value added medicines

a medicines for europe sector group



PATIENT-CENTRIC INNOVATION

Tailoring Healthcare for Europe:

The Strategy of Investing in Value Added Medicines

The Value Added Medicines Group, a Medicines for Europe sector group, calls for accelerated and sustainable access to patient-centric solutions delivered through innovation on off-patent molecules.

WHITE PAPER | OCTOBER 2026

Off-patent medicines are a category of therapeutic products that **enable timely and affordable access for patients**. While generic and biosimilar medicines have been well established and recognized for several decades, **Value Added Medicines (VAMs)** represent a more recent **category of innovation based on well-established molecules**, although they have been developed for years.

Value Added Medicines are medicines developed based on known molecules, chemical or biological, that **address healthcare needs and deliver relevant improvements for patients, healthcare professionals, and payers.** These types of medicines can deliver several improvements to society, by **targeting new populations and indications**, by enabling **better efficacy, safety, and or tolerability** profile, or via more appropriate ways of administration, as well as through new formulations that improve preparation or dosage. With **many benefits** for patients and caregivers, healthcare professionals, and healthcare systems, they enable **better outcomes and broaden access for all**.

Value Added Medicines may be achieved through:



Repurposing/Repositioning

New uses discovered for existing molecules to treat different conditions or reach new patient populations

FINDING NEW INDICATIONS TO ADDRESS UNMET MEDICAL NEEDS

Aspirin (Acetylsalicylic Acid) was initially introduced as an **analgesic, antipyretic, and anti-inflammatory agent, more than one hundred years ago.** As a well-known molecule, it is one of the most extensively studied medicines in medical history. So over time, its antiplatelet activity has turned it into a multidimensional therapeutic drug, mostly **used in the prevention of cardiovascular diseases**. Recent studies have further expanded its therapeutic potential, revealing **potential roles in cancer prevention, neuroprotection, and modulation of inflammatory and immune pathways**.

A more specific example involves **Alkaptonuria**, an extremely rare genetic condition affecting approximately one in every 250,000 people worldwide. Patients may experience brittle bones, early-onset osteoarthritis, chronic pain, and heart complications. For many years, treatment options were limited to symptom management. However, the **repurposing of Nitisinone** has emerged as a powerful therapeutic advance and has been accessible for European patients since 2020 and in the US since 2025[1].

These examples of repurposing demonstrate how off-patent medicines can **achieve new therapeutic roles through clinical evidence and guideline adoption**.

[1] https://remedi4all.org/wp-content/uploads/2025/12/Bi-weekly-post-Nitisinone-final-design.pdf



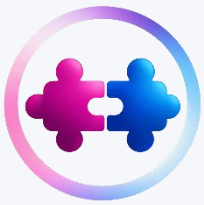
Reformulation

Changes to how a medicine is delivered and absorbed, for example through new dosage forms, routes of administration, processes that facilitate the preparation of finished medicines, or improved release profiles

OPTIMISING TREATMENTS AGAINST RESISTANT BACTERIA

Antimicrobial resistance (AMR) is one of the top global public health threats that claims more than a million lives worldwide each year[2]. **Changing the route of administration** can help **reduce toxicity** and ensure patients can complete their treatment — for example, inhaling formulations of antibiotics to treat pulmonary infections [e.g. for cystic fibrosis patients or infections with non-tuberculous mycobacteria, or formulations for local administration (ciprofloxacin for otitis, that can be used by people younger than 18 years old)].

A **ready-to-use formulation** of a 30-year-old antibiotic that can be stored at room temperature ensures **easier and faster access to treatment**, which is particularly important in life-threatening diseases such as sepsis, where early intervention is critical to survival[3]. **Ready-to-use antimicrobials** (prefilled syringes) also **reduce the burden on healthcare professionals and help direct their efforts to patient care**, where they are needed most. In England alone, moving to ready-to-administer formulations would **save the equivalent of 4,000 nurses** and free up substantial hospital capacity by enabling more care to be delivered closer to patients' homes[4]. **Furthermore,** in intensive care units (ICUs) and operating theatres, ready to use antimicrobials can **lower microbiological contamination**[5].



Combination

Pairing several known molecules together or known molecules with devices or digital tools to improve outcomes

BETTER ASTHMA MANAGEMENT: COMBINING THERAPEUTIC MOLECULES WITH MEDICAL DEVICE TECHNOLOGY

Combining molecules (Budesonide/Formoterol) **in a single inhaler** simplifies the regimen for patients, eliminating the need to juggle separate controllers and reliever devices. **Simpler regimens** are consistently associated with **better adherence** in clinical research. The addition of formoterol to budesonide therapy has also been shown to **improve symptoms and lung function**[6] without compromising asthma control, enabling intensified anti-inflammatory treatment precisely when patients need it most — during worsening symptoms — rather than waiting for a clinic visit or prescription change.

