

A PHARMACEUTICAL STRATEGY SHAPED TO ENSURE AND PROMOTE SOLIDARITY AND SUSTAINABLE HEALTHCARE IN THE EUROPEAN UNION

AIM's position on the European Pharmaceutical Strategy

Executive Summary

AIM shares the views of the European Commission on the state of the pharmaceutical markets in Europe. There is unequal access to medicines across the EU especially for “small” markets that have long been underserved. Pharmaceutical expenses put national health budgets under pressure. The supply and shortages of medicines were further worsened by the COVID-19 crisis. We agree that urgent structural solutions have to be found. Public health needs and innovation efforts from companies need to be better aligned. AIM is convinced that it is necessary to discuss how to best integrate real-world data in the regulatory and decision-making system.

AIM calls for the European Pharmaceutical Strategy to be first and foremost a **health strategy to support universal healthcare coverage**. It must be a strategy that shapes a pharmaceutical industry for better health in Europe. With this in mind, AIM has developed its response to the European Pharmaceutical Strategy and the European Pharmaceutical Strategy roadmap consultation.

AIM's input focuses on 4 axes:

- I. Ensuring access to affordable medicines for all – including the principle of fair prices
 1. Include the principle of fair prices for pharmaceuticals as an operating principle of access to innovative products.
 2. Ensure that public-private funding contracts for medicines include affordability, transparency, and availability clauses.
 3. Revise the orphan medicinal products legislation taking stock of 20 years of operation.
 4. Offer guidance on access to, and the use of off-patent medicines.

- II. Ensure the supply of medicines for patients across Europe
 1. Make sure that the Commission's study on medicines shortages includes forward-looking recommendations.
 2. Review the application of Directive 2001/83 Articles 23a and 81 with a view to clarify and strengthen them, to help ensure the continuous supply of medicines, improve the reporting of shortages, and foresee sanctions in case the supply chain is broken.
 3. Ensure the transparency of the supply chain, increase production capacity as well as support the strategic independence of Europe.

III. Getting on the market the therapies that health systems need

1. Help advance on novel economic models to develop new antibiotics to tackle antimicrobial resistance (AMR) and report on the progression of the actions of the One AMR Action Plan.
2. Lead to the adoption of a balanced legislation on health technology assessment (HTA) at EU level taking into account national specificities.
3. Critically review the European Medicines Agency (EMA)'s early access schemes mechanisms in order to make sure that the medicines that reach pricing and reimbursement authorities do so with enough evidence to assess added therapeutic value.

IV. Harnessing the challenge of real-world data for better pharmaceuticals

1. Real-World Data (RWD) can only complement robust randomised clinical trials. Clinical trials must remain the gold standard for the generation of clinical information on treatment's effectiveness and safety in order to lead market access.
2. An adequate legal and regulatory framework built on ethical guidelines is necessary to regulate the use of sensitive health data and to turn promise into positive outcomes for health systems and patients.
3. Build capacity for real-world data pooling and processing at EU and national level, for the benefit of our healthcare systems.



I. Ensuring access to affordable medicines for all – including the principle of fair prices

AIM's demands

1. The European Pharmaceutical Strategy should include the principle of fair prices of pharmaceuticals as an operating principle of access to innovative products.
2. The European Pharmaceutical Strategy should ensure that public-private funding contracts and funding programmes for medicines include affordability, transparency, and availability clauses.
3. The European Pharmaceutical Strategy should revise the orphan medicinal products legislation, looking into:
 - o Using both the prevalence and insufficient return on investment criteria to base the decision on orphan designation.
 - o Improving the conditions for the review of market exclusivity:
 - i. Ask companies to report yearly on products' EU patient population, as well as information on return on investment.
 - ii. Define what is "sufficient" and "excessive" return on investment.
 - iii. Monitor by the European Commission or EMA of the patient population actually treated by the respective orphan medicinal product.
 - iv. Increase exchanges between Member States and the European Commission on the market dynamics of orphan medicinal products.
4. The European Pharmaceutical Strategy should offer guidance on the access to, and the use of off-patent medicines.
 - o Investigate the feasibility of helping interested Member States include targets for off-patent products uptake.
 - o Look into causes delaying access to off-patent medicines once patents expire.
 - o The Commission could help disseminate its information guide on biosimilars to healthcare professionals and patients.

