EUROPEAN GENERIC MEDICINES ASSOCIATION

Making Medicines Affordable

INCREASING PATIENT ACCESS TO VALUABLE HIGH QUALITY MEDICINES THROUGH SUSTAINABLE MARKETS

THE EGA VISION

EGA Vision

To provide sustainable access to high quality medicines for all European patients.

EGA Vision: The essential pillars

The European generic, specialty and biosimilar medicines industries' Vision is built on 5 important pillars, being the essential elements of our contribution to society: **patients, quality, value, sustainability and partnership.**

- **Patients:** We create enhanced access to medicines, reducing inequalities, directly leading to improved patient outcomes. We compete, stimulating the medicines industry to innovate. We innovate, enriching patient benefit.

- **Quality:** We provide a stable and resilient supply of high-quality medicines, manufactured and developed according to stringent EU regulatory requirements, for Europe's patients and healthcare providers.

- **Value:** Our high-quality cost-effective medicines account for well over 54% of all prescription medicines used to treat European patients. We are the heart of public health delivery in Europe. We generate cost savings of more than €35bn each year ensuring the viability of Europe's healthcare systems and enable them to invest in new medicines and other treatments that Europe's patients increasingly need.

- **Sustainability:** Use of our medicines supports the economic sustainability of Europe's healthcare systems. We contribute to Europe's economies, researching, developing and manufacturing in most European countries the majority of medicines used in the EU, sustaining more than 150.000 high skilled, high value direct jobs. As a leading knowledge based industry we will continue to work with Europe's policy makers, legislators and regulators to create the right environment to support and strengthen the economic sustainability of our industry so that we can continue to contribute to European patients and society

- **Partnership:** We build constructive partnerships, focused on a strong and stable collaboration with patients and patient organisations, the EU institutions, governments and regulators, healthcare professionals and others to further enhance public health in Europe.

PATIENTS

EGA members aim to reduce inequalities between Member States providing all patients in Europe with access to valuable high-quality medicines that will lead to improved patient outcomes.

Generic medicines already account for over 54% of the medicines dispensed to patients in Europe and play an increasing role in improving patients' health. In Europe, over 12 years in 7 key therapy areas[1], the average price per treatment day has declined by 60%, while the number of treatment days provided to patients has increased by nearly 200%. By increasing patient access to existing medicines and by creating headroom for innovation, our industry delivers a significant contribution to improve health outcomes across Europe.

Furthermore, by securing patients' continued access to medicines, further deterioration of patients' health status can be avoided, which could otherwise lead to other more expensive costs, such as hospitalisation, with the resulting negative impact on productivity and economic growth.

With a projected 45% increase in the number of people aged 65 and over in the next 20 years, the use of generic, specialty and biosimilar medicines will be key for patients and for healthcare providers to ensure equitable access to medicines and to manage the social and economic burden of chronic disease. As the main provider of medicines for numerous diseases and other chronic ailments, the EGA's member companies will contribute directly to the EU2020 objective of increasing "the average healthy lifespan in the EU by two years"[2] and are committed to provide:

- A more equitable access to medicines across the EU, by increasing patient access to generic and specialty medicines by at least 25% on average in Europe by 2020.
- Enhanced access to biological treatments. Our companies will strive to increase patient access to biosimilar medicines by 50% across Europe by 2020. In partnership with governments, the availability and accessibility of biosimilar medicines will be improved by increasing the awareness and education on the safety and benefits that biosimilar medicines offer to prescribers, payers and patients.
- To create competition from generic, specialty and biosimilar medicines in a timely way, enriching healthcare systems with a large portfolio of medicines that will improve patients' lives and reduce inequities in access to care.

[1] Angiotensin II antagonists, anti-depressants, anti-epileptics, anti-psychotics, anti-ulcerants, cholesterol regulators and oral anti-diabetics; Source: IMS MIDAS, MAT 09 2012

[2] Europe 2020 – for a healthier EU, available at: http://ec.europa.eu/health/europe_2020_en.htm

QUALITY

A stable and continuous supply of high-quality medicines, manufactured, developed and delivered according to stringent regulatory requirements, for patients and healthcare providers, is key for EGA members.

The EGA actively advocates the enforcement of high EU-like standards in all countries around the world. The enforcement of these regulatory standards, such as pharmacovigilance, the falsified medicines directive and GMP practices, imposes strict requirements that increase the value proposition of medicines, enhances patient safety and creates a level playing field for all pharmaceutical companies.

However, the daily cost of treatment with a generic medicine is extremely low compared with the high costs and complexity of the requirements to make high-quality and safe medicine available and the great value provided to patients. Policy makers and stakeholders should recognise the value and cost created by increasing the regulatory requirements that generic, specialty and biosimilar medicine producers have to meet in the provision of high quality medicines in the EU, by:

- Recognising the importance of better regulation for pharmaceuticals based on a solid impact assessment that removes unnecessary administrative burden and cost, and creates a positive economic environment for the European industry as well as protecting patients;

- Improving education of clinicians and patients in the quality, safety and efficacy of generic and biosimilar medicines, highlighting the strict regulatory scrutiny of European and national medicines agencies;

- Establishing, together with EU policymakers and healthcare stakeholders, a sustainable way of financing the high costs of implementing new regulations, so ensuring the continuity of supply of all medicines and equitable access to medicines for all patients.

VALUE

Use of generic medicines creates more than €35 billion in annual savings in healthcare expenditure, making Europe's healthcare systems viable and releasing the funds that enable investment in new medicines and other treatments that Europe's patients increasingly need.