[2] https://www.who.int/news-room/fact-sheets/detail/antimicrobial-resistance
[3] Weiss SL, Peters MJ, Alhazzani W, et al. Surviving sepsis campaign international guidelines for the management of septic shock and sepsis-associated organ dysfunction in children. Pediatr Crit Care Med. 2020;21(2):52-106.
[4] Transforming NHS pharmacy aseptic services in England, UK Dept. of Health and Social Care
[5] Prefilled syringes in intensive care units and operating theatres (report) - EAHP (European Association of Hospital Pharmacists)
[6] Effect of Inhaled Formoterol and Budesonide on Exacerbations of Asthma, Romain A. Pauwels, M.D., Claes-Göran Löfdahl, M.D., Dirkje S. Postma, M.D., Anne E. Tattersfield, M.D., Paul O'Byrne, M.B., Peter J. Barnes, D.M., and Anders Ullman, M.D., for the Formoterol and Corticosteroids Establishing Therapy (FACET) International Study Group* Published November 13, 1997 - N Engl J Med 1997;337:1405-1411 DOI: 10.1056/NEJM199711133372001

PAIRING DIFFERENT MEDICINES TO IMPROVE ADHERENCE TO THERAPY

A real-world evidence study demonstrated that a **fixed dose combination** for hypertension **reduced hospitalization costs** related to disease events by 24.5% and **lowered the incidence of death and cardiovascular events by a third** compared with the equivalent single-dose combination.

As around **50% of cardiovascular patients struggle with adherence**[7] most studies of adherence to therapy in hypertension[8] have shown that **fixed dose combinations significantly improve persistence and ensure better blood pressure control** compared with individual medicine combination therapy. For example, a study in Italy showed that a single-pill combination for hypertension **reduced all-cause mortality and cardiovascular events by 30%**, while also **reducing healthcare expenditure by 18%**[9]. These improvements translate into not only better clinical outcomes for patients but also savings for healthcare budgets.



Repurposing

New uses discovered for existing molecules to treat different conditions or reach new patient populations



Reformulation

Changes to how a medicine is delivered and absorbed through new dosage forms, routes of administration, or improved release profiles



Combination

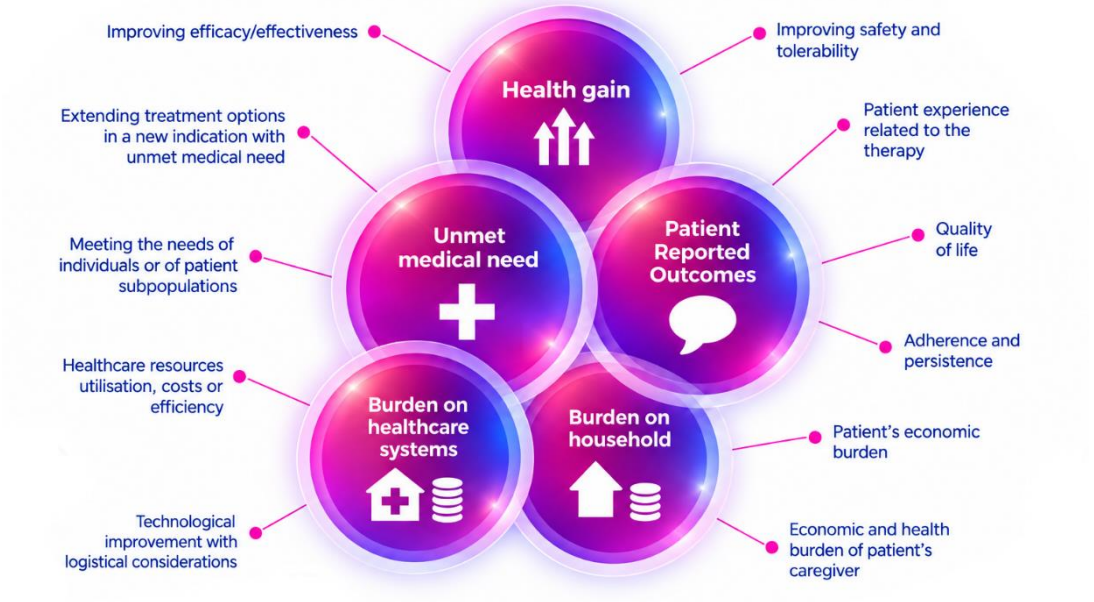
Pairing several known molecules together or known molecules with devices or digital tools to improve outcomes

