



Making Medicines Affordable

EUROPEAN GENERIC MEDICINES ASSOCIATION

# VISION 2015

THE **EGA'S THOUGHTS** ON HOW TO IMPROVE  
THE LEGAL AND REGULATORY FRAMEWORK  
FOR GENERIC AND BIOSIMILAR MEDICINES

[WWW.EGAGENERICS.COM](http://WWW.EGAGENERICS.COM)

OCTOBER 2010





**ENHANCE  
COMPETITIVENESS**

**MAINTAIN COMPETITION  
AND HEALTHCARE  
SUSTAINABILITY**

**IMPROVE PATIENT ACCESS  
TO MEDICINES THROUGH  
BETTER REGULATION**

**REINFORCE  
REGULATORY  
HARMONISATION**

**PROVIDE PATIENTS  
WITH NECESSARY AND  
APPROPRIATE INFORMATION**

**To enhance the global  
competitiveness of the  
generic and biosimilar  
medicines industry by**

**To prevent interventions  
by third parties in  
registration procedures by**

**To improve patient access  
to affordable medicines  
through better regulation by**

**To build an efficient  
MA system by**

**To ensure patient access  
to reliable information  
on generic and biosimilar  
medicines by**

- creating a level playing field for global competition;
- championing a harmonised interpretation of existing Good Practice (GxP) standards and improving inspections at EU level;
- introducing a broader interpretation of the EU reference product to create the appropriate regulatory environment for the global development of generic and biosimilar medicines

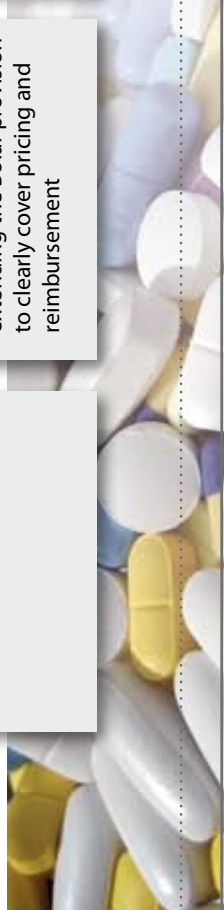
- preventing anti-competitive strategies from third parties aimed at delaying marketing authorisation for generic and biosimilar medicines;
- making it clear and unambiguous that:
  - any informal intervention should be duly justified and made transparent to the generic medicine applicant
  - intervention should not delay the approval of the MA or price and reimbursement;
- rejecting any patent linkage in regulatory processes;
- extending the Bolar provision to clearly cover pricing and reimbursement

- streamlining the Decentralised Procedure and increasing the role of the CMD(h);
- improving patient access to generic and biosimilar medicines by adapting the marketing authorisation procedure to the realities of the off- patent market;
- employing electronic interfaces to reduce administrative burden;
- embarking upon a drive towards a homogenous and consistent implementation of the EU guidelines, including the recently revised EU bioequivalence guideline

- implementing the reduction or removal of country specific requirements;
- improving marketing authorisation (MA) procedures through a more efficient use of resources;
- facilitating a more balanced and equal contribution across all Member States to the network;
- improving mutual recognition by the avoidance of repeated assessments by Concerned Member States;
- ensuring the optimisation of work-sharing systems across Member States

- creating a specific subsection on the medicines agencies' websites concerning generic and biosimilar medicines;
- helping patients and healthcare professionals to understand the concept of generic and biosimilar medicines and the issue of generic substitution;
- implementing a proactive policy to prevent and to take action against misinformation campaigns against generic and biosimilar medicines

**Ways to achieve the objectives**



# vision



## EGA VISION 2015

### THE EGA'S THOUGHTS ON HOW TO IMPROVE THE LEGAL AND REGULATORY FRAMEWORK FOR GENERIC AND BIOSIMILAR MEDICINES

#### EXECUTIVE SUMMARY

With an ageing European population and EU Member States' healthcare budgets under pressure, generic and biosimilar medicines are now more than ever a key component of sustainable healthcare. Generic medicines create savings of over 30Bn Euros and newly established biosimilar medicines already generate around 1.4Bn Euros<sup>1</sup> per year for European healthcare systems. Today, generic medicines in Europe represent almost half of the pharmaceutical market by volume but around 18% of the total cost. With many high-profile blockbuster medicines losing market exclusivity over the next few years, generic medicines will create major opportunities for governments to make healthcare savings. But this fact also creates considerable demand on the EU authorisation systems.

The European generic medicines industry operates in a highly competitive sector, creating approximately 150,000 jobs in Europe. Generic medicines companies spend more than 7% of their turnover on development, including in the fields of biosimilar medicines and difficult-to-make molecules, and continue to achieve incremental innovation, such as new release forms or molecule improvements, even after originator companies have left the market.