The European Pharmaceutical Strategy should include the principle of fair prices for pharmaceuticals as an operating principle of access to innovative products

Medicines are not goods like any other. The unaffordability of new molecules is a significant phenomenon affecting European health systems today. The Council of the European Union has rightly noted this worrying development in numerous Council Conclusions since 2016. In the US, the median cost of cancer drugs has increased by 10 times in 15 years.¹ High medicines prices are no longer a trend but a reality of healthcare systems.

The precedent of the high price tags for Hepatitis C medicines had a profound impact on healthcare systems. The treatment had indeed a therapeutic advantage, but many countries could not afford it. Surprisingly, it was not the wealthiest European countries which had to pay the highest relative price to have access to the drug.

Affordability should be the guiding principle of the future European Pharmaceutical Strategy. In the area of cancer, the second leading cause of mortality in EU, the total costs of medicines more than doubled between 2008 and 2018 in Europeⁱⁱ and cancer medicines account for a growing share of the direct costs of cancer treatment. At the same time, high cost of cancer medicines is a significant barrier to access. This either leads to governments not providing the medicine to all eligible patients, or to patients having

to pay for the medicines out-of-pocket. While medicines are an important aspect of cancer treatment, their price must not become a barrier to access them. The issue of cancer illustrates the conundrum that the European pharmaceutical strategy will need to address: ensuring the arrival on the market of needed medicines and ensuring the access to them. **We call on the European Commission to properly address the issue of cancer drug pricing in both the Pharmaceutical strategy as well as part of Europe's Beating Cancer Plan.**

AIM suggests moving from an approach where companies generate revenues for innovative drugs from launches in selected, high-priced markets, to an approach where companies generate their revenues from the volumes sold across all of Europe. The European Union's 27 Member States make up a 446 million inhabitants' market, collectively the largest market for medicinal products in the Western world. If everyone has access to medicines in every market, then it would still generate revenue for an industry which is today one of the most profitable in the world.ⁱⁱⁱ

AIM believes that its proposal for fair European prices of pharmaceuticals is a good inspiration to indicate the right way forward regarding price-setting mechanisms for medicines.^{iv} It proposes an algorithm to calculate prices for innovative medicines at a European level, based on research, development and production costs (and failure), basic profit as well as a bonus based on added therapeutic value. Better matching medicines' prices with their underlying costs of production would offer an opportunity to reconcile profit levels, access across Europe, and the fair retribution of the efforts of the pharmaceutical industry. AIM's proposed transparent algorithm will provide certainty and stability regarding pharmaceutical companies' business decisions, which is what industry need most of all. A convincing strategy for pharmaceuticals should deliver a credible, predictable business environment on which pharmaceutical companies would base their industrial decisions on.

How such calculation could practically take place at European level, with no formal power from the European Union in this field, still needs to be defined. A reflection on the careful balance between what is legal, feasible and desirable to do respectively at national and at European level will need to be led. The collection of relevant data could be done by a European body. The fair price could be delivered as part of the European Commission's medicines marketing authorisation, with actual negotiations on the final price taking place at national level. Linking the price calculation would be a condition to get access to the single market. It would therefore be relevant that the price calculation is done by a European body. Leaving the pricing decision at national level would help safeguard the subsidiarity principle.

The European Pharmaceutical Strategy should ensure that public-private funding contracts and funding programmes for medicines include affordability, transparency, and availability clauses

It should also be noted that a large amount of fundamental research is done by publicly-funded research organisations, or by using public resources.^v Currently, the European Union is in the late stages of its proposal for an Innovative Health Initiative, its flagship pharmaceutical R&D public-private partnership for 2021-2027. It is of utmost importance that strong clauses are included in this funding programme as well as in others, in order to ensure affordability, accessibility and availability of the research results and resulting healthcare products. There should also be transparency on the share of public investment in biomedical research. Public investment must be of public interest and should automatically lead to affordability and accessibility.