[7] Failure to take prescribed medicine for chronic diseases is a massive, world-wide problem, WHO.
[8] Parati G, Kjeldsen S, Coca A, Cushman WC, Wang J. Adherence to Single-Pill Versus Free-Equivalent Combination Therapy in Hypertension: A Systematic Review and Meta-Analysis. Hypertension. 2021 Feb;77(2):692-705. doi: 10.1161/HYPERTENSIONAHA.120.15781
[9] Masi S, Kobalava Z, Veronesi C, et al. A Retrospective Observational Real-World Analysis of the Adherence, Healthcare Resource Consumption and Costs in Patients Treated with Bisoprolol/Perindopril as Single-Pill or Free Combination. Adv Ther. 2023;41(1):136-142. (Note: ISPOR EU 2022 presentation, published in J Hypertension 2023)

Value Added Medicines to accelerate sustainable access to treatments in Europe

At a time when healthcare systems are under continuous pressure due to population aging, financial and human resource pressure, Value Added Medicines can be a sustainable solution to these issues and deliver access to affordable innovation.

Value Added Medicines deliver **important benefits to patients, healthcare professionals, payers, and healthcare systems** in a sustainable and affordable way. By innovating on off-patent molecules, they bring treatments to patients for indications **lacking approved therapies, reducing unmet medical needs** through repurposing and **enabling better patient-centric design**. With drug reformulations, and medicine combinations, Value Added Medicines **address healthcare inefficiencies** and offer **diverse therapeutic solutions** that deliver measurable societal benefits across multiple stakeholder groups[10]:



[10] Identified Value domains as per proposed Core Evaluation framework for Value Added Medicines, Petykó, Z. et al: Proposal for a Core Evaluation Framework of Value Added Medicines. Value in Health, Volume 23, S659 - S660.

OVERVIEW OF GLOBAL ACCESS TO VALUE ADDED MEDICINES

THE U.S LEADING PATIENT ACCESS TO VALUE ADDED MEDICINES



In the **United States**, Value Added Medicines benefit from a clear and established regulatory pathway. The 505(b)(2) framework allows companies investing in continuous innovation to receive appropriate recognition and market rewards for the value they deliver through the launch of their products.

This pathway 505(b)(2) provides several benefits. From **reducing development timelines** by several years compared to the 'traditional 505(b)(1) route and **development costs** (notably by avoiding high costs for duplicative clinical trials), to **obtaining market exclusivity** (from 3 to 7 years according to the product submitted), to **enabling flexibility in the dossier** (tailored data packages, fewer required studies, and targeted clinical programs), this option is a real platform for value driven innovation and act as a ***"scientific bridge"*** between existing treatments and new ones.

This proportionate, dedicated pathway enables US payers to accurately assess Value Added Medicines' value while giving prescribers access to a broader range of solutions for American patients. With an estimation of about 62% of the global Value Added Medicines market concentrated in the US[11], and with 47%[12] of largest revenue share in 2024 in the drug repurposing market, North America dominates this segment. The US drug repurposing market size is calculated at USD 13.17 billion in 2025 and is expected to reach USD 21.55 billion by 2034[13].

By **de-risking development**, actively supporting **multi-stakeholder collaborations**, and **creations of favorable ecosystems**, the established framework encourages companies to invest in this route, ensuring products reach patients more reliably.

ASIAN AND MIDDLE EASTERN COUNTRIES ACTIVELY DEVELOPING TAILOR-MADE GUIDANCES FOR VALUE ADDED MEDICINES



As **China** is the second biggest pharmaceutical market globally[14], it is a dynamic player for the off-patent sector. As the population ages, chronic diseases grow, and healthcare challenges evolve rapidly, authorities have to adapt their policies to attract innovation and stimulate patient access. The Chinese National Medical Products Administration (NMPA) has recently published a policy interpretation about its clinical trial data protection system [15]. It includes f**our-year data protection for 'improved new drugs'** previously marketed overseas—or not—seeking approval in China. The spirit of this new protection is to prevent "free riding" applications, **encourage market access of new indications**, and **reward all types of innovation** by companies through earned returns on investment. This complementary protection aims at **strengthening the virtuous cycle in the country's healthcare ecosystem** and bringing patients different therapies.

Similar dynamics are emerging in other regions as authorities seek to balance innovation incentives with patient access.

