ECPC POSITION ON DRAFT REPORT ON EU OPTIONS FOR IMPROVING ACCESS TO MEDICINES

WHY A POSITION FROM CANCER PATIENTS?

The European Cancer Patient Coalition (ECPC) is Europe's largest cancer patient association, reuniting under one umbrella more than 400 patients' groups across all EU countries and beyond. ECPC speaks with one voice for all cancer patients, from those affected by high incidence cancers to those fighting versus the rarest ones.

ECPC has been recognised by the European Union as a reliable representative of the cancer patients' community: we represent patients in all key EU initiatives on cancer, like:

- The European Commission's Expert Group in Cancer Control;
- The Joint Action on Cancer Control – CanCon;
- The European Medicines Agency Patients' and Consumers' Working Party;
- We are also present in a series of formal and informal discussion tables within the European Commission, and we are partners in several high-level EU-funded research projects.

The Board of Directors of ECPC is composed by a majority of cancer patients / survivors and is democratically elected every three years.

The main mission of ECPC is to fight against the unacceptable inequalities in cancer care existing today in Europe. In this context, we believe necessary to respond to the own initiative report produced by MEP Cabezon Ruiz on the pressing issue of access to medicines, focusing on those solutions and recommendations that ECPC has developed in the past years to halt the growing inequalities in cancer patients' outcomes.

This paper and the amendments attached were approved by the ECPC Board, to make sure that the position of more than 400 cancer patients' organisation on access to medicines would be would be duly represented.

THE PROBLEM: GROWING INEQUALITIES IN CANCER CARE

In September 2015 ECPC described the nature and causes of the major inequalities in cancer care in the policy paper "Challenging the Europe of Disparities in Cancer". In regards to access to medicines, ECPC recognises 2 main issues:

- **Access to essential cancer drugs:** European patients face unacceptable shortages of essential, life-saving and often inexpensive cancer medicines. There are several causes of these shortages, and include the important issue of parallel trade, where medicines are bought in a member State where the agreed price is lower and resell at a discounted price in a country where the agreed price is higher. Other major factors include production disruptions (often related to quality issues), demand spikes, quotas, globalisation of production, and unintended impacts from pricing policies (e.g. reduction in available

European Cancer Patient Coalition – ECPC
40 Rue Montoyer/Montoyerstraat
1000, Brussels, Belgium

Phone : +32 (0) 234 20 104
www.ecpc.org
@cancereu
www.facebook.com/ECPCfb

suppliers). However, information on causes of medicines shortages is unfortunately not currently consistently collected and reported across Europe, making an accurate picture of the balance of causes difficult to determine. This should be addressed by a coordination and improvement of national information portals about shortages, including the product in shortage, the likely duration of shortage, reasons for the shortage and available alternatives.

- **Access to innovative medicines**: increased understanding of disease biology is fuelling a "personalised cancer medicine" revolution. However, providing these treatments in a timely fashion to European cancer patients is hampered by a pricing/ reimbursement approach that differs markedly between individual European countries, thus accentuating disparities in access to optimal cancer care. While the EU has adopted a common procedure for granting market authorisation to cancer medicines through the European Medicines Agency (EMA), pricing and reimbursement decisions reside with national governments/agencies. Despite an EU Directive on pricing and reimbursement that specifies a 180-day limit post EMA authorisation for national implementation, adherence/compliance with this deadline is extremely variable.

Key facts

- In **17 out of 28 of EU countries**, cancer has now overtaken cardiovascular disease as the **leading cause of premature death**;
- In Europe in 2012, there were 3.75 million new cases of cancer, with 1.75 million deaths, translating to **three European patients dying every minute** from this common disease;
- Inequalities in **access to quality treatments** (medicines, radiotherapy, surgery and survivorship care) **have a direct impact on survival across countries**;
- For every Elsa in Sweden who has an 86% chance of survival following treatment for breast cancer, there is an Ilsa or Elze just across the Baltic Sea in Latvia or Lithuania, whose survival chances drop to 69% and 66% respectively;
- For every Luca in Italy with an almost 90% chance of being alive 5 years after a diagnosis of prostate cancer, there is a Luka a few kilometres away in Croatia whose 5-year survival chances have shrunk to 71%
- In Poland, lung cancer mortality is 83% (EU Average 56.4%);
- A woman in Romania has **5 times more chances of dying of cervical cancer** than the average European (14.2% vs 3.7%);
- **Inequalities affect also Western EU countries**: UK and Denmark have significantly poorer survival rates, particularly for lung, colorectal and ovarian cancers, in comparison with Australia, Canada, Norway and Sweden;
- **Cancer costs Europe more than 126 billion EUR per year**. Direct costs of treatment (including medicines) account for 40% of the total. The remaining 60% weights only on the shoulders of cancer patients and their families, in terms of loss of income, years of life lost and worsening quality of life.
- **Cancer represents a great burden on healthcare systems in Europe**: approximately **20% of the burden of illness in Europe is related to cancer**. However, on average **only 6% of the total healthcare expenditures** at the national level **are used to fight cancer**.
- Many life-preserving/ life-enhancing medicines are relatively inexpensive, yet cancer patients in many European countries are denied access to their positive benefits.

