Subaction**	**Responsible & contributing fora**	**Timeframe**	**Deliverable**
1. Develop common perspectives on the challenges associated with access to innovative medicines, including aspects such as cooperation on assessing the economic value of personalised medicine and its cost-effectiveness as compared to standard of care, both on European level and on Member States level.		Responsible: NCAPR + WPPHSL Pharmaceutical Committee (PC) Contributing: COM	Ongoing	Adoption of Council Conclusions on Personalised Medicine providing further guidance (December 2015).
2. Anticipating future trends and developments by means of a joint 'horizon scanning exercise', which includes:	2.1 Developing methods	Responsible: NCAPR + HTA Net/ EUnetHTA Contributing: COM	Starting in 2015	Written methodology
	2.2 Testing methods on specific cases	Responsible: NCAPR + HTANet/EUnetHTA Contributing: COM	May 2016?	Report
3. Reflection of the effective use and impact of the existing EU regulatory tools of accelerated assessment, conditional marketing authorization and authorization in exceptional circumstances, including ensuring a high level of patient safety (see: point 31 of the CC).	3.1 To provide a comprehensive and in-depth evaluation of the functioning of the pharmaceutical legislation in relation to several aspects (e.g. response to unmet medical needs, timely access to patients, the functioning of incentives, effect on innovation, etc.). Such an evaluation would be essential to	COM (STAMP, PC) WPPHSL	2016-I	Commission to report to the member states WPPHSL to consider relevant conclusions and consider follow-up if appropriate WPPHSL to consider conclusions and consider follow-up.

	obtain an independent view on the "fitness for purpose" of the legislation. This study is already planned under point 4.3.11 of the 2015 Work Programme of the Third Health Programme[8] (in accordance with thematic priority 3.6 in Annex I to the Programme Regulation No 282/2014).			
	3.2 Assessment of outcomes EMA Pilot on "Adaptive Pathways"	Responsible: COM (STAMP) PC Contributing: WPPHSL	2016-I	Commission to report to WPPHSL on outcomes of the pilot and lessons learned
	3.3 Debate at EU and Member State level on the effective use and impact of the existing EU regulatory tools of accelerated assessment, conditional marketing authorization and authorization in exceptional circumstances and their impact on patient safety	Responsible: COM (STAMP) PC WPPHSL	2016-I	Commission to inform WPPHSL of outcomes of the work of STAMP Presidency conference on integrated approach (see activity 8). Conclusions & follow up

[8] COM (2015) 3594 final, 2.6.2015. Point 4.3.11.

4. Analysis of the financial impact on national budgets of specific financial incentives present in specific EU market access regulation (e.g. data protection, supplementary protection certificates).		Responsible: PC + NCAPR + Member States	Ongoing	Report
5. Information exchange on drug use, market structure and circumstances and other relevant information that supports Member States in drug pricing and reimbursement decisions.		Responsible: NCAPR + Member States Contributing: COM	Ongoing	Elaboration of information needs Analyses of data availability Formulation of core data set Data collection plan
6. Development of joint approaches on pricing and access schemes, for those MS who wish to participate on a voluntary basis, with the aim to - inter alia:	6.1 Elaborate fitting voluntary payment schemes in adaptive pathway processes	Responsible: NCAPR + WPPHSL Contributing: COM	2016	Working paper NCAPR
	6.2 Enable and experiment with joint and voluntary negotiations between Member States	Responsible: NCAPR + WPPHSL	Ongoing	Experiments conducted
	6.3 evaluate methods and practices regarding voluntary joint negotiation processes and through joint contribution to the clinical protocols of Managed entry schemes	Responsible: NCAPR+ HTA Net/ EUnetHTA + WPPHSL	2016-I	Evaluation report NCAPR Start EUnetHTA JA3 in 2016
7. Elaboration of appropriate research and information tools that aim to provide a better understanding of how pharmaceuticals pricing may be applied to maximise benefits for patients and Member States' health systems, where relevant, to minimise possible unintended negative effects on patient access and health		Responsible: COM	Starting in 2016-I	Commission to propose to WPPHSL potential areas for further cooperation

