

# Towards a pharmaceutical legislation that truly enhances public health and ensures sustainable health care systems in Europe

Europe needs a modern, long-term sustainable regulatory framework for pharmaceuticals that truly enhances public health for the European population, while strengthening the competencies and decision power of Member States, responsible for national health care systems. The current revision of the pharmaceutical legislation (including the general pharmaceutical legislation, legislation for orphan medicinal products and medicinal products for paediatric use) brings new opportunities for targeted stimulation of pharmaceutical development, and for strengthened accessibility of clinically relevant – safe, effective and cost-effective – medicinal products that reach the intended patient populations, now and in the future.

## Key messages

The Swedish Association of Local Authorities and Regions (SALAR), member organisation for the 21 regions responsible for health care in Sweden, want to see the following five key messages being reflected in the revised pharmaceutical legislation.

1. The European pharmaceutical legislation needs to **consider the broader spectra of the pharmaceutical system and the contexts of national health care systems**, where new medicines are being introduced – beyond the suboptimal focus on development and authorisation of new medicines. This is important for efficient, safe and reasonably priced medicines to reach the whole way to intended patients. This is also a prerequisite for the **long-term sustainability of national health care systems in EU Member States**.
2. The regulatory framework needs to **steer towards authorisation of new medicines that addresses truly unmet medical needs**, clearly defined from patient and health care perspectives. This includes more extensive requirements of **proven added clinical benefit for patients** with unmet medical needs, taking into account all kinds of available treatment options for specific patient populations – not only authorised medicines on the European market. A more restrictive application of the term unmet medical need is needed in order for EU orphan incentive to be used effectively and in a way that stimulates development of relevant pharmaceuticals for Europe.
3. Requirements for market authorisation of new medicinal products need to be clearly linked to **relevant and robust clinical evidence, including proven safety and efficacy with clinically relevant endpoints, prior to market authorisation**. This will better enable medicinal products with added clinical benefit to reach patients in various EU Member States and will also contribute to maintaining the trust in European institutions as well as Community codes and procedures.
4. The European pharmaceutical legislation needs to **strengthen availability of both older and established treatment options as well as new medicines in health care**. The legislation's focus on industrially produced – commercial – medicinal products for human use intended to be placed on the European market should neither result in the crowding out of established medicines, nor hinder health care providers to find novel uses for existing medicinal products or impede clinically driven innovation, development and use of other treatment options – **beyond industrially produced and EMA authorised medicinal products**. The possibility for national exceptions needs to be clarified and broadened. Furthermore, pharmaceutical supply chains need to be secured and strengthened, with legally clarified responsibilities and repercussions with regard to manufacturing, warehousing and distribution chains for both old and new medicinal products.
5. The regulatory framework needs to **promote inter-changeability and availability of generic medicinal products and biosimilars** on the European market, when patents expire. Incentive schemes and market exclusivity for brand-name companies (patentees) should not hamper the development and availability of these medicines. This is key for competition and the functioning of the pharmaceutical market in Europe.

The content of the European legislation impacts the availability of medicinal products in national health care systems and does, in large parts, also affect what and how treatment options can be made accessible to and reach patients who need them. The current legislation has been successful with regard to the establishment of the Community code and common framework for market authorisation and availability of industrially produced medicinal products intended for human use, and commercialised and marketed on the European market. Incentive schemes for research and development has contributed to scientific breakthroughs and pharmaceutical development.

However, the European regulatory framework has not been able, in a satisfactory way, to target truly unmet medical needs of patients, nor has it been able to consider and build on perspectives that are relevant for national health care systems in EU Member States. Market mechanisms necessary for the functioning of the pharmaceutical market in Europe have been given insufficient attention which will, in the longer term, pose a threat to the sustainability of national health care systems.



## Introduction

The European pharmaceutical legislation consists of a regulatory framework for medicinal products in the EU. During the 2022/2023 the European Commission is expected to present revisions on the current legislation, including the legislation on orphan drugs and medicines for paediatric use.