Biosimilar medicines are equally important to increase patient access to biological medicines. As specialty medicines are forecasted to represent 50% of all medicinal expenditure by 2018[3], the healthcare systems in Europe will only survive and afford these treatments if more cost-effective medicines treatments, such as biosimilars, are widely used.

Our industry is committed to creating competition in generic, specialty and biosimilar medicines, as well as to providing added value to patients by developing new formulations, new drug combinations, new administration routes and new pack sizes that meet patients' and healthcare professionals' needs.

The value of these medicines for patients and payers in the European countries can be fully leveraged only if market stability and predictability is improved. This can be achieved by:

- Establishing a new Price and Reimbursement pathway for specialty[4] medicines that will incentivise R&D and manufacturing investment, reflecting the value and the added cost of these medicines, such as sterile injectables, transdermal patches or respiratory products.

- Limiting the number of administrative price revisions per year for generic medicines, improving market stability and predictability, therefore allowing companies to invest in the development of medicines for Europe.

[3] Prime Therapeutics & University of Minnesota College of Pharmacy, poster presented at AMCP San Diego April 4,

4 Specialty off-patent medicine : for the purpose of this project, it is defined as a generic medicinal product which requires additional clinical studies beyond the basic requirement of a bioequivalence study (eg, transdermal patch, inhalers, programmes involving therapeutic equivalence)

- Introducing clear and fair market rules that prevent abnormally low pricing by manufacturers and suppliers that drive prices to unsustainable levels, leading to market concentration, withdrawal of products from the market and the reallocation of manufacturing outside Europe.

- Avoiding the application of prices by authorities that are not sustainable, including by the application of External Reference Pricing (ERP) to generic and biosimilar medicines. The application of prices from different market settings has the potential to create serious market disruptions and undermine the continuity of medicines supply.

- Recognising that the application of claw-back (or claw-back like) mechanisms to generic, specialty and biosimilar medicines companies should always reflect that these medicines contribute directly to generate savings for Member States' healthcare budgets.

SUSTAINABILITY

In addition to the great value our medicines provide to patients and healthcare systems, the generic, specialty and biosimilar medicines industries make a significant contribution to the EU economy, through exports and by providing direct employment for 150.000 people in Europe.

EGA member companies are committed to contribute to EU independence and security in the supply of medicines to patients in Europe. Introducing constructive measures and a healthy business environment in the EU, comparable with other economies such as the USA, Canada and Japan as well as India, China and South Korea, will help our industry keep research & development, manufacturing and jobs in the EU.

Price and reimbursement systems that only aim to drive the price of medicines to their marginal cost should be avoided as they lead to discontinuities in patient treatments, market concentration and reallocation of manufacturing to non EU-countries. In addition, incentivising competition in the specific off-patent medicines market segments, where business costs or regulatory risks are high or competition is non-existent, has the potential to foster an increase in R&D investment from the current 7% and further contribute to the sustainability of the healthcare systems

To maintain and further develop Europe as the hub for high quality manufacturing of generic and biosimilar medicines, the EGA and its national associations will work with EU and National Authorities on the following policy options:

- Introducing a provision that allows the generic and biosimilar medicines industries to export to third countries during the EU Supplementary Protection Certificate (SPC) period, promoting European production for export and making Europe a globally competitive manufacturing base for pharmaceuticals.

- Removing the hurdles that delay generic and biosimilar medicines entry to the European markets. The EGA will actively support the European Commission's efforts in this respect, namely banning double assessment by authorities and patent linkage practices, which slows down competitive entry to the market and increases litigation costs for manufacturers, limiting patients' access to medicines and delaying savings for healthcare systems.

PARTNERSHIP

Our Vision and our goals will be achieved through a stable and effective collaboration with the European Commission, National Governments, Payers, Patient Groups, Healthcare Professional groups and other stakeholders.

The European generic medicines industry, as the main provider of medicines in the EU, and the European biosimilar medicines industry, as the industry that delivers the most cost-effective alternative in biological treatments, are the only partners that offer governments a solution to tackle the rising costs of healthcare budgets at the same time as positively contributing to improving health outcomes. Therefore, the EGA and the National Associations will endeavour to create a strong and trustworthy collaboration with all the stakeholders mentioned above.

EU-EGA Partnership: The EGA and its National Associations want to cooperate with the European Commission, European Parliament Member States, Pricing and Reimbursement authorities, regulators, health insurance institutions and payers to ensure cost-effective regulations, which foster rapid access to high quality and best value medicines for patients. This partnership should also serve to exchange best practices with Member States, to remove barriers and impediments to sustainable market entry of generic and biosimilar medicines.

EGA National Associations and Member State Partnerships: EGA National Associations (NA) wish to develop solid cooperation with Member States (MS) to agree on sustainable pricing and reimbursement models which encourage our industry to produce and supply the best value for money medicines now and in the future.

The EGA & National Associations can also provide frameworks to help Member States build pricing and reimbursement systems that better reflect the increasing value and complexity of off-patent medicines. These would include criteria such as stability of supply, complexity of manufacturing, development or approval, commitment to service the market, and the recognition of regulatory compliance costs and risks[5].

With this Vision, EGA expects to align all efforts in a way that will contribute significantly to tackling the challenge of equitable access to medicines and contribute to the sustainability of healthcare budgets across Europe.

[5] The originator industry already has agreements established with several Member States. A similar situation should be available for EGA National Associations.