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EUCOPE Position on Joint Price Negotiations for Medicines

A. Background & Initiatives:

During the last months, several Member States have bilaterally engaged in discussions on joint price negotiations for innovative medicines. Recently, **Belgium and the Netherlands announced their intention to jointly negotiate the price for orphan drugs and other medicines of high value or with a high budgetary impact/a high cost per patient with individual pharmaceutical companies in a pilot project** expected for early 2016. Besides price negotiation, cooperation on other aspects like horizon scanning, shared registers or moving towards harmonized value assessment methods, is also envisaged.

Building on the announcement of the Belgian and Dutch Health Ministers, on 13 May EURORDIS and European Patients Forum called on Member States to create a "table of negotiation on pricing" based on value assessment, volume and real world data generation. The aim is to ensure faster patient access, a quicker return on investment and higher volumes for manufacturers who in turn would agree on a lower price.

B. General Considerations:

1. EUCOPE recognizes that the current pricing and reimbursement procedures are not always delivering on the objective of providing broad and timely patient access to cost-effective medicines and welcomes the willingness of various stakeholders, including national governments and patient organizations, to address this challenge.

2. EUCOPE considers that any cooperation between EU Member States should be guided by **the best interest and the needs of patients rather than limiting its objectives to increasing bargaining power to obtain lower prices.** The Belgian/Dutch approach is based on the assumption that lower prices will automatically lead to improved patient access, which is contradicted by the experience of certain countries e.g. in Germany, even though the AMNOG procedure has led to drastic price decreases, roughly 10 % of new innovative medicines are not available to patients.

3. Tackling patient access challenges requires innovative solutions which are a shared responsibility of all actors of healthcare systems, including authorities, physicians, patients and industry. EUCOPE will therefore be favourable and willing to cooperate on any initiatives that will contribute to improving patient access and where all concerned actors are involved. **Nevertheless, participation of individual pharmaceutical companies in such initiatives should remain voluntary**.

4. EUCOPE considers that patient access can be improved by allowing for discussions on the value of a product even before marketing authorization and increasing predictability in the management of healthcare budgets. However, EUCOPE believes that economic considerations and P&R decisions should continue to be dealt with at national level.

5. The cooperation among Member States should take a holistic approach placing the **value of the medicine and health outcomes at the centre of the process.** To achieve this, EUCOPE recommends **a stepwise approach**:

   - The starting point should be the definition of common clinical guidelines to ensure alignment on the way patients are treated (standard of care, duration of treatment etc.) and facilitate the selection of common comparators for HTA purposes. Active involvement of physicians and guidelines committees in drawing and updating these guidelines will be crucial.

   - As a second step, common and transparent value assessment criteria and methodology should be developed, in close cooperation with industry, payers and patients. This would help streamlining the P&R process and would serve as a basis for an informed pricing decision.

   - Price negotiations should be the final stage of the process and the value of the medicine should be the main criterion for price definition. This will enable an appropriate reward for innovation and encourage continued investment in breakthrough therapies.

6. Considering the **differences between the national health systems**, improving patient access requires tailor-made solutions and therefore, P&R decisions should remain in the remit of national authorities.

   - There are still **significant differences between national health systems** in terms of clinical practice, patterns of medicine usage, as well as affordability. This requires a sufficient level of flexibility for pharmaceutical companies to be able to offer different prices and those access solutions that are most adapted to national markets' specific needs. Conversely, a single price resulting from joint negotiations would not fit with the specificities of each EU country and would lead to substantial delays in treatment availability, widening existing inequalities.

   - **Differences between national P&R processes would make joint negotiations on P&R between two or more Member States challenging, with limited benefits in terms of faster patient access**. For instance, while Belgium and the Netherlands are relatively similar from a macroeconomic and affordability perspective, their P&R systems are fundamentally different: Belgium has a centralized P&R process with a strong role for the Ministry of Health in price negotiations, whereas in the Dutch model where private insurers are the payers, negotiations with the Ministry of Health have not led to any faster patient access so far.