8. Elaboration of appropriate monitoring instruments relating to medicines shortages, due to parallel export or other reason, and measure the access to valuable innovative medicines in the context of resilient and sustainable healthcare systems in Europe.		Responsible: NCAPR, WPPHSL, PC	Starting in 2016-II	WPPHSL to identify potential areas for further cooperation
9. Elaboration of a longer-term, integrated approach in the field of pharmaceuticals, building on the activities in this long-term agenda as well as the Commission's mapping exercise taking into account developments from activities 3., 6. and 7.).		Responsible: PC + NCAPR + WPPPHSL Contributing: COM	Starting in 2016-I	Presidency conference on integrated approach towards access, pricing and reimbursement Poss. Council Strategy incl. possible further actions.
10. Proposals on how further integration and coordination can be reached between the functioning of different relevant fora		Responsible: WPPHSL + PC + NCAPR Contributing: COM	2016-II	WPPHSL to make proposals on basis of mapping exercise

Acronyms:

NCAPR: Network of Competent Authorities on Pricing and Reimbursement

WPPHSL: Working Party on Public Health at Senior Level

PC: Pharmaceutical Committee

STAMP: Expert group on Safe and Timely Access to Medicines for Patients

Annex II

Background paper on 'Mapping on Access to Innovative Medicines'

provided by the Commission

1. Problem definition

European citizens need access to innovative, safe and affordable treatment. Access to medicines is based on a process with crucial multi-level decision making from the development until the time that the patient can access a product.

In the EU, the picture is rather complex; during this process competences are distributed at various levels of governance, perspectives are differentiated between relevant stakeholder groups and competing policy goals need to be managed (competiveness, innovation, patient access, affordability). Moreover, in some Member States, economic considerations are detaining products to be available to patients (the price and the market size or the cost for authorisation and supplying). Evidence shows that current pricing systems in Member States may result in unintended effects, while the high prices of innovative medicines have seen a lot of attention.

On the one hand, pre-market regulations (i.e. the EU pharmaceutical legislation including clinical trials regulation, EU rules on authorisation, the European Medicines Agency (EMA) and the Network of national competent authorities on Pricing and Reimbursemenet) provide a robust framework to secure that innovative treatments are made available for all EU citizens. On the other hand, complex and fragmented post-market approval processes and decisions seem to have a restraining effect on accessibility. Therefore, while taking into account national competences of Member States, an improved cooperation and coordination at EU and at national level through an 'integrated approach' will be of added value.

2. Mapping of current EU level initiatives

Based on previous work and mandate given by Council Working Party on Public Health at Senior Level (WPPHSL) as well as on the Council conclusions on Innovation for the benefit of patients adopted on 1st December 2014, the LU Presidency in cooperation with the next Trio of Presidencies (NL, SK and MT), goes further and presents a detail mapping of current initiatives that need to cooperate in order innovation to work for the benefit of patients.

This exercise gives a clearer view of the EU level actions in place with a focus on five areas: (1) development of a treatment, (2) authorisation procedures, (3) Health Technology Assessment (HTA) and market access, (4) decisions on pricing and reimbursement and procurement and (5) decisions once products placed on the market (see figure on page 4).

(1) Development of Treatment.

Boosting clinical research in Europe by simplifying the rules for conducting clinical trials will give patients access to most innovative treatments. Clinical trials are vital to develop medicines and to improve and compare the use of already authorised medicines. The new *Regulation No 536/2014 of the European Parliament and of the Council* ***on clinical trials*** *on medicinal products for human use, and repealing Directive 2001/20/EC* entered into force on 16 June 2014 and will apply no earlier than 28 May 2016.