[11] IQVIA "Value Added Medicines: European Overview", Aurelio Arias (Dec. 2025)
[12] Drug Repurposing Market Size, Share and Trends 2025 to 2034, Precedence research, Deepa Pandey, Aditi Shivarkar
[13] Drug Repurposing Market Size, Share and Trends 2025 to 2034, Precedence research, Deepa Pandey, Aditi Shivarkar
[14] China – A critical yet complex market for access: key considerations for national and subnational success, IQVIA Dec. 2025
[15] 国家药监局关于发布药品试验数据保护实施办法的公告（2026 年第 47 号）(translation: Announcement No. 47 of 2026 issued by the National Medical Products Administration regarding the implementation measures for the protection of drug trial data)

In the Middle East, emerging markets see their use of pharmaceutical products growing, with the market being mainly driven by the dispensation of generic medicines. **Authorities work on developing better and faster access to medicines for their patients.** Broader regulatory modernization efforts are underway across the wider Gulf Cooperation Council, with Saudi Arabia and the UAE emerging as the primary drivers due to their economic size and strategic priorities.



Saudi Arabia's regulatory changes carry significant weight across the Gulf region. The Saudi Food and Drug Authority (SFDA) has recently published its *Guidance for Combination Products Classification and Registration 2.0*[16], **providing marketing authorization holders definitions and clear criteria for classification, outlining the regulatory framework for submission and review of combination products.** In addition, the *Economic Evaluation Studies Guidelines*[17] gives marketing authorization holders **instructions on the types of economic studies** to proceed with and submit according to the type of medicines. Finally, the **pricing rules for pharmaceutical products give companies a clear vision of expected rules for combination medicines and new dosage forms**[18].



As a dynamic country in the region, the **United Arab Emirates**, released a decree-law[19] through its Federal Government in 2024, notably on the governance for pharmaceutical products. Marketing authorization holders can submit a request for *"any minor changes in the composition of the Medical Product or in the event of new uses for the Medical Product, whether as new indications for use or suitability for a new category of patients* [20] *"*. This article **facilitates the introduction of repurposed medicines for companies** by giving them **clear instructions** on the pathway to be used for the submission of the dossier. Regarding other value-added medicines (reformulation for dosage adaptation, route of administration, etc.), marketing authorization holders shall r**eapply for a new Marketing Approval** or conditional Marketing Approval for the same Medical Product[21]. With its strategic location as a regional distribution hub, the UAE's guidelines influence neighbouring markets' approval strategies.

This emphasis on drug repurposing reflects a broader global trend—China's clinical trial expansion mirrors the UAE's streamlined pathways for new indications, suggesting regulators worldwide recognize repurposing as a cost-effective strategy for addressing chronic disease burdens.

Predictability is key for companies to penetrate markets—and as demonstrated by China's data protection tiers, Saudi Arabia's multi-layered guidance, and UAE's clear reapplication pathways—regulators are increasingly **aligning transparency with commercial incentive structures.**

[16] Guidance for Combination Products Classification and Registration 2.0, Saudi Food and Drug Authority (SFDA), Feb. 2026
[17] Economic Evaluation Studies Guidelines
[18] Article 8, Pricing Rules for Pharmaceutical Products, Saudi Food and Drug Authority
[19] Federal Decree-Law No. (38) of 2024 Governing Medical Products, Pharmacists and Pharmaceutical Establishments
[20] Article 16 Approval of Minor Changes to the Medical Product, Federal Decree-Law No. (38) of 2024 Governing Medical Products, Pharmacists and Pharmaceutical Establishments
[21] Article 15 Resubmission of Marketing Approval and Conditional Marketing Approval, Federal Decree-Law No. (38) of 2024 Governing Medical Products, Pharmacists and Pharmaceutical Establishments

PROGRESS MADE BY THE EUROPEAN UNION, BUT PATIENT ACCESS STILL TRAILS BEHIND



The European Union has recently embarked on major reforms to strengthen and revitalize its healthcare systems, aiming to better serve and protect its citizens. Through a suite of interconnected initiatives, the European Commission seeks to accelerate access to innovation, enhance equity, and stimulate competitiveness via targeted incentives.

The reform of European pharmaceutical legislation—one of the most significant sector-wide changes in over two decades—has created **substantial new opportunities for repurposed medicines**, specifically through two articles. By introducing **four years of data protection** for data generated for new indications, and by **enabling not-for-profit entities to submit substantive non-clinical or clinical evidence** for a new therapeutic indication expected to fulfil an unmet medical need to the European Medicines Agency or national agencies, the reform provides new incentives for repurposing.

Multiple European Commission-funded initiatives, such as the REMEDi4ALL and REPO4EU consortia, are actively working to **create a conducive environment for repurposing**. Furthermore, many policymakers at national level are beginning to recognize the value of Value Added Medicines and are introducing various provisions within their national systems. It is evident that without **better tailored market adaptations**, this category risks following the same path as the Pediatric-Use Marketing Authorization (PUMA), resulting in **extremely sparse utilization**.