Due to a very large portfolio and a significant number of marketing authorisations (MAs) in each Member State (MS), the generic medicines industry has always been an important contributor towards financing the functioning of the national competent authorities and now contributes even more to the EU regulatory network by a systematic increase in the amount of applications in the Centralised Procedure. The efficient and predictable "twin engine" regulatory system of the Centralised Procedure (CP) and Decentralised Procedure (DCP) is of key importance to the generic medicines industry, as 83% of all DCP and 68% of all mutual recognition (MRP) applications are related to generic medicines as well as almost 50% of applications in the CP. In addition, biosimilar medicines applicants, who are obliged to only use the CP, view an efficient functioning of the CP as critical to ensuring timely market access for their products. To fully exploit the advantages of generic and biosimilar medicines it is therefore necessary for policymakers to create the right environment for a competitive and efficient regulatory system that will ensure timely approval.

<sup>1</sup> Considering only the top 10 biotech blockbuster products

To accomplish this, there is a need to focus on five goals:

**1. To enhance the competitiveness of the generic and biosimilar medicines industry by**

- creating a level playing field for global competition;
- championing a harmonised interpretation of existing Good Practice (GxP) standards and improving inspections at EU level;
- introducing a broader interpretation of the EU reference product to create the appropriate regulatory environment for the global development of generic and biosimilar medicines

**2. To maintain competition and create sustainable healthcare by**

- preventing anti-competitive strategies from third parties aimed at delaying marketing authorisation for generic medicines. Interventions by originators must be duly justified and made transparent to the generic medicine applicant;
- rejecting any patent linkage in regulatory processes;
- extending the Bolar provision to clearly cover pricing and reimbursement

**3. To improve patient access to affordable medicines through better regulation by**

- streamlining the Decentralised Procedure and increasing the role of the CMD(h);
- improving access to generic and biosimilar medicines by adapting the marketing authorisation procedure to the realities of the off-patent market;
- employing electronic interfaces to reduce administrative burden;
- embarking upon a drive towards a homogenous and consistent implementation of the revised EU bioequivalence guideline

**4. To reinforce regulatory harmonisation by**

- implementing the reduction or removal of country-specific requirements;
- improving marketing authorisation (MA) procedures through a more efficient use of resources;
- facilitating a more balanced and equal contribution across all Member States to the network;
- improving mutual recognition by the avoidance of repeated assessments by Concerned Member States;
- ensuring the optimisation of work-sharing systems across Member States

**5. To provide patients with necessary and appropriate information by**

- improving information on generic and biosimilar medicines by creating a space on agencies' websites;
- preventing negative campaigns against generic and biosimilar medicines



*“Today, generic medicines in Europe represent almost half of the pharmaceutical market by volume and around 18% by value.”*



## INTRODUCTION

With an ageing European population and Member States' healthcare budgets under pressure, generic medicines are now more than ever a key component of sustainable healthcare, as they contribute with savings of over 30Bn Euros for chemical entities and 1,4Bn Euros for biosimilar medicines<sup>2</sup> per year to the European healthcare systems while increasing patient access to generic medicines. Today, generic medicines in Europe represent almost half of the total pharmaceutical market by volume and around 18% by value. In view of high profile blockbuster medicines losing market exclusivity over the next few years, generic medicines are becoming a pivotal asset for healthcare systems. But this also creates a big demand on the authorisation systems.

The European generic medicines industry operates in a highly competitive sector creating approximately 150,000 jobs in Europe. Generic medicines companies spend more than 7% of their turnover on development, including in the fields of biosimilar medicines and difficult-to-make molecules, and continue to achieve incremental innovation, such as new release forms or molecule improvements even after originator companies have left the market.

To fully exploit the advantages of generic and biosimilar medicines and the European generic and biosimilar medicines industry it is necessary to create the right environment for competition in the market based on three pillars: firstly, effective demand side measures to stimulate generic medicines access by patients; secondly, a balanced IP system based on quality patents and a balanced litigation system; and thirdly, an efficient regulatory system, which

ensures timely approval. Due to a very large portfolio and a significant number of marketing authorisations (MAs) in each Member State (MS), the generic medicines industry has always been an important contributor towards financing the functioning of the national competent authorities and now contributes even more to the EU regulatory network by a systematic increase in the amount of applications in the Centralised Procedure. The efficient and predictable “twin engine” regulatory system of the Centralised Procedure (CP) and the Decentralised Procedure (DCP) is a key factor for the generic medicines industry, as 83% of all DCP and 68% of all mutual recognition (MRP) applications are related to generic medicines as well as almost 50% of applications in the CP. The choice of marketing authorisation (MA) route should be driven by the best compatibility with the company's needs and strategy and not by trying to avoid the regulatory and legal hurdles related to one or another procedure.