During the past two decades the regulatory framework for medicinal products in Europe has become more and more centralised, while **stimulation of research and development** have been introduced to promote pharmaceutical development intended for the European market. This has taken place at a time of rapid scientific development and breakthroughs. The importance of a EU common framework cannot be stressed enough, and has been key for the ability of Member States to manage such development. Incentive schemes in combination with i.a. simplified regulations for clinical studies, flexible evidence requirements and adaptive pathways for earlier market authorisation have been introduced with the purpose to increase availability of new medicinal products in Europe.

However, **availability of new medicines is not the same as the use of new medicines and de facto patient access ("accessibility")**. The European regulatory framework has in this regard failed in securing the functioning of the complete system, from research and development to market authorisation, implementation and use of new medicinal products in clinical practice. One key explanation to this is that the **current regulatory framework is lacking a clear health care perspective**. Far from all medicinal products that are authorised at European level are clinically relevant from a health care perspective, and many new medicines are approved with limited documentation and clinical evidence, which translates into great uncertainty when it comes to their intended use. Furthermore, not all medicinal products are introduced to the market and those that are introduced not seldom come with increasingly high prices from the pharmaceutical companies. In combination with the uncertainties of actual safety and efficacy, this results in greater difficulties of solid health economic evaluations and decision making for introducing a medicine into clinical practice. Consequently, national health care systems are faced with greater risks of misallocation of resources and crowding out of other pertinent health care interventions.

The regulatory framework has also proven to be **vulnerable to unintended use, or misuse, by pharmaceutical companies** who gain advantages from the broad application of orphan drug designation criteria and the generous incentives that comes with it. Numerous examples of "regulatory innovation" show that new orphan drugs are being approved in areas where treatment options already exist. This sometimes leads to impaired access to well-established, well-functioning and cost-effective treatment options to broader patient populations.

The focus on development of new medicinal products for patient sub-groups of common diseases rather than more targeted focus on new treatments for truly unmet medical needs for patients with rare diseases has also been recognised by patient organisations in Europe such as EURORDIS. The organisation stresses the importance for national, European and global authorities to curb this trend, many times packaged as under the term "precision medicine". This kind of regulatory ingenuity does not only impair

the health and care of patients in Europe, but it also contributes to a malfunctioning pharmaceutical market and inflates company pricing of medicinal products.

Currently, **the European pharmaceutical legislation builds on an industry perspective on medicinal products** as the regulatory framework assumes market authorisation of industrially produced medicinal products intended for human use, commercialised and marketed on the European market, as the main process for availability of new medicines to patients in Europe. This is executed through the mandate given to the European Medicines Agency (EMA) and with the purpose of setting high standards of quality and safety for medicinal products. The focus on industry perspective **however disregards, to a great extent, both academia and health care and their important role when it comes to research, development, and innovation within the pharmaceutical field** – many times as driving forces in terms of development of new therapies and treatment options for patients.

Historically, health care professionals and health care providers could apply science and proven experience in the search for new areas of use for older and well-established medicines and also drive the development of new, more technologically advanced therapies. This generated new treatment options for patients with rare diseases and severe conditions, e.g. for patients with transthyretin-related familial amyloid polyneuropathy and multiple sclerosis (off label in line with science and proven experience) and advanced cell therapies and lifesaving treatment for patients with severe burns (hospital exemption for ATMPs). Today, these kinds of possibilities are severely limited unless driven by commercial purposes.

**More and clearer pathways for approval and use of both new and older – safe and effective – treatments are needed at the national levels, beyond the commercially driven pathway.** The exclusion from the European legislation (expressed in article 5, Directive 2001/83/EC) is too vaguely formulated and has not resulted in broader use of non-commercialised medicinal treatment options within national health care systems.

A European regulatory framework which primarily builds on industry perspectives – and thus steers national health care systems towards the use of commercial medicinal products – **results in de facto limitations of how EU Member States can execute their national competencies** with regard to decision making and the management and resource allocation for health services and medical care. This is not sustainable for national health care systems. For Sweden this also hampers principles of local governance, the free right of prescription for health care professionals, and the possibility of choosing from different types of safe and effective treatment options (not only EMA approved and commercialised medicinal products). These limitations also impact on the possibilities of managing cost-effective health care and undermines efforts towards maximised health outcomes within the publicly funded health care system.