Unfortunately, other categories of Value Added Medicines (specifically reformulations and combinations) have not benefited from improved recognition through this reform.

Patient access to Value Added Medicines in Europe remains challenging. A fragmented landscape—spanning regulatory submission, market access, and uptake within healthcare systems—creates a complex environment for developers, hindering their ability to access European markets. In worst cases, this fragmentation can even lead to market withdrawals of medicines that are life changing for patients.

This unpredictability creates significant risks for developers who need to decide to make a significant investment, without having clarity on the data needed for development, a consistent path to market, or ensured financial returns. Shorter timeframe, lower costs and higher success rates associated with Value Added Medicines help to create a more competitive business model and are more likely to attract pharmaceutical companies.

Without timely access to Value Added Medicines, **patients lose therapeutic options**—notably for rare diseases or pediatric populations—and **face delays in high-quality care**. Healthcare professionals, already facing workforce shortages, **miss innovations** that could reduce costs, save time and patients' lives. Additionally, healthcare systems do not benefit from more sustainable and affordable medicines for their citizens.

Regulatory Approval Disparity Between US and EU: Colchicine Cardiovascular Indication

Colchicine is a well-established anti-inflammatory medication traditionally used for the prevention and treatment of gout flares. Following extensive investigation and clinical studies, Colchicine has been successfully repurposed for secondary prevention of cardiovascular events. Clinical evidence demonstrated that low-dose colchicine reduces cardiovascular risk in patients with stable coronary artery disease.

The United States Food and Drug Administration (FDA) approved this new cardiovascular indication in June 2023[22]. In contrast, within the European Union, regulatory approval for this indication has only been granted in the Netherlands as of December 2025[23]. Although the European Medicines Agency (EMA) recently issued a positive opinion regarding the marketing authorization for the cardiovascular indication [24], patients across most EU member states continue to await full regulatory approval and reimbursement coverage.

Yet **Value Added Medicines have the potential to address all these issues**, delivering better health outcomes for patients, more efficient care for and by professionals, and more sustainable solutions for healthcare systems. To facilitate market access to this category of medicines, the European Union needs a systematic approach on the topic.

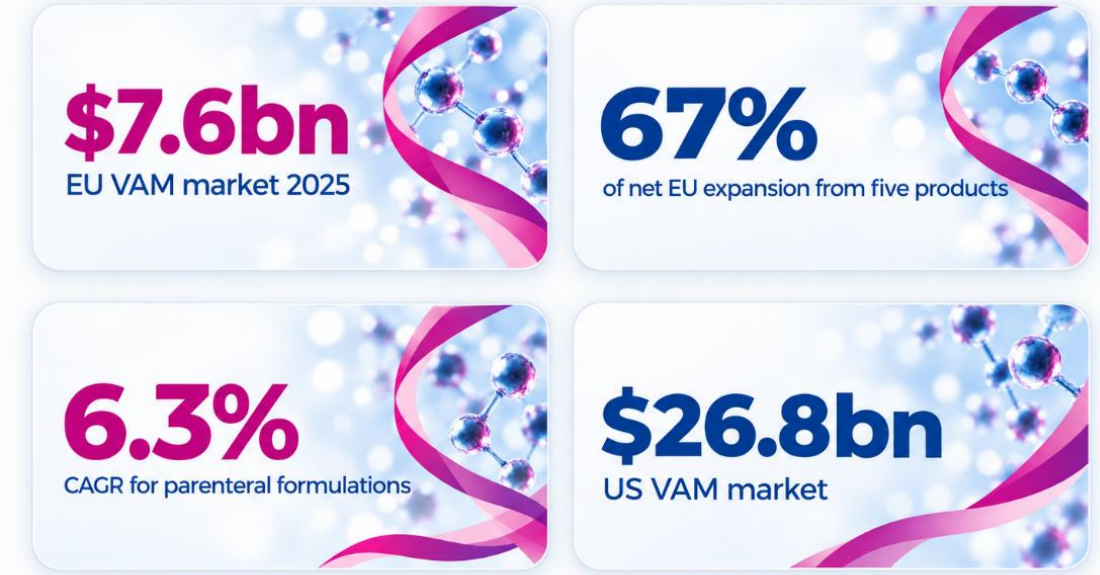
But while formal EU-level Value Added Medicines recognition is still maturing, the convergence of regulatory pilots, national initiatives, and stakeholder advocacy signals a clear trajectory toward the urgent need of comprehensive Value Added Medicines integration in the coming years.