The European Pharmaceutical Strategy should revise the Orphan Medicinal Products legislation taking stock of 20 years of operation

The orphan medicinal products area deserves a specific attention. There is evidence that orphan medicinal products development is now turning into a commercial opportunity for many companies.^{vi,vii,viii} Conditions to access and retain orphan medicinal products incentives must be revised in order to take stock of 20 years of operation of the Orphan Medicinal Products Regulation and to keep the spirit of this legislation. As a rule, both the prevalence and return on investment criterion should be used in the future to grant orphan designation. The conditions to revoke market exclusivity need to be strengthened and substantiated in Article 8(2) of Regulation (EC) No 141/2000 and in the Guideline on aspects of its application. Companies should report yearly on orphan medicines' EU patient population to make sure that an orphan medicinal product actually covers an orphan population and not more. Cases of subdivision of patient populations into orphan sub-indications that collectively count more than an orphan population, must be mentioned in the guidelines. The European Commission needs to define what is "sufficient" and "excessive" return on investment as well. Better conditions for the review of market exclusivity should also be adopted, allowing for more frequent opportunities to do so. More exchanges between Member States and the European Commission on the market dynamics of orphan medicinal products could also help facilitate the implementation of Article 8(2) Regulation 141/2000 and of the corresponding guideline.

The European Pharmaceutical Strategy should offer guidance on access to, and the use of off-patent medicines

In many countries, the uptake of off-patent (generic and biosimilars) medicines is still disappointing, despite the positive effects that these medicines can offer to healthcare systems in terms of better sustainability. Should a single, or a group of Member States require it, the European Commission could help those Member States with the setting-up of benchmarks and policies to support the uptake of those off-patent products in their country. Looking into the causes delaying access to off-patent medicines is very important too. A significant work will also need to be done to dispel misconceptions that can sometimes exist against off-patent medicinal products. Such misconceptions among patients and doctors significantly hamper the proper uptake of generics and biosimilars. The Commission could help disseminate its information guide on biosimilars to healthcare professionals and patients.

II. Ensure the supply of medicines for patients across Europe

AIM's demands

1. Make sure that the Commission's study on medicines shortages includes forward-looking recommendations.
 - o Include a definition, as well as an analysis of the scale and root-causes of medicines shortages and critical shortages in the EU.
 - o Foresee the creation of a permanent platform for the collection and sharing of data on shortages with clear responsibilities for doing so, shared between Member States, the European Commission, the European Medicines Agency, pharmaceutical companies, distributors, pharmacists and physicians. Access could be broadened to payer and consumer organisations.
2. Conduct and publish a review of the application of Directive 2001/83 Articles 23a and 81 with a view to clarify and strengthen them, so that manufacturers and distributors ensure the continuous supply of medicines on national markets, develop shortage management plans and improve the reporting of shortages. The European Commission should also clarify sanctions foreseen in the case companies fail to notify shortages and/or supply products on the market.
3. Ensure the transparency of the supply chain, increase production capacity as well as support the strategic independence of Europe.

The European Pharmaceutical Strategy must make sure that the Commission's study to address medicines shortages is forward-looking

The COVID-19 crisis has laid bare the fragility and the intransparency of pharmaceuticals' supply chains as well as the overdependence of Europe on trade partners regarding the supply of critical products needed in hospitals and pharmacies. This logistical issue has become of strategic and public health importance. It did not start with the COVID-19 crisis as alerts regarding shortages were already issued in the summer of 2019. The COVID-19 crisis has however put forward the need for immediate action. **Europe needs a plan to make sure that it does not fall short on the supply of needed pharmaceuticals or medical devices in the future.**

Shortages of medicinal products in Europe can be the result of many factors related to companies' decisions regarding their supply chain, quality issues, regulatory issues, companies' quota allocation or parallel distribution for instance. However, no matter the reason, shortages have very serious consequences on patients, including lack of access to treatment or treatment delays, treatment disruption, potential side effects in case of switch to therapeutic alternatives, emotional and psychological distress, but also increased financial burden on patients, which can lead to treatment exclusion. All of these can be the source of complications and therefore of collective damage to the patient and consequently the whole healthcare systems.

The European Commission should adopt a forward-looking study on medicines shortages which includes forward-looking recommendations. This study should investigate the definitions of medicines shortages, especially of critical shortages, their root causes and the scale of the issue. A future plan on medicines shortages should also strengthen and leverage the European Medicines Agency (EMA)'s COVID monitoring system including Member States, the European Commission and EMA, pharmaceutical companies, distributors, pharmacists and physicians. Access could be broadened to

payer and consumer organisations. Such a platform should be based on similar standards and data, include the warning system provided in Article 23a of Directive 2001/83, and include real-time information on medicines shortages or appropriate information and alert mechanisms.