To accomplish this, there is a need to focus on five goals:

- enhancing the competitiveness of the generic and biosimilar medicines industry;
- maintaining competition and sustainable healthcare;
- improving patient access to affordable medicines through better regulation;
- reinforcing regulatory harmonisation;
- providing patients with necessary and appropriate information

In the following pages this document outlines the vision for the optimal regulatory environment and the way in which it can be achieved within the existing legal framework.

<sup>2</sup> Considering only the top 10 biotech blockbuster products

## GOAL 1: ENHANCE THE COMPETITIVENESS OF THE GENERIC AND BIOSIMILAR MEDICINES INDUSTRY

Objective	How to achieve the objective
<p><b>Intensification of efforts to ensure global competition on a level playing field</b></p>	<p><b>To establish a true level playing field</b> (particularly in the area of pharmaceutical Good Practice (GxP) inspections), supporting fair global competition while overcoming the issue of limited resources in the EU, there is a <b>need for the extension of the scope of Mutual Recognition Agreements (MRAs)</b>, the development of alternative (less formal) collaborative schemes<sup>3</sup> and a more centralised coordination of activities. For existing MRAs, the scope could be extended so that not only local inspections are recognised but also inspections carried out by the partner country within any other territory, thereby avoiding duplicative work. MRAs should also be amended to encompass active substances in addition to medicinal products.</p> <p><i>Justification: The pharmaceutical industry operates on a global scale with manufacturing facilities located throughout the world, and supplies medicinal products to many regions, including the EU. It is important that the EU rules laid out in the pharmaceutical legislation are equally applied and implemented, regardless of the location where the operations take place, as long as the intent is to have the medicinal products concerned used by EU patients.</i></p> <p><b>Improvement of harmonised interpretation of existing GxP standards in the MS and better coordination and recognition of the inspections at EU level.</b></p> <p><i>Justification: With increasing demand for inspections but still very limited resources at national level, the development of a more centralised and better coordinated system will be highly appreciated. The creation of a well-resourced EU Inspectorate should be the ultimate goal. As a short/mid-term solution, the creation of a formal Inspection group within the current legal framework should be considered in order to optimise the existing network of national inspectors and to provide more inspection capability. The positive experience of informal coordination groups e.g. the MRFG (Mutual Recognition Facilitation Group which was a precursor of the CMD(h)) could be used to achieve better coordination and recognition of the inspections in the EU, without changing the existing legal framework.</i></p> <p><b>An accessible on-line GxP database</b> providing information on inspection outcomes, GxP compliance and operator licenses (e.g. importers) would provide a valuable tool for industry and regulators alike.</p> <p><i>Justification: This information is largely available within the national authorities but limited information is exchanged at a central level. This information is of relevance for cooperation within the EU and outside. It is also of importance for industry operators to perform their risk assessment and audit prioritisation. With an increasing demand for inspections, the development of a more centralised system, integrating data from European (Eudra)<sup>4</sup> databases, data from the MAA<sup>5</sup>, the number of inspectors and number of inspections performed per year, would allow a systematic prioritisation at EU level and enhanced capabilities of collaboration with international partners. The EMA should further develop its inspections sector with dedicated expert inspectors who can participate in the overall EU coordination and roll-out of activities and populate the EudraGMP database.</i></p>

<sup>3</sup> e.g. FDA-EMA-TGA pilot initiative on API inspections or FDA-EMA on GCP inspections twinning projects with other countries

<sup>4</sup> European databases are usually called a EudraXXX database, where XXX specifies the nature of the data collected; e.g. Eudra GMP on Good Manufacturing Practices or EudraCT on Clinical Trials

<sup>5</sup> MAA Marketing Authorisation Application

Objective	How to achieve the objective
<p><b>Broader interpretation of the EU reference product to create the appropriate regulatory environment for the global development of generic and biosimilar medicines</b></p>	<p><b>To allow the use of batches of the EU reference product sourced from the ICH regions in the abridged applications for EU territory.</b></p> <p><i>Justification:</i> The pharmaceutical industry operates on a global scale and supplies medicinal products to many regions. This includes the development of a new product with the intention of marketing this product globally. Clinical studies performed with a batch of the reference product from the ICH region (e.g. from the US), should be accepted in support of an EU dossier.</p> <p>Duplication of preclinical and clinical studies for each country/region clearly hampers the development of new products (particularly for biosimilar medicines, where the development program involves significant financial investment). Unethical duplication of studies should also be avoided when they are not necessary from a scientific point of view in accordance with the Helsinki Declaration.</p> <p>Relevant guidelines should consequently be amended to clarify this important point in order to support the global development of biosimilar and generic medicines.</p> <p>In order to further reassure the regulators, additional information about the non-EU sourced reference product could be shared under confidentiality arrangements between authorities (e.g. via transatlantic dialogue FDA/EC-EMA).</p> <p>Furthermore, the ICH M5 topic regarding the identification of medicinal products will provide in the future an excellent framework to reassure the regulators about the identity of medicinal products.</p>