## Call for legislative measures that incorporates national health care perspectives

SALAR, member organisation for the 21 regions responsible for health care in Sweden, want to see a pharmaceutical legislation that enables the use of a variety of medicines and treatment options in the care and treatment of patients in Sweden and in other EU Member States.

The following five key messages therefore needs to be reflected in the legislative action and revision of the regulatory system for new medicines in Europe.

### 1. A European legislation that considers the broader spectra of the pharmaceutical system

The European legislation needs in a clearer way take the broader context of national health care systems, where new medicinal products are being introduced. From research, development and market authorisation of new medicines which is a subject to a joint Community code, to introduction, use and patient access of new medicines which is managed by national health care systems in EU Member States, according to national competencies.

Market authorisation is key in order for pharmaceutical companies to market and sell medicinal products in Europe and is therefore of importance for the availability of medicines in the European market. At the same time, the prerequisites for market approval also affects how new medicines are being adopted by health care systems and becoming accessible to patients. E.g. through the evidence levels prior to market approval and accepted uncertainties regarding safety and efficacy. The regulatory framework is also precedent to what and when incentive schemes are being used and in what cases competition restriction measures and market benefits are granted. The de facto possibilities of health care systems to lead research, development, innovation and the ability to choose the right type of treatment option for the right patient – based on needs – has to be safeguarded in the legislation. This requires a more holistic approach in the European legislation. As such, the revision of the pharmaceutical legislation should not only aim at increasing available medicines and setting high standards of quality and safety for medicinal products but needs an overarching goal of contributing to the long-term sustainability of national health care systems. This creates conducive conditions for patient accessibility of new medicines and is the path towards enhanced public health in Europe.

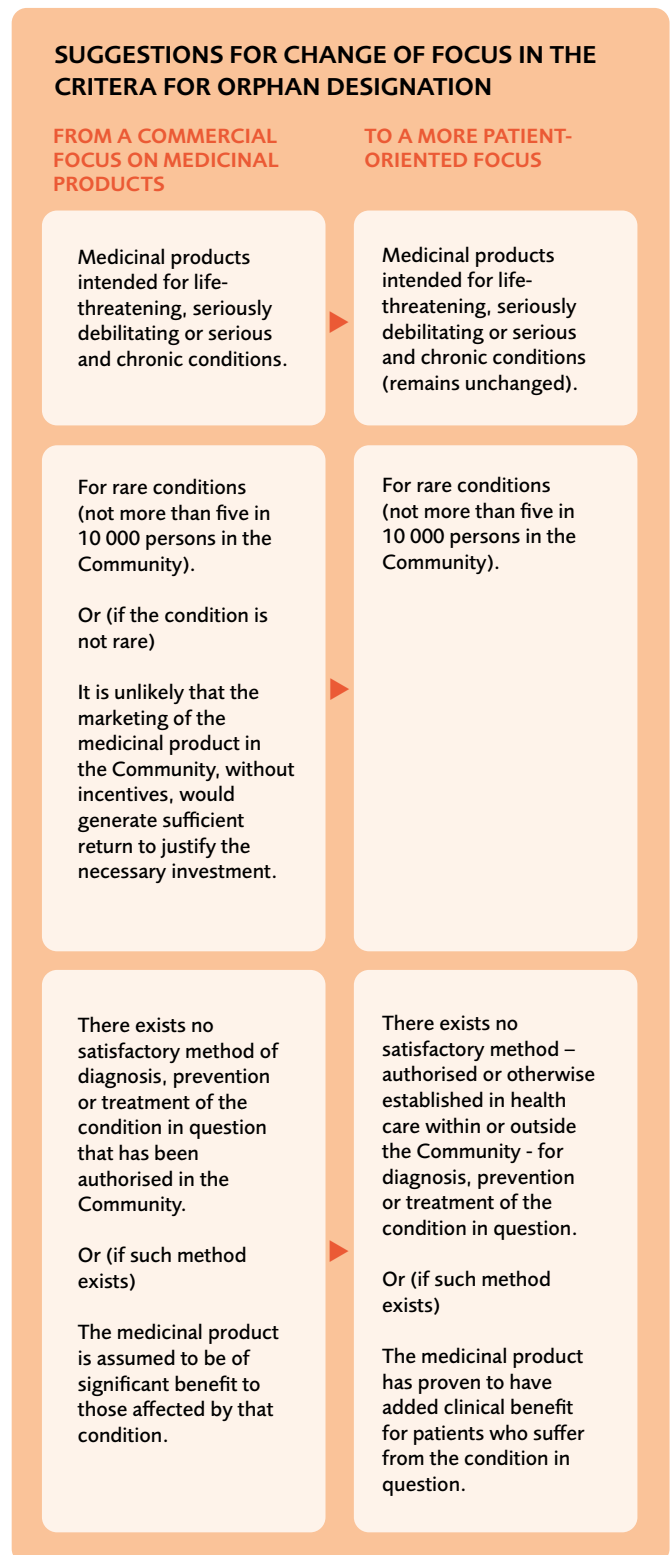
National competencies and responsibility for health care as well as the possibility of local governance and de facto subsidiarity – in national health care systems in EU Member States – needs to be safeguarded in the revision of the pharmaceutical legislation.