Conduct and publish a review of the application of Directive 2001/83 Articles 23a and 81

A greater use of the opportunities offered by the existing legislation must be done too. Directive 2001/83 Articles 23a and 81 foresee mechanisms intended to help address and better mitigate shortages. Given shortages scale before and during the COVID-19 crisis, a review of its implementation is urgently needed, with a view to make sure that distributors and manufacturers ensure the continuous supply of medicines on national markets, develop shortage management plans and improve the reporting of shortages. The European Commission should also clarify sanctions foreseen in the case companies fail to notify shortages and/or supply products on the market.

The new European Pharmaceutical strategy should ensure the supply of medicines in Europe in normal and crisis times as well as transparency of the supply chain

The European Union must develop tools to prevent shortages in the future. Public tenders for critical medicines (which notion will need to be defined) must, as a rule, require shortage management plans, transparency of the supply chain, as well as the diversification of supply to make sure that sudden rises in demand don't lead to supply issues. Emergency contingency plans must be in place, co-financed by the industry, in order to mitigate future crises. The opportunities offered by digital tools should be used to their full capacity to monitor current and foreseen demand and supply of medicines. The COVID-19 crisis shows how devastating pandemics can be to our societies. Pharmaceutical systems need to be ready for the potential occurrence of a new one.

The relocation back in Europe of some of the production of chemicals needed for pharmaceuticals manufacturing has been considered by many as a solution to address shortages and we would like to provide a few caveats. Such a solution can only be implementable in the middle- to long-term. Shorter-term solutions, such as those mentioned in the paragraph above, remain fully relevant even in the context of relocations. The relocation decisions also remain the sole responsibility of companies themselves. In this respect a clear, transparent, informed plan, looking into issues such as what kind of medicines we need to relocate, the needs at European level, and the costs of the incentives needed to reshore production is a prerequisite, should the European Commission wish to go down this path. Consultation of all relevant stakeholders will of course be needed all along this process. Any relocation of production sites should not place a financial burden on payers and the insured population in a direct or indirect matter either. Relocation would take the shape of a multi-year exercise, looking among other things into:

- what are essential and critical medicines – we believe that this might depend on the disease area, the type of procedure that these medicines are involved in, as well as on the existence of therapeutic alternatives or not,
- a mapping of where these are produced today including the production capacity,
- the needs in terms of consumption of these medicines in the European Union,
- the reasons for the relocation of the production of those medicines if they are produced outside of Europe,
- the kind of actions that are needed to relocate production in the European Union.

III. Getting on the market the therapies that health systems need

AIM's demands

1. Engage internationally to help advance on novel economic models for the development of new antibiotics.
2. Report on the progression of the actions of the new 'EU One Health Action Plan against Antimicrobial Resistance' on making the EU a best practice region and on boosting research on new antibiotics.
3. Lead to the adoption of a balanced legislation on health technology assessment (HTA) at EU level taking into account national specificities, as this will provide the much-needed basis for the assessment of the added therapeutic value of medicinal products.
4. Critically review the European Medicines Agency (EMA)'s early access schemes mechanisms in order to make sure that the medicines that reach pricing and reimbursement authorities do so with enough evidence to assess added therapeutic value.
 - o Establishing a permanent working structure and information exchange process between EMA and payers with relevant objectives, planning and responsibilities.
 - o Lead to a stricter, patient-centered definition of unmet medical needs, or at least to a stricter method for demonstrating them in its incentives' legal framework.

Engaging internationally to help advance on novel economic models for the development of antibiotics

On the front of antimicrobial resistance (AMR), at least 700.000 people in the world are estimated to die every year due to drug-resistant pathogens. This number is expected to rise to 10 million by 2050 with an estimated cost of \$100 trillion^{ix} in terms of economic output if no action is taken. The level of investment in antimicrobials is disappointing too. No new antibiotic classes were discovered since the 1980s; the last antibacterial class to fight superbugs belonging to the very resistant gram-negative bacteria was even found in the 1960s. According to the World Health Organization (WHO), the pipeline is not very promising either: the 60 products in development (50 antibiotics and 10 biologics) are expected to bring little benefit over existing treatments and very few target the most critical resistant bacteria.^x It is urgent to address this problem as, if uncontrolled, AMR might turn trivial surgery operation into high-stakes endeavours.