## GOAL 2: MAINTAIN COMPETITION AND HEALTHCARE SUSTAINABILITY

Objective	How to achieve the objective
<p><b>To prevent interventions by third parties in registration procedures</b></p>	<p><b>In general, the competent authorities should not take into account third party submissions when considering the granting of marketing authorisations or the pricing and reimbursement status of generic and biosimilar medicinal products.</b></p> <p>The procedure should be unambiguously clear that any informal and unforeseen intervention by originator companies should be duly justified, made <b>transparent to the generic medicine applicant and should not delay the approval of the MA or price and reimbursement approval.</b></p> <p>For transparency reasons, all assessors (including the assessors from the national competent authorities) should submit a <b>conflict of interests declaration</b> as in the case of experts involved in EMA activities.</p> <p><i>Justification:</i> The final report of the Pharmaceutical Sector Inquiry carried out by the European Commission<sup>6</sup> confirmed that originator companies delay regulatory proceedings via third party interventions to marketing authorisation bodies. The European Commission recalled that marketing authorisation procedures are bilateral proceedings between the applicant and the administration. Third party submissions and even less formal interventions during the assessment of an application for a marketing authorisation are not foreseen in Community pharmaceutical legislation.</p>

<sup>6</sup> [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication\\_en.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf)

Objective	How to achieve the objective
<p><b>Pathways leading to patent linkage creating barriers to generic medicine market entry should be abandoned</b></p>	<p>The EGA strongly <b>opposes any proposal for a mandatory notice mechanism for all generic medicine marketing authorisation applications</b>, since this notice would give the originator company the right to immediately commence patent infringement proceedings.</p> <p><b>Any practice of patent linkage</b> that arises by notifying the patent holder of a generic medicine application, requires declarations of non-patent infringement to the regulatory authorities, disallows an application or granting an authorisation during the patent period and the submission of patent status to pricing and reimbursement authorities for a decision, <b>should be abandoned</b>.</p> <p><i>Justification: The European Commission clearly stated in the recent report on the Pharmaceutical Sector Inquiry that “under EU law, it is not allowed to link marketing authorisation to the patent status of the originator reference product. Article 81 of the Regulation<sup>7</sup> and Article 126 of the Directive<sup>8</sup> provide that authorisation to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in the Regulation and the Directive. Since the status of a patent (application) is not included in the grounds set out in the Regulation and in the Directive, it cannot be used as an argument for refusing, suspending or revoking MA”.</i></p> <p><i>The Commission’s report also states that in the context of the public consultation for the Pharmaceutical Sector Inquiry, the originator association submitted that “applications for marketing authorisations by generic companies would not amount to a violation of patent law.” The European Commission adds to this that “the same logic should apply to applications for pricing and reimbursement status”.</i></p>
<p><b>Clarification of the Bolar provision</b></p>	<p>The <b>Bolar provision should be clarified</b> in such a way that all administrative acts and necessary steps before the launch of the product on the day immediately following patent expiry (including application for and granting of MA, and awarding of price and reimbursement status needed to put a generic medicine on the market) are covered and consequently fall out of the scope of patent protection.</p> <p><i>Justification: The Bolar provision introduced in Article 10.6 of Directive 2004/27/EC of 31 March 2004, amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, is not sufficiently explicit in the legislation, and therefore has led to a series of court cases. Extending the Bolar provision to clearly cover pricing and reimbursement should be included in the expected revision of the Price Transparency Directive 1989/105/EC.</i></p>

### GOAL 3: IMPROVE PATIENT ACCESS TO AFFORDABLE MEDICINES THROUGH BETTER REGULATION

Objective	How to achieve the objective
<p><b>Quicker access to generic medicines by refining the Decentralised Procedure</b></p>	<p><b>Certain elements from the CP could be transposed into the DCP</b> such as a single list of questions, clear rules for restarting the procedure after clock-stop, clarity within the decision-making process when disagreement occurs (a majority vote at the CMD(h) instead of consensus).</p> <p>The ability to place the product onto the market prior to the final document being issued at national level (e.g. based on the positive closure of the DCP European Phase plus positively-assessed translations of product information and allocation of the MA number in advance) should be explored as an <b>option in those countries with long administrative procedures for the issuing of a final MA document</b>.</p> <p><i>Justification: EGA members welcomed the introduction of the DCP, which was a great improvement to the marketing authorisation process compared with the MRP. However, there are still some areas for improvement based on the DCP/CP experiences gained over the last 5 years.</i></p>