Several other EU initiatives also aim to bring innovative treatments to the patient. The Innovation Union strategy the ***European Innovation Partnership on Active and Healthy Ageing*** fosters innovation in products, processes and services, and in parallel facilitates the innovation chain while reducing the time to access market for innovative solutions. Ultimately this will produce benefits for the older people and care providers. Other initiatives are the European Commission's ***Scientific Panel for Health (SPH)*** a science-led expert group based on the provisions of the Horizon 2020 Specific Programme and the ***Innovative Medicines Initiative (IMI)*** which supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe.

(2) Authorisation procedure.

Over the years, flexibility has been built into 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.

Several other initiatives have been on-going in recent years in relation to this issue, including the European Medicines Agency's (EMA) pilot project on ***Adaptive pathways*** and the *Platform on Medicines Adaptive Pathways to Patients (**MAPPs**)* under IMI. EMA's concept of adaptive pathways foresees an initial approval in a well-defined patient subgroup with a high medical need and subsequent widening of the indication to a larger patient population, and where uncertainty is reduced through the collection of post-approval data on the medicine's use in patients. The *adaptive pathways* approach builds on regulatory processes already in place within the existing legal framework. The two main elements of the approach are 1) the early discussion between a wide range of stakeholders including EMA, the pharmaceutical industry, health-technology-assessment (HTA) bodies, patient organisations, and healthcare professionals and 2) reliance on post-authorisation data (real-life data collected through e.g. patient registries and pharmacovigilance tools) in order to reduce uncertainty. EMA's approach was designed with the hope to reduce the time necessary for a medicine's approval or for its reimbursement for targeted patient groups, especially in case of high unmet medical need. It is important to ensure that this approach is based on a balanced approach between on the one hand the importance of timely patient access and, on the other hand, the need for adequate, evolving information on a medicine's benefits and risks.

Responding to these developments and to the *Council conclusions on innovation for the benefit of patients,* the *Pharmaceutical Committee* created a Commission expert group on *"Safe and Timely Access of Medicines to Patients" (**STAMP**)* to discuss issues regarding the market access from the point of view of the pharmaceuticals regulatory framework. The STAMP is examining how to optimise the use of current regulatory tools such as conditional marketing authorisation and accelerated assessment, including the adaptive pathways approach, to facilitate patient access to innovative medicines. Even if the mandate of the STAMP is limited to regulatory issues related to pre-market approval of medicines, it is evident from discussions so far (two meetings took place in 2015) that the optimisation of authorisation procedures and time to approval cannot alone improve patient access to innovative medicines which is directly linked to *Health Technology Assessment (HTA)* and pricing and reimbursement decisions. The need has therefore been identified to create synergies at EU level between the STAMP and other fora such as the *HTA Network*, the network of *competent authorities on pricing and reimbursement* (the "CAPR") etc. Similar efforts for collaboration between different actors (regulators, HTA bodies, payers) should also be created at national level, but this seems to be often complex depending on the structure and relations of national bodies.

(3) Health Technology Assessment (HTA).

HTA is a key tool for decision makers to provide cost effective healthcare. The European Commission has funded cooperation among national HTA Agencies on scientific issues since the mid-1990s through research projects and two Joint Actions. Overall the Commission has invested about 30 million € in supporting cooperation and research in HTA. The second Joint Action on HTA (***EUnetHTA***) will end in October 2015. The European Commission has proposed a 12 million € third Joint Action (2016-2019) in the 2015 Work Programme of the Health Programme. Since October 2013 an ***HTA Network*** was set up by Directive 2011/24/UE on patient mobility which gathers Member States representatives responsible for HTA and focuses on strategic issues. A Strategy for EU cooperation has already been agreed in October 2014, which will be implemented through the new Joint Action.

The ***HTA Network strategy*** and the proposed third Joint Action on HTA are key instruments to implement the objectives of the HTA Network, namely to support Members States in their HTA activities and avoid duplication of assessments (Article 15, Directive 2011/24). HTA cooperation is not interfering with decisions on the price level of medicines as well as their reimbursement status, which are Member State competence.

(4) Market access: Decisions on Pricing, Reimbursement, and Procurement.