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@cancereu
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- More than 50% of European hospitals have experienced significant shortages in access to essential cancer medicines, ranging from 33% (Northern Europe) to 59% (Western and Southern Europe) and 65% (Eastern Europe);
- **Cancer patients are living a paradox: research has provided us new weapons to fight cancer, but they are not available to all cancer patients.**
    - A ground-breaking innovative breast cancer drug (trastuzumab), included in the WHO list of essential cancer drugs, was immediately made available in several countries (Germany, the Netherlands, Finland, Austria etc.) but **patients in Denmark, Hungary, Slovakia and Latvia had to wait 1891, 2713, 3686 and 4660 days after the EMA market authorisation** before the drug was reimbursed.
- One third of all EU patients affected by metastatic melanoma (more than 5000 EU citizens) **do not have access to first line therapy recommended by European guidelines** and **do not have access to innovative medicines that are proved to be able to save their lives.**

GENERAL COMMENTS ON THE REPORT

We welcome the report as a great chance for the European Parliament to take a proactive stance on the issue of access to medicines. We strongly believe that the European Parliament has a responsibility to work in a fast and effective manner on those pressing issues of EU relevance and within the remit of the EU competence,

First and foremost, the European Union must work harmonise health technology assessment (HTA) at the EU level, in order to cut inefficiencies and delays in access to innovative medicines. **The Parliament has already worked on this topic (amendments of the regulation 726/2004 and relative debate in EP plenary in March 2016) and the Commission is running a Joint Action specific on this issues**. It is time to yield the fruits of our work and we urge the European Parliament to take a strong and ambitious stance on the proposals made by the European Commission in October 2016 on the harmonisation of HTA.

Secondly, it is imperative to increase the collaboration at the EU level on the information related to access to medicines. Shortages of essential cancer drugs are having unacceptable impact on the overall survival of millions of EU citizens and we call for a European effort to tackle such shortages. The issue of parallel trading is of particular EU relevance: we understand the principles of the Single Market, but we call the European Parliament and the Commission to take a truly patient-oriented policy stance recognising that medicines are not simple goods, but an integral component of our healthcare systems and therefore must be governed by social and equity principles beyond those of the free market. the pricing and reimbursement strategies. Finally, we recognise that pricing and reimbursement are national competences, but we agree with the report that more transparency and collaboration must be established to guarantee that the decision made by national bodies are backed up by

In the scenario of growing inequalities in cancer care, the real issue is not the price of medicines *per se*, but the overall sustainability of healthcare systems and their capacity to deliver quality services to all EU citizens. ECPC recognises the important issues affecting access to medicines in Europe, but underlines that focusing only on the price of medicines risks to shift the attention on the real problem, which is the financing and organisation of our healthcare systems as a whole, and in particular in the treatment of cancer. For this reason, we call the European Parliament and the Commission to promote the use of existing monitoring systems like the European Semester to provide guidance to Member States in relation to the financing and management of healthcare systems.

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SPECIFIC COMMENTS

INTRODUCTORY NOTES

The report does not mention important policy and legislative files on which the European Parliament is already working on, like the approved amendments to the Regulation 726/2004, voted by the ENVI Committee and the Parliament in the first quarter of 2016.

PHARMACEUTICAL MARKET

We agree with an increased transparency and cooperation between companies and governments and patients' organisation to agree on research priorities.

However, the points regarding pricing and costs are inaccurate and overall generic. We expected more precision and punctuality in identifying the real issues related to the sustainability of healthcare systems.

