

COMMUNICATIONS TOOLKIT

Value Added Medicines Group

November 2016

Contents

1. About us	3
2. Our Vision & Mission	3
3. What is a Value Added Medicine?.....	4
Example of Therapeutic Areas: Respiratory Diseases	4
4. Medicines for Europe 5 pillars: Patients, Quality, Value, Sustainability & Partnership - How Value Added Medicines deliver	5
Patients	5
Quality	5
Value	6
Sustainability	6
Partnership	7
5. Contact Us	8
ANNEX	8
Factsheet: The Value Added Medicines Group	9
Factsheet: On Value Added Medicines	12
Infographic: Rethink, reinvent & optimise medicines, improving patient health & access.....	14

1. About us

The **Value Added Medicines Group** is a sector group of *Medicines for Europe*, which provides high-quality cost-competitive medicines to millions of patients in Europe and around the world. The vision of *Medicines for Europe* is to provide sustainable access to high quality medicines for all patients, based on 5 important pillars: patients, quality, value, sustainability and partnership.

The **Value Added Medicines Group** aims to optimise, rethink and reinvent medicines based on known molecules and by bringing untapped innovation to improve care delivery. The Value Added Medicines Group adopts a complementary perspective compared to the other *Medicines for Europe* sector groups by tackling the targeted portion of patient needs that remain unmet to this day, delivering additional improvement to the healthcare community as a whole.

2. Our Vision & Mission

VISION: By optimising, rethinking and reinventing existing medicines, we aim to provide European patient access to value added medicines, delivering considerable outcomes for patients, payers and/or healthcare professionals over existing alternatives.

MISSION: Establish, in collaboration with patients, payers and healthcare professionals, a sustainable market model that incentivises R&D and access to value added medicines in Europe.

3. What is a Value Added Medicine?

Value added medicines are based on known molecules that address unmet healthcare needs and/or deliver relevant additional improvement for patients, healthcare professionals and/or payers. The added value may be achieved through drug repositioning, drug reformulation, drug combination or new added service.

Relevant benefits include improved efficacy, safety and tolerability profile, better adherence, better quality of life, better convenience of use and/or patient preference.

These benefits are expected to impact healthcare systems through the reduction of healthcare use, budget impact, preventing therapeutic escalation, rational use of medicines and improving equity, ultimately contributing to efficiencies in the healthcare system.

Many stakeholders believe innovation only leads to generating new molecules, while innovation can come from other areas as well. There is significant untapped potential in Europe to optimise existing therapies to best meet the needs of patients and healthcare professionals and address current inefficiencies. Enhanced customisation of existing therapies to address unmet patient or healthcare needs can lead to better outcomes for the entire healthcare community.

Example of Therapeutic Areas: Respiratory Diseases

68 million people in the EU suffer from common respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD)¹. Due to known risks, the management of asthma and COPD is associated with high healthcare and societal costs². Asthma and COPD are respectively responsible for 250,000 and 1.1 million annual hospital admissions³ and their estimated annual economic burden in terms of direct (healthcare) and indirect (lost production) costs amounts €82 billion in total⁴.

Despite the availability of efficacious molecules to treat asthma and COPD, evidence shows that low adherence to treatments contributes to poor patient outcomes⁵ associated with an increased risk of hospitalisation, medical visits, and administration of antimicrobials or oral corticosteroids⁶.

There are convincing health benefits in investing more time and resources to understand and address these risks. Value added medicines can enable known and efficacious active substances to deliver on their promises to patients, averting or reducing complications and exacerbations and associated costs.

¹ European Respiratory Society. European lung white book 2013. Available from <http://www.erswhitebook.org>

² European Respiratory Society. European lung white book 2013. Available from <http://www.erswhitebook.org>

³ European Respiratory Society. European lung white book 2013. Available from <http://www.erswhitebook.org>

⁴ European Respiratory Society. European lung white book 2013. Available from <http://www.erswhitebook.org>

⁵ National Institute for Health & Care Excellence. Medicines Adherence. Nice Clinical guideline 2009. Available from: <http://publications.nice.org.uk/medicinesadherence-> cg76 accessed: Nov 2013.