The ***'Transparency Directive'*** (89/105/EEC) sets timelines for pricing and reimbursement decisions at national level and lays down procedural rules applicable to any national measure regulating prices of medicines and their inclusion in the scope of health insurance systems. It does not interfere with Member States' competence to regulate the substance of pricing and reimbursement, but sets timelines for pricing and reimbursement decisions at national level.

Whereas decisions on the price level of medicines as well as their reimbursement status are Member State competence, action at EU level has played a supportive role in several ways:

- Through a ***voluntary network of competent authorities on pricing and reimbursement*** *(the "**CAPR**")*, which was set up to deal with issues related to pricing and reimbursement policies. The network may also discuss issues impacting the accessibility and sustainability of health systems, depending on the priorities of each rotating Presidency.

- The ***Process on Corporate Responsibility in the pharmaceutical sector*** **(2010 – 2013)**[9], achieved concrete results (e.g. consensus reports / documents). Under this process, Member State representatives and other relevant stakeholders – industry, patients, health professionals, insurers, etc., - have worked together and achieved consensus based results on specific topics and pricing and reimbursement policies (a mechanism for coordinated access to orphan medicinal products, facilitating the supply in small markets, capacity building on managed entry agreements for innovative medicines, market access for biosimilars and good governance for non-prescription medicines).

- The Commission adopted a ***Staff Working Document*** **on 26 June 2014** which underlines the economic importance of the European pharmaceutical industry, identifies main challenges of the sector and takes note of the work concluded under the ***Process on Corporate Responsibility in the Field of Pharmaceuticals***. As a follow-up to the Staff Working Document, the Commission organised *two multi-stakeholder meetings* (Rome – October 2014, Riga – April 2015) for an exchange of views on topics of high interest and pricing and reimbursement policies.

- The Commission's ***Communication on "effective, accessible and resilient health systems"*** (4 April 2014)[10], recognises that the work on cost-effective use of medicines is one of the actions that can increase accessibility (other two actions recognised: adequate planning of EU health workforce, optimal implementation of the cross-border directive).

- A project grant[11] to support and improve ***information sharing and statistical data*** in the area of medicinal product pricing in Member States, expected to start in second half of 2015 for a duration of 3 years.

- A study[3] exploring ***alternative pricing approaches as well as related cooperation mechanisms*** in view of possible impacts, including on patient access. This study is expected to be delivered by the end of 2015.

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9 http://ec.europa.eu/growth/sectors/healthcare/competitiveness/corporate-responsibility/index_en.htm

10 http://ec.europa.eu/health/healthcare/docs/com2014_215_final_en.pdf

11 See entries 2.1.3.2 and 3.3.7 of the 2014 work plan of the public health programme, available via http://ec.europa.eu/health/programme/docs/wp2014_annex_en.pdf

- The ***possible use of the Joint Procurement agreement (JPA)*** under the decision on *Cross Border Health Threats* to purchase high-cost innovative treatment has been confirmed by a technical analysis which was published in December 2014. It is Member States' decision to use the tool.

(5) Products placed on the market.

After their placing on the market, innovative treatments have to be monitored for safety and public health reasons. The *EU* ***pharmacovigilance*** *system*[12] is now one of the most advanced and comprehensive systems in the world. In addition, a major threat to public health comes from ***falsified medicines*****,** which are fake medicines that pass themselves off as real, authorised medicines. Directive 2011/62/EU has provided for the obligation for Member States to take the necessary measures.

Furthermore, work at EU level is going on to ensure that market players (Member States, national health services and pharmaceutical companies) respect the Treaty rules within the internal market. In July 2010 European Commission integrated its *antitrust activities* in a unit called "***Antitrust: Pharma and Health services***"[13]. The Commission cooperates with national competition authorities through the European Competition Network in this area, and the European Competition Network Pharma subgroup.

[12] The legal framework of pharmacovigilance for medicines marketed within the EU on http://ec.europa.eu/health/human-use/pharmacovigilance/index_en.htm

[13] http://ec.europa.eu/competition/sectors/pharmaceuticals/overview_en.html

3. Figure- Mapping EU on access to innovative medicines.