[22] https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/215727s000lbl.pdf
[23] https://www.geneesmiddeleninformatiebank.nl/smpc/h132800_smpc.pdf
[24] https://www.ema.europa.eu/en/documents/smop-initial/chmp-summary-positive-opinion-colchicine-agepha-pharma_en.pdf

VALUE ADDED MEDICINES AND EUROPEAN PUBLIC HEALTH: DECADES OF STRATEGIC OPPORTUNITY

The current European VAM market provides a foundation upon which to build, though significantly untapped potential remains.

In 2025, the EU VAM market reached approximately $7.6 billion (excluding repurposed medicines), up from $6.8 billion in 2020. Growth has been steady but highly concentrated, with five products accounting for approximately 67 percent of net European VAM expansion during this period. The Central Nervous System therapy area represents the largest segment at $829 million, followed by the Respiratory ($619 million) and Antihypertensives ($611 million). Parenteral formulations have emerged as the fastest-growing route of administration, expanding at a compound annual growth rate of 6.3 percent and surpassing $1.1 billion in 2025[25].



These figures, while substantial, underscore a structural opportunity rather than a ceiling. The U.S. VAM market stands at approximately $26.8 billion[26], roughly 3.5 times the size of the European market. **Closing this gap over the coming decade requires deliberate policy action that transforms Europe** from a fragmented landscape of national approaches into a coherent, unified strategy.

As the European Union confronts escalating public health imperatives over the coming decades—from antimicrobial resistance and aging populations to climate-related health risks and women's health gaps—**Value Added Medicines offer targeted therapeutic solutions aligned with many challenges.** To fully unlock this potential and provide greater access to medicines for European patients, European institutions are **uniquely positioned to shape Europe's healthcare future by cultivating an enabling ecosystem that attracts and accelerates market access for Value Added Medicines.**

[25] IQVIA data for Medicines for Europe
[26] IQVIA data for Medicines for Europe

EMPOWERING EUROPE TO LEAD THE FUTURE OF VALUE ADDED MEDICINES

Europe is refining its ecosystem to maintain its leadership in patient access. By establishing and supporting key initiatives, significant improvements can rapidly benefit European patients. A committed stance in supporting Member States will foster fruitful and seamless collaboration.

KEY MESSAGES:

Value Added Medicines are already being developed and have proven beneficial in other countries, such as US, China or the Middle East yet have not been able to reach European patients. To deliver sustainable products and reach European patients in a timely manner, we recommend that **the Value Added Medicines sector benefit from better-tailored access and valorisation** through the following pillars:

- **Streamlining regulatory requirements for value added medicines**
- **Proportionate value recognition through better tailored national market access policies**
- **National implementation and supportive policy to promote better access**

1. STREAMLINING REGULATORY REQUIREMENTS FOR VALUE ADDED MEDICINES

Pharmaceutical companies developing products usually consult regulatory authorities to better understand and design their drug development programs, through scientific advice addressed to the Europe Medicines Agency (EMA) or National Competent Authorities (NCA). The current regulatory structure and pathways are not well-suited for Value Added Medicines products. Because the process for a Scientific Advice lacks sufficient agility for small or less staffed entity, the type and volume of data requested are not appropriately adapted for Value Added Medicines products. Also, the collection and use of real-world data, and conversion into real-world evidence for Value Added Medicines need clear guidance. Consequently, companies lack reassurance in using this service for product development, hence they will not receive the massive investment required as no development can be assured.

Furthermore, with the removal of one of the key legal bases—particularly Article 10(b) of Directive 2001/83/EC, which was notably used for fixed-dose combination dossiers—the industry now has less guidance for filing regulatory submissions. As Value Added Medicines still lack a dedicated regulatory pathway, companies face considerable financial and strategic challenges in determining the most suitable approach for their products. Regulatory requirements that are too rigid and not adapted to the type of products or the entity's capacity can directly discourage them from entering EU markets and focus only on the US. Without appropriate incentives, investment may be redirected away from the EU, ultimately limiting access for European patients.

For companies investing in or wishing to develop Value Added Medicines products, **clarity on scientific advice and data requirements is needed**. As budgets, timelines, and human resources are

often more limited in Value Added Medicines companies (or business units), **a more fit-for-purpose scientific advice process** would help companies navigate the requirements expected by the EMA in a more agile way. A better-coordinated pathway to directly encourage the development of Value Added Medicines products would attract companies to serve European patients.

The generation of data requested by different bodies (e.g. Health Technology Assessment (HTA) bodies, payers) can rapidly become burdensome and expensive for Value Added Medicines companies. To **make data generation more efficient**, less costly, and better tailored to incentivize Value Added Medicines companies to market their products in the EU, **all relevant stakeholders should be involved in the scientific advice process**. Also, the **cost of evidence generation would need to be proportionate** to the claimed benefit and the price premium in play[27]. For instance, to secure more development in repurposing, it is crucial that national authorities commit to exploring ways to **prioritize the use of such approved medicines over off-label use of unapproved products**.