⁶ Melani, AS, et al. Respir Med. 2011;105(6):930-8

4. Medicines for Europe 5 pillars: Patients, Quality, Value, Sustainability & Partnership - How Value Added Medicines deliver

Patients

Value added medicines contribute to addressing unmet patient needs. Moving from a one-size-fits-all to a much more tailored and patient specific approach, value added medicines are one of the key components of the customisation of healthcare. By answering patients' unmet needs, they represent a new horizon for those who are currently looking forward to a better quality of life with their treatment.

All patients differ and what works for one may not work as well for another. In a society where patients want to take ownership over their own health, value added medicines can help empower patients to feel better with their treatment.

While the majority of existing treatments deliver on their promises to a large number of patients, some may need to be adapted to match specific patients' needs. Value added medicines aim to offer patients a more tailored experience so they will feel more comfortable and satisfied with their treatment. For example, value added medicines can enhance a patient's quality of life and ultimately ensure better adherence and compliance by reducing side effects or by offering a better mode of administration more adapted to their lifestyle.

We see value added medicines as an opportunity to understand and support patients' unmet needs. The improvement of treatments containing known molecules should ultimately deliver additional health benefits and help patients to better manage their health condition. Attentive to patients' healthcare journey insights, the Value Added Medicines Group is developing a framework to unlock new opportunities to help patients in their healing process, offering more adapted medicines to those who need it.

Quality

Value added medicines greatly contribute to improving access to high quality care. They provide healthcare professionals and patients with unprecedented flexibility in terms of therapy choices. Value added medicines offer a wider range of treatment options, using well known molecules but allowing for a much more tailor-made approach, increasing patient, as well as healthcare professional, and satisfaction. Value added medicines offer a well-known safety profile, creating confidence in using alternatives that are more adapted to some patients' lives than existing treatment options.

Value added medicines contribute to the balance between accessing innovation and a high quality healthcare system. Using the right treatment for the right patient will help capture some inefficiencies that are impacting access to, and sustainability of, high quality healthcare systems. This valuable gain can then be re-allocated for efficient use of healthcare resources, responding to the growing concerns of equitable access to high quality patient care.

The Value added Medicines Group is dedicated to providing better access to high quality care. At a time where the concept of universal access to quality care and innovation is under pressure, value added medicines enable the healthcare system to reap the benefits of innovation without compromising equitable access to tailored treatment.

Value

Value added medicines represent new untapped research potential for the healthcare community. Tailored medicines are not a futuristic utopian dream. The move towards a more patient centric approach, identifying what works best for some patients rather than others, is real and represents a radical change for our industry.

Research and development of value added medicines requires taking science into account, but also integrates patient and physician needs early in the development process. It requires a full understanding of the patient's journey in order to identify, integrate and deliver adapted medicines using new technologies that will enhance the patient and healthcare professional experience.

Value added medicines represent a new form of R&D merging a pharmacological approach of well-known active substances with more patients and/or healthcare professional insights, leveraging new technologies to transform existing molecules to address specific needs that could not be tackled 20 years ago.

Value added medicines aim to bring innovation continuously through the entirety of a molecule's lifecycle, particularly those molecules no longer protected by patent. Working with proven compounds whose toxicity and other effects have been studied, can reduce development times, but to combine new technologies with known molecules requires considerable R&D investment and effort. Our ambition is to play a leading role in unlocking this new and untapped research potential, focusing on existing molecules.

Sustainability

The healthcare community, including patients, faces challenging times with the sustainability of our healthcare systems. The total number of people aged above 65 is forecasted to grow by more than 50 million by 2050⁷, creating new needs and challenges in addressing the healthy and active ageing process. In parallel, the number of people affected by chronic diseases across all age groups is steadily increasing⁸ and despite the recent slowdown in pharmaceutical spending growth, the high cost of new specialty medicines for diseases like cancer and hepatitis will likely cause spending to rise again, says the OECD⁹.