<sup>7</sup> Regulation 2004/726/EC laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

<sup>8</sup> Directive 2004/27/EC, amending Directive 2001/83/EC on the Community code relating to medicinal products for human use



Objective	How to achieve the objective
<p><b>Increasing the role of the CMD(h)</b></p>	<p>The <b>mandate of the CMD(h)</b> (Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human) should be <b>broadened, its operation adapted and its role increased.</b></p> <p>The CMD(h) could establish a <b>central co-ordination system</b>, acting as the point of coordination for the distribution of slots for DCPs and MRPs, the applicant's right to indicate the preferred RMS is still maintained. This would help in obtaining slots and thereby discourage the practice operated by companies of double-booking slots with multiple authorities in order to be assured of achieving one.</p> <p>The operation of the CMD(h) meetings could be changed to one of a majority-voting system, similar to CHMP meetings, rather than being consensus-based.</p> <p><b>Agreement reached by the CMD(h)</b> should be more <b>binding</b> on the MS at the national level without significant national deviation from the decisions as agreed.</p> <p>The establishment of a <b>"legal/regulatory emergency action group" within the CMD(h)</b> would provide an added enhancement to the EU structures and an additional benefit to the generic medicines industry. Such a specific group could offer the possibility of communication on issues occurring during the daily practice related to non-compliance with EU legislation and the CMD(h) agreements. The composition of the group could be extended to the EMA and the EC, in order to cover the full spectrum of institutions involved in the MA process.</p> <p><i>Justification: The involvement of 27 MS and 3 members of the EEA in the DCP and MRP procedures brings with it the significant advantage of being able to cover many countries in one MA procedure but also increases the complexity of the MA process. The efficient coordination by the CMD(h) plays a critical role in the process. The reinforcement of the coordinating role of the CMD(h) should be foreseen.</i></p>
<p><b>MA procedures for generic medicines better adapted to the realities of the off-patent market</b></p>	<p>The legal framework and MA procedure should <b>better reflect the market specificity</b> for the generic medicines industry, including <b>all types of cooperation between business partners as well as the consequences of mergers and acquisitions.</b></p> <p>Some flexibility in the MA procedure will be welcome, e.g. the <b>possibility to duplicate a MA in the CMS</b> without involving the RMS provided there is full maintenance of duplicates in line with the initial MA.</p> <p>The <b>way in which the Active Substance Master File (ASMF) is handled</b> as the basis of the drug substance module could also be improved. The use of EU assessors' resources could be optimised by creating a central ASMF assessment system whereby an approved ASMF could be accepted by all authorities without the need to re-assess the documentation (based on the model provided by the CEP procedure). This would significantly help to optimise the resources of assessors and inspectors. A future extension of this concept could <b>envisage a mutual recognition agreement regarding assessment of drug master files.</b> The outcome should be included in a database and be accessible to companies.</p> <p><i>Justification: The use of a database listing all assessed/approved ASMFs could greatly streamline the resources used for generic medicines applications, particularly where no EP monograph has yet been developed, and simplify what is currently a complex 'triangular' process. The future MRA would further reduce the duplication of work by authorities, limiting the multiple assessments of ASMFs by regional authorities.</i></p>