   - Any bilateral or wider cooperation among EU Member States **should not create any unnecessary duplications, which would delay patient access**. This requires that the framework for the cooperation should either be in line with national P&R rules or that exemptions are in place to ensure that the results of the cooperation are effectively recognized at national level and to **avoid any potential conflicts due to the application parallel mechanisms**.

C. Orphan Medicinal Products:

7. When it comes to specific medicines, such as **orphan medicinal products (OMPs)** the following considerations should be taken into account:

   - OMPs provide treatments to patients suffering from rare and ultra-rare diseases. Due to their severity, most of these diseases strongly impact the quality of life of both patients and their families (e.g. high number of hospital visits or costly and time-consuming diagnostic tests; missed days of school/work).

- Prices of OMPs reflect the value of the medicines and the circumstances of use (e.g. disease burden; clinical practice), which vary from country to country. A single price resulting from joint price negotiations would therefore increase the existing inequalities and would not fit with the specificities of each EU country. **This could lead to substantial delays in treatments' availability for patients suffering from rare diseases, for which a timely access is crucial.**

- Rare diseases affect a limited number of patients and the price of an OMP is directly linked to its therapeutic value and to the rarity of the disease**.** Companies developing OMPs face higher risks than companies developing drugs for larger patient population (which is often also reflected in the expected return by investors in the RD area). There is often little knowledge of the rare disease itself. Additionally, access to the appropriate treatment for rare diseases avoids additional and expensive misdiagnoses.

- Innovative medicines, like OMPs, are characterized by a strong therapeutic value for patients (e.g. life-transforming medicines). **Member States should consider the best interest and the needs of patients first, particularly those suffering from rare diseases rather than only focusing on cost containment.**

- The budget impact of OMPs is limited if compared to the overall national healthcare expenditures. **If any, joint price negotiations should first consider the overall budget impact of medicines and the size of their target patient population.** Member States should bear in mind the need to preserve the sustainability and competitiveness of the innovative medicines' sector in Europe, if research into rare diseases is to be continued and incentivised.

D. Legal Considerations:

8. Several **requirements in Member States' and EU legislation** may have an impact on Member States' cooperation. In particular, the following should be carefully considered:

   - **National Fiscal Laws**: Fiscal Policy provides that budgets within Health Care Systems can only be spent for patients insured in that system (budget allocation is restricted to the system itself, e.g. for usage within the British NHS or the German GKV system). **Any multi-national fund created by joint procurement or usage of budgets for patients not covered by the national system would likely be in conflict with national fiscal laws.**

   - **EU Procurement Law:** In case of pure "joint price negotiations" EU public procurement law is likely to be applicable if a certain product is chosen by the government / payer instead of another products (selection process). **The European Commission has clearly underlined that EU procurement law is applicable if payers use public money to purchase medicines.** For this reason, generics are already today tendered via the Official Journal in a selection process in line with EU procurement law in many countries.

   - **National P&R Legislation:** Due to national competency for Pricing & Reimbursement, national procedures already govern cost control and cost containment and provide for price finding mechanisms for innovative pharmaceuticals. **Any bilateral joint procurement would have to be in line with those national laws. Also, exemptions would have to be in place to avoid possible conflicting results** by regulating the same product twice once at the bilateral and at the national level. Double assessments need to be avoided due to the requirements of the Transparency Directive[1].

[1] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems

- **EU Competition Law:** Each Member State has to assess on a case-by-case basis whether the joint price negotiation is compatible with EU competition law before it enters into such negotiations. **A high risk of infringement of competition law exists if the Member State (also) acts for private health insurers such as Allianz, ING or AXA** (EUCOPE Legal Statement).

- EUCOPE acknowledges the need for joint procurement of vaccines and other medical countermeasures by Member States **in exceptional cases of "serious cross-border threats to health" as foreseen in the respective Decision**[2]. However, Member State activities **should focus on these communicable diseases and patient access** rather than using joint price negotiations as a pure cost containment tool.

[2] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health