### 2. A shift towards medicines for truly unmet medical needs

Incentive schemes for the development of medicinal products should be based on truly unmet medical needs – premiering development in areas where real treatment gaps exist – and thus result in new medicines that reach the whole way to the patients. The term unmet medical need ought to emanate from patients' real needs and therefore also consider the broader health care perspective by i.a. relating to all types of treatment options available for the patient population – not only commercial

medicinal products approved for the European market. Greater emphasis and requirements of proven added clinical benefit for patients is also key, e.g. in the form of increased length of disease-free or progression-free survival; safer and more efficient ways of restoring, correcting or modifying severe medical conditions; as well as freedom from debilitating adverse effects of treatment.

A more precise definition with a patient-oriented approach for how to determine orphan designation would premiere and stimulate research and development in areas where the needs are greatest.



This kind of approach would also be better suited for the incentives and market advantages that are currently associated with the medicinal products with orphan designation. This would also steer the pharmaceutical industry and the associated multi-billion financial investments towards relevant products and a clearer focus for future development. In the long-term this also bring more relevant and competitive pharmaceutical companies.

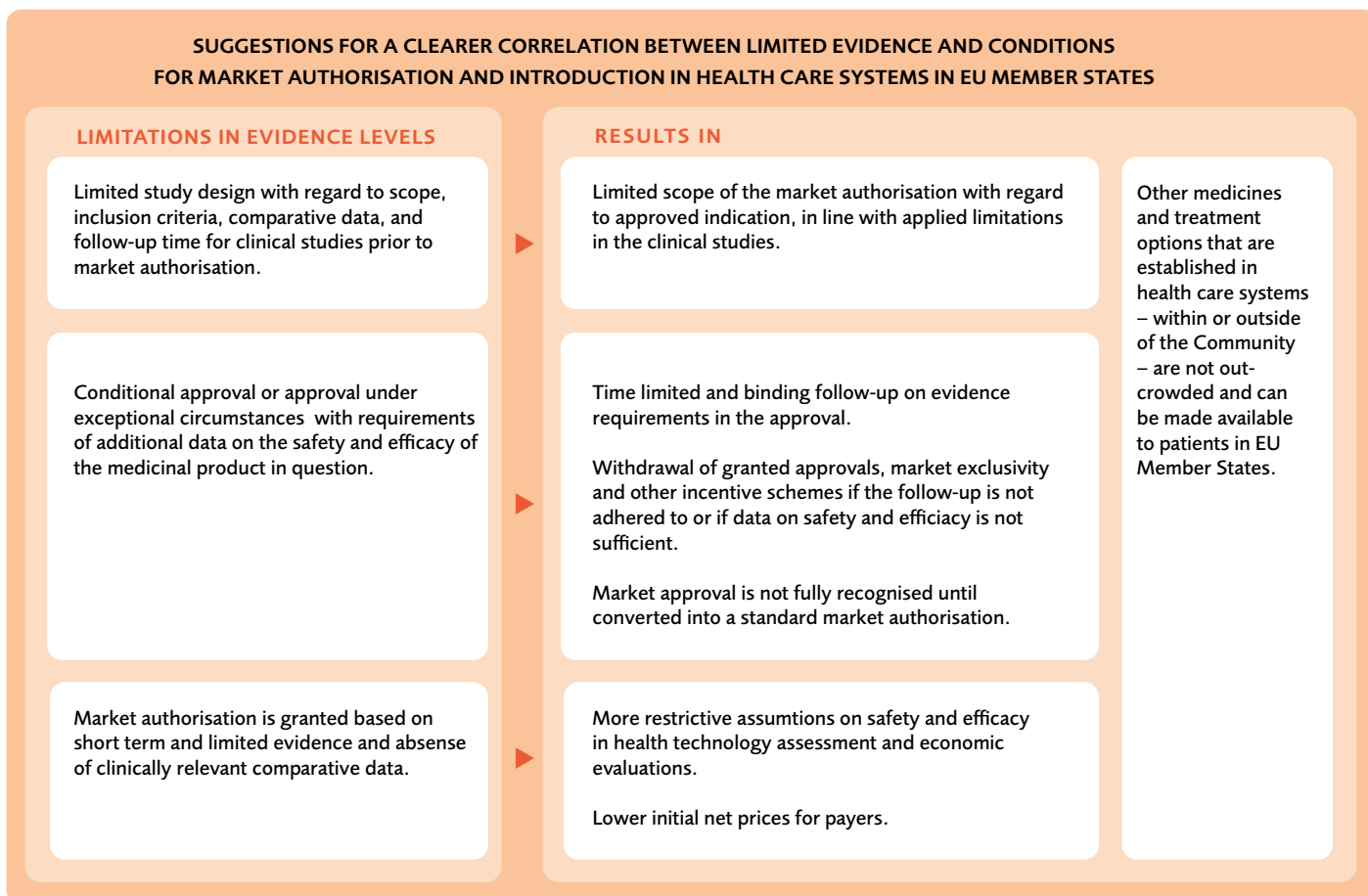
This suggestion needs to be understood in the light of the current generous incentives that have been introduced to stimulate pharmaceutical development for orphan and paediatric use, i.a. extended scientific advice, prolonged patent and market exclusivity, lower regulatory fees. These incentives have been effective but have also been overused, not the least when it comes to orphan drugs. The medicinal products that are covered by the incentives are not seldomly associated with higher price expectations from the pharmaceutical companies which means de facto double compensation, first through the regulatory incentive schemes and market advantages in the phase for research, development and market approval, and later in terms of introduction to higher prices and expectations of higher reimbursement. This hampers patient access which in the end means that the initial incentives have been used in vain.

