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VALUE ADDED MEDICINES TOOLKIT

May 2016

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Contents

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1. About us

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 represents the European generic, biosimilar and value added medicines industries, which provide 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.

2. 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/or 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.

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3. What is a Value Added Medicine?

Value added medicines are medicines based on known molecules that address healthcare needs and deliver relevant improvement for patients, healthcare professionals and/or payers.

Relevant improvements include:

- A better efficacy, safety and/or tolerability profile;
- A better way of administration and/or ease of use;
- New therapeutic uses (indication/population);

These improvements contribute to:

- Better adherence, health outcomes or quality of life;
- Improved safety and efficiency of healthcare professional resources;
- Increased treatment options & preventing therapeutic escalation;
- Improved cost-effectiveness and ultimately access to healthcare;

The added value may be achieved through:

- Drug repositioning;
- Drug reformulation;
- Drug combination (drug/drug or drug/device or drug/service).

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, healthcare professionals and payers and address remaining healthcare inefficiencies. Enhanced customisation of existing therapies to address existing 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). Due to known risks, the management of asthma and COPD is associated with high healthcare and societal costs. Asthma and COPD are respectively responsible for 250,000 and 1.1 million annual hospital admissions and their estimated annual economic burden in terms of direct (healthcare) and indirect (lost production) costs amounts to €82 billion in total[1].

Despite the availability of efficacious molecules to treat asthma and COPD, evidence shows that low adherence to treatments contributes to poor patient outcomes[2] associated with an increased risk of hospitalisation, medical visits, and administration of antimicrobials or oral corticosteroids[3].

[1] European Respiratory Society. European lung white book 2013. Available from http://www.erswhitebook.org
[2] National Institute for Health & Care Excellence. Medicines Adherence. NICE Clinical guideline 2009. Available from: https://www.nice.org.uk/guidance/cg76

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

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 as well as associated costs.

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

Patients

Value added medicines contribute to addressing present 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 patient 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 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

Value added medicines greatly contribute to improving access to high quality care. They provide patients and healthcare professionals 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 and healthcare professional satisfaction. Value added medicines offer a well-known safety and tolerability 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 when 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 medicines to address specific needs that could not have been tackled 20 years ago.

Value added medicines aim to bring innovation throughout 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. However, to combine new technologies with known molecules requires considerable R&D investment and effort. The ambition of the Value Added Medicines Group is to play a leading role in unlocking this research potential, focusing on existing molecules.

Sustainability

The healthcare community, including patients, is facing 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 2050[4], 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 increasing[5] and despite the

[4] IMS Institute report: Bringing Healthy Living to Ageing Citizens: The Role of Technology, June 2014
[5] http://www.who.int/chp/chronic_disease_report/full_report.pdf

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 OECD[6].

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. OECD data show that new specialty medicines are expected to account for 50% or more of pharmaceutical spending growth within the next five years[7].

If one aims at ensuring universal access to healthcare by addressing the sustainability challenge of the needs outpacing budget growth, changes are needed. 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 125 billion euros per year. Addressing the adherence challenge could be a significant step to ensure better outcomes for 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 existing needs and expect genuine improvement, more innovation and sustainable access models in the future.

[6] OECD - Health at a Glance, 2015
[7] ibed

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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.

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ANNEX

factsheet | Medicines for Europe Vision

Providing sustainable access to high quality medicines for all European patients

Patients 1

- **Patient** access to medicines significantly increases when generic, biosimilar and value added medicines enter the market.
- Our members portfolio covers 80% of therapy areas, and supplies the majority of all prescribed medicines in Europe.

Quality 2

- Generic, biosimilar and value added medicines are developed and manufactured according to **stringent EU regulatory requirements**.
- Our members advocate the enforcement of high quality standards around the world.

Value 3

- Generic, biosimilar and value added medicines deliver **better value** to patients and healthcare systems.
- Our members provide an invaluable service to patient health and support **sustainable healthcare systems**.

Sustainability 4

- Over **160,000 skilled, high value direct jobs** in over **350 sites in Europe** produce your essential medicines.
- Our member companies are innovating: **up to 17% of their turn-over is invested in R&D**.
- Our industries export to over 100 countries worldwide.

Partnership 5

- **Medicines for Europe** works in close collaboration with the EU Institutions, governments, patient groups, healthcare professionals and other stakeholders to enhance public health in Europe.

patients • quality • value • sustainability • partnership

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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 160,000 people at over 350 manufacturing and R&D sites in Europe, and invest up to 17% of their turnover in medical innovation.

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.

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 56% of all prescribed medicines but for only 22% 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

MEDICINES FOR EUROPE MEMBER COMPANIES

Accord Healthcare
Alfred E. Tiefenbacher
Alkaloid
Allergan
Apotex Europe
Baxalta
Boehringer ingelheim
Cipla Europe
Combino Pharm
Consilient Health
Egis Pharmaceuticals
Farmoz
Fresenius Kabi
Gedeon Richter
Helm
Infarco
Jadran Galenski Laboratorij
KRKA
Lupin
Medochemie
Merck Serono
Mylan
Polpharma
Sandoz
Sanofi Generics
Sopharma
Stada
Synthon
Teva Europe

MEDICINES FOR EUROPE AFFILIATE MEMBER COMPANIES

Acino Pharma
AMCo
Anapharm Europe
Billev Pharma
Disphar
Farmaprojects
Glenmark Generics
JSC "Farmak"
Hetero
PharOS