INTELLECTUAL PROPERTY AND R&D

We welcome the principles state in point 7, whereby new products derived from public funded R&D should be priced taking in consideration the financial contribution of public actors.

PRICING AND TRANSPARENCY

While pricing and reimbursement remain competences of Member States, we welcome a debate on those issues at the European Parliament, as was already done during the March 2016 plenary.

However, we suggest focusing on those components of the pricing and reimbursement process that can be affected by the European legislator, most notably on the relative efficacy assessment and, more in general, on the health technology assessment methodology.

We also welcome the statements related to added therapeutic value, whereby the added value of new medicines must take into better consideration existing standard treatments and the overall socio-economic impact of the new medicine.

EU COMPETENCES AND COOPERATION

In line with the previous comments, the statements of the report in this sections are not completely clear.

Nonetheless, we welcome the principle of increase transparency and we recommend to increase also the involvement of patients' organisations in the decision making processes related to access to medicines, both at the European and national level.

RECOMMENDATIONS

- ECPC greatly welcomes and fully endorses the following recommendations: 17, 24, 28, 34, 35, 36;
- Recommendation 19: we are dubious regarding the feasibility of such recommendation within the existing European and international legal frameworks. The report fails to provide concrete examples or

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assessments regarding the implementation of such recommendation. On the other hand, we believe that the role of patients' organisations must be embedded in the research and development strategies;

- Recommendation 23: ECPC welcomes the efforts made by EMA to implement effective and safe fast track authorisations. These models, including adaptive pathways and pilot projects like PRIME, can provide viable solutions to the unmet needs of highly vulnerable patients' groups. For example, rare cancer patients often face dire prognosis, with no available treatment for their disease: we must ensure they would be given the choice to access to innovative drugs that might provide positive results, on the basis of solid research and toxicity data. ECPC values the safety of new medicines, but recognises the different risk assessment evaluation that different group of patients have, and supports further efforts to implement adaptive licensing for medicines tackling well defined unmet medical needs;
- Recommendation 25: we welcome the first statement of the recommendation related to the promotion of future EU legislation aimed at harmonising HTA. However, we are concerned regarding the second statement related to the harmonisation of pricing and reimbursement criteria: we hope that further debate on the 5 scenarios presented by the Commission's impact assessment on HTA harmonisation will clarify the position of the Parliament on this matter;
- Recommendation 26: we welcome the main message of the recommendation. However, we would appreciate more clarity on the second statement, related to "conditional funding"
- Recommendation 31: we welcome the proposal to amend the existing legal framework on pricing of medicines. However, we would focus the revision of the Transparency Directive on those issues that are affecting patients' life the most, in particular in relation to the delays in pricing and reimbursement decisions.

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AMENDMENTS

New recital

Motion for a resolution	*Amendment*
	- having regard to the report approved by the Committee on the Environment, Public Health and Food Safety and by the European Parliament on the amendment of the Regulation 726/2004;

New paragraph after paragraph 2 (Pharmaceutical market)

Motion for a resolution	*Amendment*
	3. Stresses that patients' organisations should be better involved in the definition of private and public clinical trials research strategies, to ensure that they meet the true unmet needs of European patients

Paragraph 6 (Intellectual Property and Research and Development)

Motion for a resolution	*Amendment*
6. Emphasises that most medicines are not examples of genuine innovation, **but often 'me-too' or 'evergreening' products, which are permitted notably by complementary patent extensions**;	6. Emphasises that new medicines **bringing insufficient added clinical value** do not provide genuine innovation;

New paragraph before paragraph 10 (Pricing and transparency)

Motion for a resolution	*Amendment*
	10. Recognises that pricing and reimbursement of medicinal products are competences of Member States;

Paragraph 10 (Pricing and transparency)

Motion for a resolution	*Amendment*
10. Stresses that most national assessment agencies are already using clinical, economic and	**11.** Stresses that most national assessment agencies are already using clinical, economic and social benefit criteria to assess new drugs in terms of

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social benefit criteria to assess new drugs in terms of pricing and reimbursement;	pricing and reimbursement **and stresses the importance of increasing collaboration among Member States in the field of pricing and reimbursement of medicinal products to ensure sustainability of healthcare systems and preserve the rights of European citizens to access quality healthcare**