AIM is in favour of a financing model for antimicrobials that delinks R&D costs and innovation from price and sales volumes in order to prevent overselling. Such a model should provide long-term supply continuity. A market entry reward (MER) system is suggested by major reports and many journal articles as a solution^{xi, xii, xiii, xiv, xv}. A pharmaceutical company can receive initially (minimum) incentives to cover some of the expenses for efficient R&D and to set up a supply system. Later, the annual payments may increase depending on the outcome of post-marketing data on effectiveness, resistance profiles and stewardship arrangements (based on the concepts of the Health Impact Fund^{xvi}).

Report on the progression of the actions of the new 'EU One Health Action Plan against Antimicrobial Resistance' on making the EU a best practice region and on boosting research on AMR

Above all, the antibiotics that are available and future ones must be used in a responsible way in every sector including the veterinary sector. Many countries are working hard to make patients and healthcare workers become aware of the problem. Public campaigns, incentives, stewardship programmes and

other measures that are taken, meet with varying degrees of success. This is not enough. **We need ambitious preventive measures (e.g. vaccination, hygiene, infection control practices) and rational prescribing and use, as it will take a while before new drugs will come out of the pipeline.** Government, healthcare workers and citizens have to work together as it is in the interest of all of us to prevent bacteria to develop further resistance to the available antibiotics.

Lead to the adoption of a balanced legislation on health technology assessment at EU level considering national specificities

AIM supports the overall objective of the proposal on HTA to bring EU collaboration in the field of HTA further. However, AIM put forward conditions. AIM thinks that mandatory scientific assessments of clinical aspects can only be possible if Member States have the possibility to do national, context-specific additional clinical assessments.

A number of products that reach the market today do not deliver the innovation that we need today. In the area of cancer, according to the World Health Organization (WHO), 35% of the cancer medicines approved by the European Medicines Agency (EMA) in 2009–2013 had established prolonged survival at the time of approval. Only 10% of these approved cancer medicines had evidence of improvement in the quality of life.^{xvii} However, survival for those new medicines was often a few months or sometimes only weeks longer in comparison with already existing medicines. At the same time, cancer medicines lead to a growing cost of overall treatment.^{xviii} With cancer medicines being an important share of the current pipeline and with cancer medicines prices expected to rise, this worrying trend is set to continue.

Critically review EMA's early access schemes mechanisms in order to make sure that the medicines that reach pricing and reimbursement authorities do so with enough evidence to assess added therapeutic value

AIM supports the goal that the latest scientific and technological knowledge is built into medicines development where it benefits public health. However, it is important that EMA keeps its independence and objective nature and does not become co-developer of pharmaceuticals that might seem promising at the first glance as this may jeopardize the quality of its risk/benefit assessments. The development of early access schemes (conditional marketing authorisation, adaptive pathways, PRIME) is worrying in this respect. It is indeed important not to value the mechanism of action / type of product (cell, gene etc.) itself more than the actual outcome to patients.

A critical review of early access schemes mechanisms is needed. We need to understand how health systems benefit from them and make sure that the medicines that reach pricing and reimbursement authorities do so with measurable and strong evidence to assess added therapeutic value. **EMA should establish a permanent working structure and information exchange process with payers with relevant objectives, planning and responsibilities.** AIM understands EMA's efforts to shorten medicines development times to enable patient access to promising medicines faster. It is however crucial to keep the focus on the value that the medicines bring for these patients. If the product is only slightly better than a placebo, it might be giving a false hope to patients in great need. At the final stages of the approval process, payers have to make a decision based on complete data with regard to the benefit to patients.

Too quick an access can jeopardize safety. We must not forget that it is sanitary scandals that led in the 1960s to the harmonisation and reinforcement of European medicines authorisation standards. In the area of orphan medicinal products, the 169 products authorised cover only a limited number of

therapeutic areas. Less than 30% of these medicines targeted diseases for which there were no alternative treatment options, while 95% of rare diseases still remain without a treatment. Therefore, EMA should not only be limited to identifying therapies that address unmet medical needs but should also highlight with stakeholders areas where unmet need exists, but no/not sufficiently effective therapies are available yet. Otherwise, the type of products that reach healthcare systems will continue to be determined by the commercial interests of companies.

IV. Harnessing the challenge of real-world data for better pharmaceuticals

AIM's demands

1. Real-World Data (RWD) should complement robust randomised clinical trials. Clinical trials must remain the gold standard for the generation of clinical information on treatment's effectiveness in order to lead market access.
2. An adequate legal and regulatory framework built on ethical guidelines is necessary to regulate the use of sensitive health data and to turn promise into positive outcomes for health systems and patients.
3. Build capacity for real-world data pooling and processing at EU and national level, for the benefit of our healthcare systems.