### 3. Increased focus on satisfactory, relevant and robust – clinical evidence for market authorisation

It is of great importance that the regulatory system for market authorisation of new medicinal products ensures sufficient levels of clinical evidence, for patients and for health care providers and payers. This is particularly key also from an affordability

perspective. Uncertainties of clinical benefits in combination with high prices from pharmaceutical companies inhibits the possibilities of prioritisation and decision making in terms of introducing and adopting new medicines in national, regional and local governance structures in EU Member States, which in the end hampers patient access. The Community code and processes for market authorisation therefore needs to incorporate perspectives, needs and specific considerations from national HTA authorities, authorities responsible for pricing and reimbursement, payers as well as health care providers and patients – to ensure that the requirements for documented clinical evidence prior to market authorisation are relevant also for decision making processes on introduction and adoption of new medicinal products in health care.

This suggestion needs to be understood against the backdrop of current approach to evidence requirements at European level, with shorter and more adaptive pathways towards market authorisation with increasing number of medicinal products being approved with limited clinical evidence regarding safety and efficacy. It is certainly positive that value creating medicines reach the market in a timely manner, but in practical terms the fast-tracked market approvals at European level can also results in lengthy processes and delays in patient access, at national level, in the EU Member States. It would here be desired to see a more restrictive approach to the application of adaptive pathways and a clear link to areas with truly unmet medical needs (according to suggestions made in the previous point). As such, truly unmet medical needs would be a defining criterion for what kind of medicinal products that require a more urgent management of the market authorisation procedure.