Establishing clear, predictable, and proportionate regulatory tools is essential to de-risk the sector, support investment, and ultimately facilitate patient access.



2. PROPORTIONATE VALUE RECOGNITION THROUGH BETTER TAILORED NATIONAL MARKET ACCESS POLICIES

While there is no harmonized EU framework for Value Added Medicines, growing awareness of their benefits brought to healthcare systems and patients has led several Member States to act at the national level. Despite varying value assessment processes across the EU—and Value Added Medicines often being categorized as generics (due to innovation occurring primarily on off-patent molecules)—some markets are addressing this gap independently.

Multiple European countries have established dedicated or more adapted market access pathways for Value Added Medicines to facilitate market access.

Belgium was among the first to implement a formal classification system with Class 3C, which includes a specific subclass for *'generics with added value'* and *'biosimilars with added value*'. Portugal has created separate regulatory pathways distinguishing between *'generic'* and *'not generic'* categories. France introduced a *'hybrid medicines'* pathway to accommodate reference specialty that does not meet the definition of a generic specialty. Italy has developed mechanisms allowing medicines to demonstrate added value through specific assessment processes.

More recently, Spain incorporated a new Value Added Medicines pathway directly into its national legislation, while Ireland is establishing a dedicated pilot project scheduled to run from 2028 to 2029.

As Member States establish their respective pathways, **coordinated knowledge sharing with European institutions, especially the European Commission on repurposing,** could accelerate harmonized requirement development and improve market access across Europe.

[27] Zsuzsanna Ida Petykó, András Inotai, Anke-Peggy Holtorf, Diana Brixner & Zoltán Kaló (2020) Barriers and facilitators of exploiting the potential of value-added medicines, Expert Review of Pharmacoeconomics & Outcomes Research, 20:3, 229-236, DOI: 10.1080/14737167.2020.1758558.



By **establishing national recognition of Value Added Medicines**, Member States are creating their own **mechanisms to reward this kind of innovation**, address unmet medical needs, and promote more equitable, affordable patient access.

In most EU healthcare systems, **pricing and reimbursement mechanisms formally recognize the value of the product, the R&D investments and commercial efforts**. But as Value Added Medicines bring a wide range of benefits and value (therapeutic benefits, quality of life, financially more affordable etc.), it is essential to categorize them as a separate class—from innovators, generics, and biosimilars- to better assess and recognize all the innovation and their impact and value they bring to society. Current pathways for generics (e.g. internal price referencing, mandatory discounts) or innovative medicines (e.g. clinical benefit assessments) are unsuitable for Value Added Medicines.

Pricing and reimbursement rules must be tailored to assess the importance and quality of continuous innovation and reflect Value Added Medicines' specific characteristics. For instance, premium pricing could make it economically viable to develop tailored, high-value formulations for small pediatric populations in niche indications. This approach would have a limited impact on overall healthcare budgets while improving the availability of age-appropriate treatments and reducing the risks associated with unsuitable formulations.

Furthermore, better-adapted regulatory and assessment models would enable **faster and more efficient market access for Value Added Medicines**, such as fixed-dose combinations (FDCs). HTA bodies and healthcare payers typically require evidence from randomized clinical trials (RCTs) demonstrating the health gains associated with a product prior to pricing and reimbursement decisions. For FDCs, however, demonstrating improved medication adherence—and its downstream effects on hard clinical endpoints—may necessitate reliance on generalized evidence rather than trial-level data alone. Observational studies could be employed to assess potential reductions in mortality and major adverse cardiac events attributable to FDCs. A **more suitable approach for FDCs** would instead prioritize facilitated ex post evidence generation using real-world data, such as coverage-with-evidence-development schemes implemented and reassessed following pricing and reimbursement decisions[28].

[28] Inotai A, Kaló Z, Petykó Z, Gyöngyösi K, O'Keeffe DT, Czech M, Ágh T. Facilitators and Barriers of Incremental Innovation by Fixed Dose Combinations in Cardiovascular Diseases. J Cardiovasc Dev Dis. 2024 Jun 21;11(7):186. doi: 10.3390/jcdd11070186. PMID: 39057609; PMCID: PMC11277553.

Healthcare payers should recognize and incentivize the added value of VAMs through **innovative payment models**—moving beyond conventional, risk-averse pricing structures—to mechanisms that **support equitable premium pricing commensurate with incremental health gains**.

Without attractive and adapted pricing and reimbursement schemes, a dedicated pathway alone will not sufficiently help de-risk the sector.