Real-World Data (RWD) can only complement robust randomised clinical trials

The explosion of data generation is a distinctive characteristic of XXIst century societies. Just like any other sector, healthcare has seen an enormous increase in terms of health data generation. The health system is also historically a significant generator of data, be they clinical, administrative, financial or demographic. This data hold significant potential for the improvement of health systems' performance. In addition, developments such as artificial intelligence (AI) can radically change the face of our health systems. However, the integration of these datasets in decision-making about pharmaceuticals remains a challenge. A significant amount of data is generated via uncontrolled, real-world setting, whereas decision-making regarding the clinical effectiveness of medicines, across their lifetime, is traditionally based on data generated by randomised clinical trials. Despite their limitations, we believe that randomized clinical trials remain the gold standard for the definition of effectiveness and added therapeutic value. RWD should come as a complement, with careful definition of the purpose and desired outcome of the use of RWD, as well as their end users. RWD should not become an opportunity to shift the costs of clinical trials to public authorities, after medicines marketing. Other significant challenges that need to be faced are the standardisation of data and combining different data-sets.

An adequate legal and regulatory framework built on ethical guidelines is necessary to regulate the use of sensitive health data and to turn promise into positive outcomes for health systems and patients.

Nevertheless, there is a vast potential in developing RWD's use. AI can reduce the costs of the development of innovative medicines by rapidly assessing a huge amount of health data, which facilitates drug discovery and insights generation. Faster than humans, AI is able to analyse health data coming from clinical trials, health records, genetic profiles, preclinical studies and research papers, allowing it to correlate and connect new information with existing data. Machine learning enables AI to

be trained so that it is able to work out the solution to a problem instead of relying on the answers being given to it by programmers.

If well implemented, this could lead to new ways of discovering the underlying mechanisms of action of medicines and their interaction with the patient's genes, better monitor medicines' safety, comparative performance, and better follow the care process and see how the medicine performs in comparison with initial expectation. Such solutions could also help adapt medicines prices to their performance in real life better.

Industry and public authorities should guarantee transparency about the algorithm used for automatic decision-making processes and the objective and data behind it. AI is not only about technological and social innovation but must be a trustworthy tool while complying with applicable laws and ensuring adherence to ethical principles and values. Performance transparency is key to building this trust. Therefore, a technology assessment is needed to analyze the efficiency of AI, especially if it concerns medical care reimbursed by compulsory health insurance.

Build capacity for real-world data pooling and processing at EU and national level, for the benefit of our healthcare systems

A significant and very specific challenge is the fact that healthcare insurance bodies that hold the data do not always hold the capacities to process them and turn them into insight. Technology companies are often the ones that develop solutions needed to exploit data. This means that the power over healthcare systems-relevant information risks shifting further away from public authorities and citizens to these new players. Some countries in Europe are launching data hubs to try to come ahead of this curve. This is a very important development that could benefit from coordination at European level. Pulling these initiatives' resources, in order to facilitate decision-making in healthcare systems and pharmaceutical policies, could also be envisioned. Full respect of the GDPR is however a prerequisite for these initiatives to work. **The European Pharmaceutical Strategy should therefore also focus on giving the structural capacity for decision-makers in healthcare systems to integrate this new kind of data in their work and make the best decisions based on them in an appropriate way.** Only then will decision-makers be able to actually have a sound discussion with technology developers about the therapeutic performance of innovative products.



AIM Healthcare and social benefits for all

The International Association of Mutual Benefit Societies (AIM) is an international umbrella organisation of federations of health mutuals and other not-for-profit healthcare payers. It has 57 members from 30 countries in Europe, Latin America and Africa and the Middle East. 33 of its members, from 20 countries, are based in the European

Union. AIM members provide compulsory and/or supplementary health coverage to around 240 million people around the world, including close to 200 million people in Europe, on a not-for-profit basis. Some AIM members also manage health and social services. Collectively, they have a turnover of almost €300 billion. AIM members are either mutual or health insurance fund.

They are: private or public legal entities; solidarity based; not-for-profit oriented organisations: surpluses are used to benefit the members; democratically-elected members play a role in the governance of the organisation.

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