When medicinal products are approved despite high level of uncertainty regarding safety and efficacy it is difficult to assess the clinical benefit as well as potential adverse safety considerations of a new medicines compared to other already existing treatment options. In particular, health economic evaluations and cost-effectiveness analysis – assessing the safety and efficacy in relation to the price – becomes a challenge for national health care systems. In Sweden for example, the use of value-based pricing and possibility to prioritise treatment options in ways that ensures maximum health outcomes for the population, for each Swedish crown spent, is undermined. Uncertainties with regard to safety and efficacy implies higher risks of mis-prioritisation of health care resources and, as a result, risks of crowding out other health care interventions for other patient groups. A greater transparency around documented clinical evidence used as a basis for market approval is desired from a health care perspective.

Furthermore, the applied study design, inclusion criteria for the study population, relevant control groups as well as scope of the clinical study with regard to number of patients included and time for follow-up of results from the studies need to better correspond with the scope of the market approval granted in terms of intended indication and conditions for introducing a medicinal product on the European market. The withdrawal of medicinal products that are not delivering according to expected safety and efficacy need to be applied in a more systematic way than what is currently the case.

#### **4. Increased availability of both old and new treatment options within national health care systems**

The revised pharmaceutical legislation needs to create mechanisms that maintain older, established, well-proven and effective medicines on the market while at the same time harnessing the research, development, innovation and proven experiences of using various medicines within the health care systems. This needs to be understood in the light of the primarily commercial perspective of the current legislation. To safeguard access to older medicines (sometimes with expired patents) as well as other treatment options give increased possibilities of clinical practitioners to choose among various kind of treatment options when deciding on a course of treatment. This would result in greater access to treatment options for patients in Europe.

It is here important to note the regulated definition of medicine is not limited to only commercial medicinal products and a modern regulatory framework should be able to relate to the use of non-commercial medicinal products and/or commercial medicinal products that are not primarily intended for the European market. The exclusions from the European regulation that is articulated in "Article 5" of the general pharmaceutical legislation (Directive 2001/83/EC) therefore needs to be clarified in ways that grant national health care systems the right to secure availability and access to safe, effective and cost-effective medicinal treatment in a more predictable way and in larger scale. There is a need of clarifying roles and responsibilities in relation to national competent authorities and an expressed legal mandate for national actors to manage health care applications of approval for the use of medicinal products in new areas (health care-driven "repurposing" processes) or new medicinal products developed through research and innovation within health care system (e.g. hospital exemption ATMPs).

This has the potential to contribute to great value for patients where treatment gaps currently exist, foster cost-effective use of resources within national health care systems, disseminating good clinical praxis within the EU, while medicinal products that are unlikely to reach the market without targeted incentives could still be made available and accessible to patients who need them.

It is therefore unfortunate that the pharmaceutical companies associations are arguing for the opposite and call for legislative measures to restrict the prescription of medicinal products outside of market authorised indications (off-label), limit the use of pharmacy prepared medicines and medicines that are not approved specifically for the European market including older and established medicines that have been withdrawn from the European market – as well as hospital exemption ATMPs. Harder restrictions would result in extensive consequences for treatment options available for patients. Health care providers would be regulatorily steered towards commercial medicinal products and EU Member States would have national competencies restricted with regard to delivery of health services and medical care as well as prioritisation and allocation of resources. In Sweden this would also mean a de facto limitation of the free prescription right and the use of a range of well documented treatment options while such regulatory restriction also risks reducing innovation capacity and incentives within national health care systems.

Lastly, it is also key for the regulatory framework to address the need for a reliable pharmaceutical supply in Europe with legally clarified responsibilities and repercussions with regard to manufacturing, warehousing and distribution chains for both old and new medicinal products. It is necessary that the new legislation addresses the need of a more robust supply of pharmaceuticals in Europe. It is also key that requirements for environmental risk assessments for medicinal products are strengthened, from manufacturing to actual use.

#### **5. Increased availability of interchangeable medicines, generic medicinal product and biosimilars**

To maintain the possibility of applying interchangeable medicines and ensuring availability of generic medicinal products and biosimilars – i.e. copies of medicinal products whose patents have expired – is a key legislative action. This is also important for the competition on the pharmaceutical market in Europe. Well-functioning incentive schemes for research and development as well as marketing of generic medicinal products and biosimilars is of essence for the future-proofing of the regulatory framework.