Objective	How to achieve the objective
	<p><b>The difference in the legal basis</b> (art. 10.1 or 10.3), should not be seen by some MS as a barrier for reimbursement and generic substitution listing.</p> <p><i>Justification:</i> The difference in the legal basis for the generic medicine application across the MS (depending on the presence of the reference product on the market and necessity to perform some studies or not to do so) may have an impact in those MS with very strict rules for pricing and reimbursement as well as for substitution (10.3 (hybrid application) not seen as generic medicine).</p>
<p><b>Improvement of access to generic medicines by using the Centralised Procedure</b></p>	<p><b>Eligibility to use the Centralised Procedure for generic medicine applications on the basis of “community interest” should be further explored</b> in order to increase access to generic medicines in the Community.</p> <p><i>Justification:</i> Access to the Centralised Procedure for generic medicines is currently limited by legislation allowing the use of the CP only in cases where the RP was authorised centrally. Although the generic medicines industry would like full flexibility regarding the choice of the procedure, independently of the authorisation route of the RP, we are aware of the importance of keeping the right balance within this EU network. Being the main user of the Decentralised Procedure (DCP) and the Mutual Recognition Procedure (MRP), a shift of the generic medicines industry’s regulatory activities towards the Centralised Procedure may jeopardize this balance as well as the high-quality specialist expertise provided by Member States today. The solution to finding the right balance between the choice of procedure and maintaining the EU regulatory network may be a broader interpretation of <b>eligibility to use the Centralised Procedure for generic medicine application on the basis of “community interest” and appropriate amendments to the guideline.</b></p>
<p><b>Centralised Procedures for biosimilar and generic medicines better adapted to the market realities, which are the basis for access</b></p>	<p><b>Duplicate marketing authorisation applications</b> by marketing authorisation holders belonging to the same group of companies should continue <b>to be accepted in the Centralised Procedure</b> by the European Commission.</p> <p><i>Justification:</i> The April 2010 European Commission clarification (Doc ref: ENTR/F/2/RSR es D(2009)380166) severely limits the possibility to obtain duplicate applications for companies belonging to the same group. The generic medicines market environment, as operated by the individual Member States, differs from country to country. Different naming (INN, branding) requirements and other national policies and medical practices need to be taken into account in order to get access to the market and make generic medicines available to patients, governments and healthcare providers. Forcing generic medicine companies now to switch to the DCP will have a major impact on the availability of cost-effective medicines, as it will delay the access of generic medicines to the market (in some countries for up to or even more than 1 year) and exacerbate the already severely limited and overburdened resources of both the national competent authorities and healthcare providers. This situation is likely to worsen given the number of blockbuster products losing their patent protection over the next few years.</p> <p>For biosimilar medicines’ applications, which are locked into the Centralised Procedure, the impact of the European Commission clarification is even more limiting. There is only a small number of companies that have the scientific, technical and financial background to develop and manufacture biosimilar medicines. This relatively new category of medicines offers equivalent and more cost-effective alternatives to existing, high-cost biopharmaceuticals. Reducing the number of biosimilar medicines now available in the EU will dramatically reduce competition. As a consequence, fewer patients will have access to these life-saving medicines since all Member States operate under restricted healthcare budgets.</p>

Objective	How to achieve the objective
<p><b>To use electronic interfaces to reduce administrative burdens</b></p>	<p>The ability to submit regulatory documentation through a <b>single IT interface</b> and have a <b>central repository for submissions</b> with full access capabilities for the Competent Authorities.</p> <p><i>Justification: A central repository would significantly optimise the business processes and exchange of information between the industry and authorities. This would encourage common standards and the continued development of an efficient regulatory network for the benefit of the industry, authorities and patients alike.</i></p>
<p><b>The fees should be indicative of an efficient service and the actual work performed by the Competent Authorities</b></p>	<p>Due to a very large portfolio and a large number of MAs in each MS, a significant proportion of generic medicines producers' budgets is attributed to fees associated with regulatory processes. The <b>fees should be indicative of an efficient service and also the actual work performed by the Competent Authorities (CA)</b>. Any future reform of fees should take this into consideration.</p> <p><i>Justification: Due to the significant financial contribution to the system from fees paid by the generic medicines industry, it would appreciate an appropriate value-for-money service, especially with regard to the review, processing and granting of marketing authorisations in a timely manner, reflecting in addition the actual work performed by the CA.</i></p>
<p><b>Harmonisation of bioequivalence</b></p>	<p>Bioequivalence is a pillar in the establishment of the status of a generic medicine. The <b>revised bioequivalence guideline</b> was eagerly awaited as it defines the design and planning of bioequivalence clinical studies in the very near future. The EGA would encourage the expansion of bioequivalence assessors and industry interactions through meetings, conferences and trainings to <b>ensure a homogenous and consistent implementation by all</b>.</p> <p><i>Justification: In the past, varying interpretations of the provisions of the guideline by different experts in the different Member States have proven to create major hurdles to the timely review and approval of generic medicines. The EGA will closely follow the progress and monitor potential implications for the generic medicines industry.</i></p>

#### GOAL 4: REINFORCE REGULATORY HARMONISATION

Objective	How to achieve the objective
<p><b>Elimination of additional national requirements</b></p>	<p>Although we recognise progress has been made, the industry is still experiencing requests for many national-specific documents to be provided. <b>Additional country-specific requirements should be significantly reduced or omitted</b> in order to achieve full harmonisation of the requirements across all EU MS. <b>All elements not related to the quality, safety and efficacy of a product should be excluded from the final MA document.</b></p> <p><i>Justification: The generic medicines industry is facing delays in the granting of MAs due to some additional elements appearing in the final MA, which are not related to the assessment of the quality, safety and efficacy of the product, e.g. price or reimbursement status.</i></p>