New innovative treatments are reaching the healthcare community, offering new hope to patients. However their financing represents a real challenge in terms of equitable access in a context where healthcare budgets

⁷ IMS Institute report: Bringing Healthy Living to Ageing Citizens: The Role of Technology, June 2014

⁸ http://www.who.int/chp/chronic_disease_report/full_report.pdf

⁹ OECD - Health at a Glance, 2015

are barely succeeding in the face of current needs of patients. OECD data shows that new specialty medicines are expected to account for 50% or more of pharmaceutical spending growth within the next five years¹⁰.

If one aims at ensuring universal access to healthcare by addressing the sustainability challenge of need outpacing budget growth, changes are needed and, as main healthcare partners, it is our responsibility to react today. The healthcare system must adapt its mechanisms and research focus to respond to these sustainability and access challenges. There are opportunities to address this situation which should be explored. Sustainability can be achieved in different ways, including through more efficient use of healthcare resources.

The WHO estimates that between 20 to 40 percent of healthcare spending is inefficiently allocated, either through unnecessary or non-cost effective services. For example, it is estimated that lack of adherence costs the European system around 125b euros a year. Addressing the adherence challenge could be a significant step to ensure better outcomes to patients and the healthcare communities, supporting system sustainability.

Healthcare inefficiencies represent opportunities to rethink and optimise current health delivery systems as well as reinvent current therapies in a context where patients are more empowered on all aspects of their health and related well-being. In this frame, the Value Added Medicines Group comes forward with an answer to bring innovative healthcare while preserving system sustainability.

Partnership

Value added medicines provide an opportunity to inject more competition and innovation into the pharmaceutical sector. However, the current pharmaceutical market framework does not encourage innovation after the end of the patent term.

Value added medicines offer a credible, real time opportunity to deliver innovative treatments for patients at a fair price for healthcare systems while recognising R&D investments by the industry. In addition to the competition they bring, value added medicines will also improve the cost effectiveness and efficiency of the healthcare system, either in terms of improved outcomes, reduced medication errors or improved patient adherence.

The Value Added Medicines Group engages with the healthcare community and policy makers to support greater access to medicines and to medicines innovation for all European patients. Recognising that healthcare systems are under considerable financial strain, we encourage greater collaboration between stakeholders. We recognise that patients, HCPs and payers have unmet needs and expect genuine value added improvement, more innovation and sustainable access models in the future.

¹⁰ OECD - Health at a Glance, 2015

5. Contact Us

If you want to learn more about value added medicines, you can find us at www.medicinesforeurope.com and on Twitter [@medicinesforEU](https://twitter.com/medicinesforEU).

ANNEX

FACTSHEETS

factsheet | About Medicines for Europe



About Medicines for Europe

Medicines for Europe (formerly EGA) represents the generic, biosimilar and value added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines for Europe, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members employ 190,000 direct employees at over 400 manufacturing and R&D sites in Europe, and invest up to 17% of turnover invested in R&D.



Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients.

For more information please follow us at www.medicinesforeurope.com and on Twitter [@medicinesforEU](https://twitter.com/medicinesforEU).



The Generic Medicines Group

The Generic Medicines Group is a sector group of **Medicines for Europe**, representing the generic medicines developers and manufacturers, which provide high-quality cost-competitive medicines to millions of patients in Europe and around the world. Generic medicines account today for 67% of all prescribed medicines but for only 29% of the pharmaceutical expenditure, or 2-4% of total healthcare costs, in Europe. The generic medicines industry has increased access to medicines by over 100% in 7 key therapeutic areas without increasing the overall treatment cost across Europe.



The Biosimilar Medicines Group

The Biosimilar Medicines Group is a sector group of **Medicines for Europe** representing the leading companies developing, manufacturing and/or marketing biosimilar medicines across Europe. With more than 10 years of positive patient treatment experience and 20 products successfully launched, biosimilar medicines provide today a huge opportunity to deliver significantly improved access to modern therapies for millions of European patients in both chronic and acute care. Our members bring competition to the biological medicines market, thereby increasing access to highly innovative treatments to patients, in Europe and around the world, and supporting the sustainability of the European healthcare systems.