Sweden has today one of the most effective generics markets in Europe where the pharmacies can exchange the prescribed medicinal products against an equivalent medicines with a lower price. This results in sizeable cost savings and can free resources for other medicinal products or for other health care interventions. Experiences and lessons learned from Sweden could be applied in other EU Member States as a way to promote cost-effective use of medicinal products in Europe. For biological medicines – which includes the growing number of increasingly lucrative medicinal products – there is currently some challenges with regard to competition after patent expiry, which is hampering the development of biosimilars.

Targeted legislation measures are thus needed to stimulate and premiere the development of generic medicinal products as well as biosimilars. The new pharmaceutical legislation therefore needs to promote the possibility to introduce these kind of medicines on the European market. Competition after patent expiry is an important factor for the balance and functioning of the pharmaceutical market.

To further enhance the patent protection and market exclusivity of brand-name companies (patentees), as the pharmaceutical companies have advocated for, would lead to reduced availability and patient access to these medicines and have an extensive budget impact for national health care systems in EU Member States, even after patents have expired. In addition, the discerning trend of competition restriction collaborations between brand-name companies and generic companies – with the aim of delaying the introduction of generic medicinal products – needs to be curbed from a regulatory perspective.







## The pharmaceutical industry join forces with patient organisations for legislative action – Consequences for national health care systems

EURORDIS, an alliance of over 1000 patient organisations with focus on rare diseases, is an active voice in the European arena. Equally, the European Federation of Pharmaceutical Industries and Associations (EFPIA) has become a prominent and influential actor in pharmaceutical matters. Both parties have joined forces and made a joint statement including legislative measures for the revision of the European regulatory framework, with the aim to foster broader and faster patient access to medicines for rare diseases.

**Low price and high price corridors for medicinal products in Europe (“tiered pricing”) – Suggestions that limit Member State competencies on pricing and reimbursement and reduce possibilities for fair pricing for payers.**

The **tiered pricing** concept for low price and high price corridors, developed by EFPIA and the pharmaceutical industry, and proposed by EURORDIS and EFPIA, is launched as “equity-based pricing” and “solidarity among EU Member States”. The concept assumes establishment of **price corridors with confidential net prices – proposed by the companies** – according to “best price” principles from the industry, where differential pricing would be based on wealth and as a way to meet the varying ability to pay for medicines in Europe. Factors such as gross national income and human development index would be used to determine the relative prices for different countries.

In practical terms, the suggestion implies greater influence over pricing from the pharmaceutical industry. The proposal does not address the underlying challenges of pricing and disregards the mere fact that ability to pay for medicine is not based on aggregated figures such as gross national income, but is a matter of budget constraints within the national health care systems – a fact that applies to all EU Member States. The proposal means higher risks for less transparent pricing, a reduced possibility for competitive exposure and price pressure. Neither does it bring any guarantees for more reasonable pricing from a payer perspective. For countries with higher economic wealth the proposal is likely to lead to even higher prices.

For Sweden this would also mean a divergence from the value based pricing and reimbursement of medicinal products and the legislated requirements of cost-effectiveness in health care. A mismatch between the ability to pay within national health care systems and the pricing of companies will by extension affect

patients in Europe and result in higher financial burden on taxpayers and insurance policy holders. It does neither result in broad nor speedy access to medicines for patients. Furthermore, pricing is part of national competencies

**Evaluation of medicinal products at European level – Suggestions that hinders contextually relevant evaluations and poses limitations on cost-effective use of resources for medicines in Member States.**

The parties also propose further **harmonisation between EU Member States on value assessments and greater EU-level influence and guidance over health technological assessments, pricing and reimbursement procedures for orphan medicinal products**. For example, joint EU-level clinical assessments are suggested to supersede national clinical assessments used in pricing and reimbursement processes. Increased flexibility in terms of evidence requirements for rare diseases and orphan medicinal products are proposed, including direct linkages between the EMA labelling from the market approval and the scope of reimbursement at national level. The parties also wish to see greater use of adaptive processes for value assessments and decision-making regarding reimbursement, using real world evidence as a way to manage uncertainty over time (similar to the adaptive pathways for market approvals). Furthermore, **novel payment and pricing models** such as outcomes-based payments, over-time payments, indication and combination-based pricing, and subscription payments are assumed to address clinical and financial uncertainty, affordability constraints, or issues linked to medicines being used across indications and combinations, and thus ultimately contribute to accelerating patient access.