Objective	How to achieve the objective
<p><b>Building efficient marketing authorisation procedures through efficient use of resources</b></p>	<p><b>A more balanced and equal contribution across all Member States</b> should be assured, especially for the purpose of acting as a RMS, by harnessing the existing expert's network.</p> <p><i>Justification:</i> The introduction of the Decentralised Procedure (DCP) has been a major positive step forward with the potential for a more rapid assessment of generic medicine applications and thereby the ability to bring affordable medicines quickly to the patient. Currently, the majority of DCPs are run by about 4-5 Member States with some Member States actively refusing to take this responsibility, or having no slots to accept a dossier. It is also recognised that some of the smaller EU Competent Authorities feel they do not have the resources and experience that would be required to take on a leadership role in a DCP. Operationally, the smaller authorities could take a step-wise approach, working within their specific skill-set as applicable, and could be supported by a network of experts from other authorities or from external institutions.</p> <p><b>The reinforcement of the mutual recognition of the assessment performed by one authority by other authorities is needed to ensure the optimal use of existing resources.</b></p> <p><i>Justification:</i> The full application of the mutual recognition of the assessment made by the RMS and elimination of duplicate assessments would liberate authority resources and would create the necessary capacity for assessment of further applications as an RMS.</p> <p>The regulatory processes could be optimised by <b>work-sharing systems across Member States</b> and the true recognition of an assessment made by the lead authority either in DCP or MRPs, thereby freeing up authority resources to handle the continuing workloads.</p> <p>For those Member States experiencing a high volume of generic medicine applications, <b>improvements in project management training</b> could be beneficial in order to prepare countries to act as the RMS and lighten the workload of the authorities most frequently used as RMS. The creation of an efficient regulatory network would strengthen the competitiveness of the European pharmaceutical market and of European companies.</p>

## GOAL 5: PROVIDE PATIENTS WITH NECESSARY AND APPROPRIATE INFORMATION

Objective	How to achieve the objective
<p><b>To ensure patient access to reliable information on generic and biosimilar medicines</b></p>	<p>The European generics medicines industry would particularly welcome the <b>creation of a specific subsection on the agencies' websites related to generic and biosimilar medicines, aimed at helping patients and healthcare professionals to understand the concept of generic/biosimilar medicines and the issue of generic substitution.</b></p> <p><i>Justification: To ensure that necessary and appropriate information about generic and biosimilar medicines by the general public and by health professionals is recognised. The websites of the Portuguese Medicines Agency (INFARMED), the French Medicines Agency (AFSSAPS) and the US FDA provide useful examples to follow.</i></p> <p><b>Generic medicines companies should be allowed to inform the European public about what generic and biosimilar medicines are, as long as they do not refer – even indirectly – to individual products.</b></p>
<p><b>To stop negative information about generic and biosimilar medicines</b></p>	<p>The National Competent Authorities (NAC) should implement a proactive policy to <b>prevent misinformation campaigns</b> on their territory.</p> <p>The European Commission in its Pharmaceutical Sector Inquiry urges Member States to <b>take action towards negative information campaigns against generic and biosimilar medicines</b> on the basis of Article 97 of Directive 2001/83/EC, if any such campaigns are detected in their territory. The generic medicines industry strongly supports this approach. Although such information and marketing may be prohibited under national rules on unfair advertising or competition in some Member States, the position varies across the EU and the <b>general prohibitions are insufficiently precise to constitute an effective deterrent to this form of behaviour.</b></p> <p><i>Justification: Information and marketing campaigns by third party companies that call into question the efficacy, quality or safety of generic and biosimilar medicinal products cause significant harm to generic and biosimilar entry and are, by their very nature, misleading, given the need to establish the quality and the bio-equivalence of generic products or comparability of biosimilar medicines as part of the marketing authorisation process. The final report of the Pharmaceutical Sector Inquiry recalls that all medicinal products (whether originator or generic) authorised for placing on the Community market are subject to the same requirements of quality, safety and efficacy. Any campaigns that put this fact in question ignore the key principles for marketing authorisation in the EU and may mislead the public.</i></p>



## GLOSSARY

AFSSAPS	Agence française de sécurité sanitaire des produits de santé (France)
API	Active Pharmaceutical Ingredient
ASMF	Active Substance Master File
CA	Competent Authority
CEP	Certificate of Suitability to the monographs of the European Pharmacopoeia
CHMP	Committee for Medicinal Products for Human Use
CMD(h)	Coordination Group for Mutual Recognition and Decentralised Procedures – Human
CMS	Concerned Member State
CP	Centralised Procedure
DCP	Decentralised Procedure
EC	European Commission
EEA	European Economic Area
EGA	European Generic medicines Association
EMA	European Medicines Agency
EP	European Pharmacopoeia
FDA	US Food and Drug Administration
GxP	Good Practice
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
ICH	International Conference on Harmonisation
INFARMED	National Authority of Medicines and Health Products (Portugal)
INN	International Nonproprietary Name
IP	Intellectual Property
MA	Marketing Authorisation
MAA	Marketing Authorisation Application
MRA	Mutual Recognition Agreements
MRFG	Mutual Recognition Facilitation Group
MRP	Mutual Recognition Procedure
MS	Member State
NCA	National Competent Authorities
RMS	Reference Member State