The Value Added Medicines Group

The Value Added Medicines Group, a sector group of **Medicines for Europe** aims to rethink, reinvent and optimise medicines based on known molecules by bringing untapped innovation to improve care delivery. The Value Added Medicines Group adopts a complementary perspective compared to the other **Medicines for Europe** sector groups by tackling the targeted portion of patient needs that remain unmet to this day, delivering additional improvements to the healthcare community as a whole. Medicines for Europe Membership

MEMBER COMPANIES

3M
 Accord Healthcare
 Alfred E. Tiefenbacher
 Alkaloid
 Apobiologix
 Camargo
 Cinfia Biotech
 CinnaGen
 Cinfia Biotech
 Consilient Health
 DSM
 Egis Pharmaceuticals

Farmoz
 Formycon
 Fresenius Kabi
 Gedeon Richter
 Glenmark
 INFARCO
 Insud Pharma
 JGL
 KRKA
 Lupin
 Medichem
 Medochemie

Mylan
 OJER Pharma
 Oncomed
 Polpharma
 Samsung Bioepis
 Sandoz
 Stada
 Sun Pharma
 Synthon
 Teva
 Theranexus
 ZENTIVA

AFFILIATE MEMBER COMPANIES

Acino Pharma
 Anapharm Europe
 Billev Pharma
 Billev Pharma East

Cipla
 Disphar
 Farmaprojects
 JSC Farmak

Pharma Patent
 PharOS

PARTNER MEMBERS

BioPharma Services Inc
 Extedo

Pharma Medica Research Inc.
 Sanaclis

NATIONAL ASSOCIATIONS FULL MEMBERS

AMMU (Ukraine)
 AESEG (Spain)
 APOGEN (Portugal)
 AssoGenerici (Italy)
 BGMA (United Kingdom)

BOGIN (Netherlands)
 GEMME (France)
 IEIS (Turkey)
 IGL (Denmark)
 Medaxes (BE)

Medicines for Ireland
 Pro Generika (Germany)
 PZPPF (Poland)

NATIONAL ASSOCIATIONS AFFILIATE MEMBERS

APM GR (Romania)
 BGPharma (Bulgaria)
 CAFF (Czech Republic)
 CEA - PIA (HR)

FGA (Finland)
 FGL (Sweden)
 GE (Hungary)
 GENAS (SK)

Intergenerika (Switzerland)
 MAGYOSZ (HU)
 OEGV (Austria)
 VGA (LT)

Factsheet | The Value Added Medicines Group



About the Value Added Medicines Group

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Medicines for Europe represents the European generic, biosimilar and value added medicines industries, which provide high-quality cost-competitive medicines to millions of Europeans. The vision of **Medicines for Europe** is to provide sustainable access to high quality medicines for all European patients, based on 5 important pillars: patients, quality, value, sustainability and partnership.

The **Value Added Medicines Group** is open to pharmaceutical companies interested in developing this industrial sector.

Existing **Medicines for Europe** members benefit from a membership fee reduction.

For more information please follow us at www.medicinesforeurope.com and on Twitter [@medicinesforEU](https://twitter.com/medicinesforEU)

Our Vision & Mission

VISION: By rethinking, reinventing and optimising existing medicines, we aim to provide European patient access to value added medicines, delivering considerable outcomes for patients, healthcare professionals and payers over existing alternatives.

MISSION: Establish, in collaboration with patients, healthcare professionals and payers, a sustainable market model that incentivises R&D and access to value added medicines in Europe.

Value Added Medicines Group Membership

Companies

3M
Accord Healthcare
Alfred E. Tiefenbacher
Camargo
Consilient Health Ltd
DSM

EGIS
Fresenius Kabi
Medichem
Mylan
OJER Pharma
Oncomed
PharOS

Polpharma
Sandoz
Teva
Theranexus
Zentiva

Associations

GEMME (France)
IEIS (Turkey)
GENAS (Slovakia)
MAGYOSZ (HU)
Medaxes (BE)
VGA (LT)

5 pillars

Patients



The **Value Added Medicines Group** sees value added medicines as an opportunity to understand and support patient needs. The improvement of treatments containing known molecules should ultimately deliver additional health benefits and help patients to better manage their health condition. The **Value Added Medicines Group** is developing a framework to unlock new opportunities to help patients in their healing process, offering more adapted medicines to those who need it.