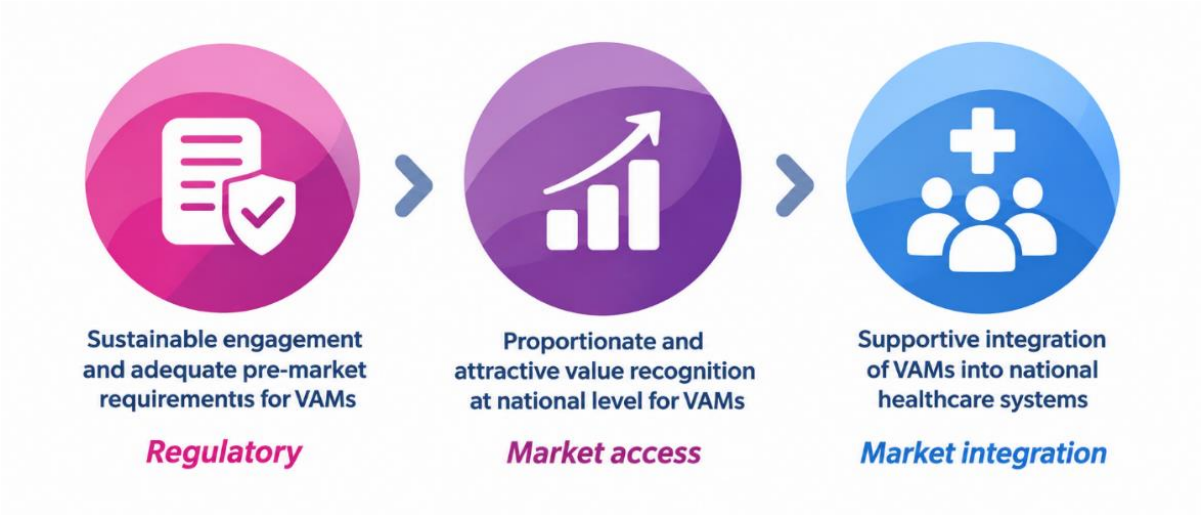
With no European guidance currently available, countries developing such frameworks need support to create viable opportunities for both companies and patients.

3. NATIONAL IMPLEMENTATION AND SUPPORTIVE POLICY TO PROMOTE BETTER ACCESS

Value Added Medicines have the potential to address many conditions and particularly target unmet medical needs. From reaching pediatric populations through reformulation, to supporting treatment adherence with fixed-dose combinations, to preventing disease through repurposed medicines, their benefits are substantial. In this sense, they are a **key element in addressing current health challenges in Europe**. To tackle the growing number of health-related issues in Europe—e.g. the rise of antimicrobial resistance, the needs of an ageing population, or medicine shortages—Value Added Medicines can address a range of medicines-related healthcare inefficiencies, including irrational medicine use, lack of appropriate treatment options, shortages of established products, and geographic inequities in access to medicines.

Value Added Medicines can form part of the **response to emerging health threats and emergency preparedness needs**. Ready-to-use antibiotics, products with improved storage conditions and heat-stable formulations may support rapid deployment in civil protection, defense and other emergency settings. However, their development **requires strong cooperation, sustainable financing and credible routes to market.**

But creating a framework for Value-Added Medicines, accompanied by sound pricing and reimbursement mechanisms, is not sufficient to ensure effective market penetration and patient reach. **Recognition of their value** must also be **expressed through various complementary mechanisms**: a **robust procurement system** where criteria extend beyond price alone, clear, and precise **prescribing guidelines**, and **awareness-raising** across the care ecosystem (patients, healthcare professionals, caregivers, etc.) to actively support the adoption of such products. All these measures combined would **enable better management of Value-Added Medicines market entry** and counteract all remaining barriers, ensuring patient access.



Medicines for Europe's **Value Added Medicines members** are actively **committed to raising awareness** about the benefits of VAMs and **stand ready to collaboratively tackle the remaining barriers and challenges** that lie ahead.

By fostering dialogue and expert cooperation across stakeholders, the group seeks to **accelerate market access across Europe** and **unlock the full potential of these innovations for patients**. Members are already pioneering such technologies, delivering increasingly tailored solutions that meet the specific needs of both patients and healthcare systems.

Achieving broader, sustainable access to Value Added Medicines would bring to market **solutions that address pressing public health challenges and unmet medical needs**, **optimize care** within financial constraints, and **reinforce Europe's competitiveness and resilience** in the global landscape. Together, members believe these efforts can pave the way for **a stronger, more patient-centered future for European healthcare.**

value added medicines

a medicines for europe sector group

Medicines for Europe
Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11 - F: +32 (0)2 736 74 38
info@medicinesforeurope.com
www.medicinesforeurope.com
@medicinesforEU