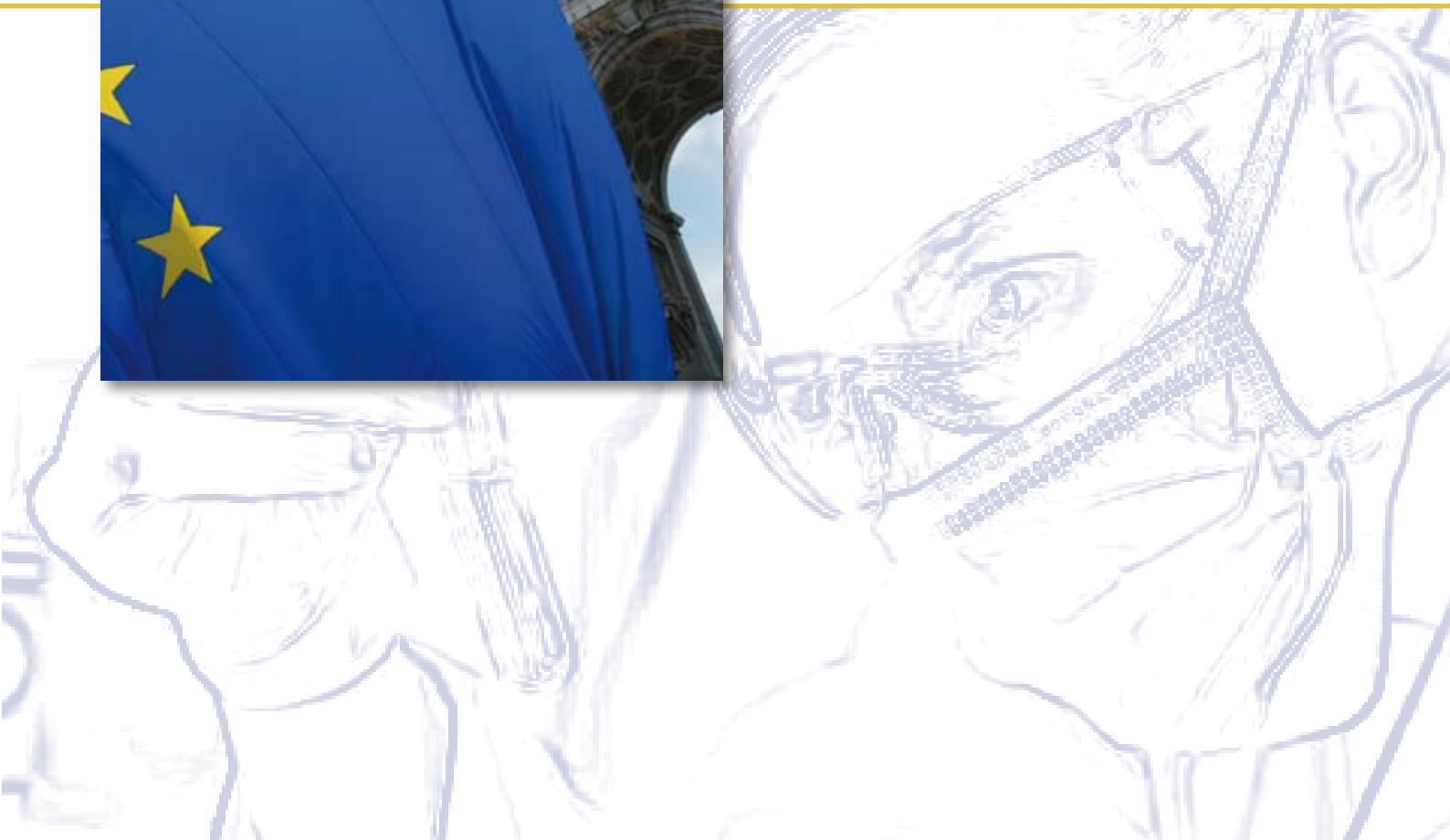


**EGA** | European Generic Medicines Association

The EGA is the official representative body of the European generic and biosimilar medicines industry, which is at the forefront of providing high-quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the pharmaceutical sector.

---

[www.egagenerics.com](http://www.egagenerics.com)





*Making Medicines Affordable*

**EUROPEAN GENERIC  
MEDICINES ASSOCIATION**

Rue d'Arlon 50  
B-1000 Brussels | Belgium  
T: +32 (0) 2 736 84 11  
F: +32 (0) 2 736 74 38  
[www.egagenerics.com](http://www.egagenerics.com)  
[info@egagenerics.com](mailto:info@egagenerics.com)

EGA VISION 2015

---