The proposals are partially derived from the truly unmet medical needs apply and treatment gaps exist. 2021/2282 on HTA, health technology assessment, but also extend to areas relating of national competencies where EU Member States are responsible and mandated. In essence, the suggestions lack a clear health care and payer perspective. For value assessments to be relevant for decision making at national level, it is key that such assessments are contextually relevant and continue to build on national circumstances, conditions and processes. The use of adaptive pathways for market approval has proven insufficient with regard to the actual withdrawal of medicines that fail to generate satisfactory follow-up evidence on clinical benefits. The risk is that the same inefficiencies will arise for value assessments,

pricing and payment under such adaptive schemes. The consequences for payers within national health care systems is that resources can no longer be purposefully prioritised and allocated according to patient needs and principles of cost-effective use of resources, crowding out other health care interventions for other patient groups. As such, the long term sustainability of national health care systems will be undermined which would negatively affect public health in Europe.

The proposals also disregard the underlying problems with regard to patient access: Clinical evidence at the time of market approval, ambiguity in terms of clinically relevant endpoints and added clinical benefit over other treatment options, uncertainty regarding safety and efficacy over time – in combination with high prices from the companies – implies multiple uncertainties. For adaptive value assessments, conditional reimbursements and novel payment models to be feasible in practice, the net prices from companies need to be substantially reduced from today's price levels. Certainly, without eliminating the pharmaceutical industry's possibilities to make ends meet and make profit. As a balanced proposal, EURORDIS vision paper "Rare 2030" raises a suggestion for greater transparency in research and development costs as a basis for reasonable pricing of medicines for payers, while companies could still make profit, and without limiting patient access.

**Incentive schemes, data and patent protection and market advantages – Suggestions that impedes pharmaceutical development and limits health care providers' use of different types of treatment options, beyond commercial medicinal products approved for the European market.**

EFPIA has also proposed suggestions that include continued and increased investments and **incentives for research and pharmaceutical development** and wish to see **expedited processes for market approval** and possibilities of even lower evidence requirements at the time of approval, with reference to the processes for approval of covid-19 vaccines and possibilities of real world data follow-up from use in clinical praxis.

These proposals aim to stimulate the increased quantity of medicinal products, approved for marketing and sales at the European market, but does not necessarily mean that relevant medicines are made available to patients. Too broad incentives bring increased risks of inaccurate, non-targeted, pharmaceutical development in Europe. Too low evidence requirements create greater uncertainty in the later stages of decision-making for introduction and use of new medicines and can de facto inhibit or delay patient access.

EFPIA also want to see a greater **data and patent protection** as well as extended mechanisms for market exclusivity as a way to secure the **competitive advantages for market authorisation holders**. Furthermore, the industry is calling for **legislative limitations to the possibility of national exceptions** to the EU-common regulatory framework.

These proposals pose great concern from a health care and payer perspective for many reasons. First, it risks hindering the development of generic medicines and biosimilars. Secondly, it implies great limitations on the use of different types of treatment options within national health care systems. Although referred to as a matter of quality, safety, efficacy, it is important to note that not only – and far from every – industry developed, commercial, medicinal product approved for the European market, guarantee quality, safety and efficacy for patients. Medicines that are not intended for commercial purposes – researched and developed by academia and health care providers – can also be of uttermost relevance as a treatment options. They can be equally of high quality and safe and effective – sometimes even well-proven in clinical practice – and commonly both medically and financially motivated as treatment option. Steering national health care systems towards commercial medicinal products is therefore not recommended. The risks associated with this is also that market mechanisms fail and competition on the pharmaceutical market is weakened. The EFPIA proposal is thus contra productive from both a patient perspective and a health care perspective.