New paragraph after paragraph 16 (EU competences and cooperation)

Motion for a resolution	***Amendment***
	17. Highlights the role of the European Union in monitoring and providing guidance on economic policies within the framework of the European Semester, and welcomes the production of country-specific recommendations in the field of healthcare sustainability;

Paragraph 18 (Recommendations)

Motion for a resolution	***Amendment***
18. Calls for EU-wide measures on the pharmaceutical market to reinforce the negotiation capacities of Member States in order to achieve fair prices for medicines;	18. Calls for EU-wide measures on the pharmaceutical market to reinforce the negotiation capacities of Member States in order to **ensure fast and equitable access to innovative medicines;**

Paragraph 19 (Recommendations)

Motion for a resolution	***Amendment***
19. Calls on the Commission to promote R&D driven by patients' needs, **while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform for R&D funded by contributions from profits made by the pharmaceutical industry through sales to public health systems; calls for transparency on the costs of R&D**;	19. Calls on the Commission **to involve patients and their organisations in the definition of research priorities of all its programmes related to health**, to promote R&D driven by patients' need;,

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New paragraph after paragraph 20

Motion for a resolution	*Amendment*
	21. Calls on EU Member States and the pharmaceutical industry to increase transparency on the process of pricing and reimbursement of pharmaceutical products, including the costs of R&D;

Paragraph 22 (Recommendations)

Motion for a resolution	*Amendment*
22. Calls on the Commission to review the regulatory framework for orphan medicines, to define clearly the concept of unmet medical needs, to assess the impact of incentives to develop effective, safe and affordable drugs compared to the best available alternative and to promote the European register of rare diseases and reference centres;	22. Calls on the Commission to **update** the regulatory framework for orphan medicines, **to provide guidance on priority** unmet medical needs, **and to review existing** incentives **schemes to facilitate the development of** effective, safe and affordable drugs **for rare diseases, including rare cancers,** compared to the best available alternative and to promote the European register of rare diseases and reference centres;

Paragraph 23 (Recommendations)

Motion for a resolution	*Amendment*
23. Calls on the Commission to guarantee safety and efficacy in any fast-track approval process and to introduce the concept of conditional authorisation based on effectiveness;	23. Calls on the Commission **promote** fast-track approval processes **for unmet medical needs**, and to introduce transparent **and accountable process to monitor safety and** effectiveness

Paragraph 25 (Recommendations)

Motion for a resolution	*Amendment*
25. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible**, and to assess added-value medicines compared with the best available alternative; also calls on the Commission to harmonise pricing and reimbursement criteria to take into account the level of innovation and the social and economic cost-**	25. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible;

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benefit analysis, and to put in place a European classification on the added value level of medicines;	

New paragraph after paragraph 25 (Recommendations)

Motion for a resolution	*Amendment*
	26. Calls on the European Medicines Agency to assess added-value medicines compared with the best available alternative; also calls on the Commission to harmonise pricing and reimbursement criteria to take into account the level of innovation and the social and economic cost-benefit analysis, and to put in place a European classification on the added value level of medicines;

Paragraph 27 (Recommendations)

Motion for a resolution	*Amendment*
27. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays;	27. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays, **based also on the work of the EURIPID project and existing bilateral and multilateral collaborations;**

Paragraph 29 (Recommendations)

Motion for a resolution	*Amendment*
29. Calls on the Commission and the Council to explore new measures to control prices, such as **horizontal** scanning and coordinating joint procurements;	29. Calls on the Commission and the Council to explore new measures to control prices, such as **horizon** scanning and coordinating joint procurements;

Paragraph 31 (Recommendations)

Motion for a resolution	*Amendment*
31. Calls on the Commission **to propose a new directive on transparency of price-setting**	31. Calls on the Commission **to review the existing EU Directive 89/105/EEC, and in particular to put in place more solid implementing measures to**

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@cancereu
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procedures and reimbursement systems, taking into account the challenges of the market;	**ensure that Member States abide to the limit of 180 days imposed to them to fix the price of new medicines approved by EMA (Article 6).**

New paragraph after paragraph 36

Motion for a resolution	*Amendment*
	37. Calls on the European Commission to assess the impact of parallel trade in hampering access to treatments, in view of producing a legislative proposal to control and decrease the phenomenon of parallel trade;

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www.facebook.com/ECPCfb