Quality



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Sustainability



Healthcare inefficiencies represent opportunities to optimise and rethink current health delivery systems as well as reinvent current therapies in a context where patients are more empowered on all aspects of their health and related well-being. In this frame, the **Value Added Medicines Group** comes forward with an answer to bring innovative healthcare while preserving system sustainability.

Partnership



The **Value Added Medicines Group** engages with the healthcare community and policy makers to support greater access to medicines and to medicines innovation for all European patients. Recognising that healthcare systems are under considerable financial strain, we encourage greater collaboration between stakeholders. We recognise that patients, healthcare professionals and payers have existing needs and expect genuine improvement, more innovation and sustainable access models in the future.

Factsheet | On Value Added Medicines



What is a Value Added Medicine

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5 pillars

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Value



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Sustainability



New innovative treatments are reaching the healthcare community, offering new hope to patients. However their financing represents a real challenge in terms of equitable access in a context where healthcare budgets are barely succeeding in the face of current needs of patients.

Partnership



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Example of therapeutic areas: respiratory diseases

68 million people in the EU suffer from common respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD)¹. Due to known risks, the management of asthma and COPD is associated with high healthcare and societal costs². Asthma and COPD are respectively responsible for 250,000 and 1.1 million annual hospital admissions³ and their estimated annual economic burden in terms of direct (healthcare) and indirect (lost production) costs amounts €82 billion in total⁴.

Despite the availability of efficacious molecules to treat asthma and COPD, evidence shows that low adherence to treatments contributes to poor patient outcomes⁵ associated with an increased risk of hospitalisation, medical visits, and administration of antimicrobials or oral corticosteroids⁶.

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About the Value Added Medicines Group

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Medicines for Europe represent the European generic, biosimilar and value added medicines industries, which provide access to high-quality cost-competitive medicines to millions of patients in Europe and worldwide. Medicines in Europe's vision is to provide sustainable access to high quality medicines for all patients, based on 5 important pillars: patients, quality, value, sustainability and partnership.

¹ European Respiratory Society. European lung white book 2013. Available from <http://www.erswhitebook.org>

² European Respiratory Society. European lung white book 2013. Available from <http://www.erswhitebook.org>

³ European Respiratory Society. European lung white book 2013. Available from <http://www.erswhitebook.org>

⁴ European Respiratory Society. European lung white book 2013. Available from <http://www.erswhitebook.org>

⁵ National Institute for Health & Care Excellence. Medicines Adherence. Nice Clinical guideline 2009. Available from: <http://publications.nice.org.uk/medicinesadherence-cg76> accessed: Nov 2013

⁶ Melani, AS, et al. *Respir Med*. 2011;105(6):930-8

INFOGRAPHIC

RETHINK, REINVENT & OPTIMISE MEDICINES, IMPROVING PATIENT HEALTH & ACCESS

SUBOPTIMAL USE OF DRUGS REPRESENTS OPPORTUNITIES TO RETHINK AND OPTIMISE CURRENT HEALTH DELIVERY SYSTEMS AS WELL AS REINVENT CURRENT THERAPIES

HEALTHCARE INEFFICIENCIES

20-40% of healthcare spending allocated to unnecessary or non cost-effective services



FACE CHALLENGES WITH MEDICATION ADHERENCE

IMPACT OF NON-ADHERENCE



EXTRA COSTS
PER YEAR

DISEASE
WORSENING

THERAPEUTIC
ESCALATION

BETTER
ADHERENCE AND
QUALITY OF LIFE

PATIENTS



IMPROVED SAFETY
AND EFFICIENCY

HEALTHCARE PROFESSIONALS



INCREASED
TREATMENT
OPTIONS

PAYERS



IMPROVED
BUDGET
EFFICIENCY

RESEARCHERS



INNOVATION THROUGHOUT
A MOLECULE'S LIFECYCLE

VALUE ADDED MEDICINES

Medicines based on known molecules that address healthcare needs and deliver relevant improvements for patients, healthcare professionals and/or payers

IMPROVEMENTS



HOW



DRUG REPOSITIONING
Finding new indications



DRUG REFORMULATION
New delivery system



COMPLEX COMBINATION
New regimens
or adding technology

WHAT'S IN IT FOR...