NATIONAL ASSOCIATIONS FULL MEMBERS

AESEG (Spain)
APOGEN (Portugal)
AssoGenerici (Italy)
BGMA (United Kingdom)
BOGIN (Netherlands)
FeBelGen (Belgium)
GEMME (France)
IEIS (Turkey)
IGL (Denmark)
Pro Generika (Germany)
PZPPF (Poland)

NATIONAL ASSOCIATIONS AFFILIATE MEMBERS

APM GR (Romania)
BGPharma (Bulgaria)
CAFF (Czech Republic)
FGA (Finland)
FGL (Sweden)
GE (Hungary)
HEA (Ireland)
Intergenerika (Switzerland)
OEGV (Austria)

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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

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

Accord Healthcare
Alfred E. Tiefenbacher
Allergan
EGIS
Fresenius Kabi
Helm
Medichem
Mylan
PharOs
Polpharma
Sandoz
Sanofi Generics
Teva

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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

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 aim to bring innovation continuously throughout 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. However, to combine new technologies with known molecules requires considerable R&D investment and effort. The ambition of the **Value Added Medicines Group** is to play a leading role in unlocking this new and untapped research potential, focusing on existing molecules.

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.

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Factsheet | On Value Added Medicines

What is a value added medicine?

Value added medicines are medicines based on known molecules that address healthcare needs and deliver relevant improvements for patients, healthcare professionals and/or payers. The added value may be achieved through finding **a new indication** (drug repositioning), finding **a better formulation or dosage** (drug reformulation), or developing **a combined drug regimen, adding a new device or providing a new service** (drug combination).

Improvements that they can deliver

- New therapeutic uses (indication/population)
- A better efficacy, safety and/or tolerability profile
- A better way of administration and/or ease of use

Those improvements contribute to

- Better adherence, health outcomes or quality of life
- Improved safety and efficiency of healthcare professional resources
- Increased treatment options & preventing therapeutic escalation[1]
- Improved cost-effectiveness and ultimately access to healthcare

Examples of Value Added Medicines

Repositioning *(new indication)*: a very famous and classical example of a repurposed drug is Sildenafil. Originally developed as an antihypertensive, Sildenafil has been repositioned later on for the treatment of erectile dysfunction and pulmonary arterial hypertension.

Reformulation *(better dosage or mode of administration)*: from standard release to quick release of the active substance; from an intravenous to a subcutaneous injection; from an injectable solution to a ready-to-use prefilled syringe; from a sublingual tablet to a transdermal patch.

New combination: a new treatment combining more than one molecule or the association of a molecule and a new device/service.

What's in it for:

Patients

Value added medicines can offer patients new healing opportunities. They can also help them to feel better with their treatment, offering more adapted medicines to those who need it.

Healthcare professionals

Value added medicines provide healthcare professionals with unprecedented flexibility in therapy choices: new therapeutic uses, fewer side effects, new dosage forms, better ways of administration or easier to handle medicines are among the benefits that value added medicines offer to healthcare professionals so that patients can be treated more effectively without resorting to expensive next line therapies.

[1] Preventing therapeutic escalation: by offering new treatment options, patients will receive more tailored treatment preventing them from moving to more expensive treatments (e.g. more expensive medicines, surgery, etc.)

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Payers

Value added medicines provide an opportunity to tailor treatments to specific patient subgroup needs and therefore to reduce misuse of medicines which can lead to therapeutic failure and escalation, which are unnecessarily consuming healthcare resources. This will allow a more efficient use of current budgets.

Research Community

Value added medicines R&D merge a pharmacological approach of known molecules with a well-known safety and tolerability profile together with more patients and/or healthcare professional insights, also leveraging new technologies to transform existing molecules to address specific needs that could not have been tackled 20 years ago. They bring **innovation throughout a molecule's lifecycle**, particularly those molecules no longer protected by patent, **without impacting patient access**.

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).
- Despite the availability of efficacious molecules to treat **asthma and COPD**, evidence shows that low adherence to treatments contributes to poor patient outcomes [2] associated with an increased risk of hospitalisation, medical visits, and administration of antimicrobials or oral corticosteroids[3].
- Asthma and COPD are respectively responsible for 250,000 and 1.1 million annual hospital admissions and their estimated annual economic burden, in terms of direct (healthcare) and indirect (lost production) costs, amounts to €82 billion in total[4].
- There are convincing health benefits in investing more time and resources to understand and address this situation. **Value added medicines** can enable known and efficacious active substances to deliver on their promises to patients who need them, averting or reducing complications and exacerbations as well as associated costs.

About 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 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 whole.

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. 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.

[2] National Institute for Health & Care Excellence. Medicines Adherence. NICE Clinical guideline 2009. Available from: http://publications.nice.org.uk/medicinesadherence- cg76 accessed: Nov 2013
[3] Melani, AS, et al. Respir Med. 2011;105(6):930-8
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Q&A | Value Added Medicines

What are value added medicines?

Value Added Medicines are medicines based on known molecules that address healthcare needs and deliver relevant improvements for patients, health care professionals and/or payers.

What type of improvements can they deliver?

Relevant improvements include:

- A better efficacy, safety and/or tolerability profile;
- A better way of administration and/or ease of use;
- New therapeutic uses (indication/population);

How do value added medicines deliver these benefits?

The added value may be achieved through finding a new indication (**drug repositioning**), finding a better formulation or dosage (**drug reformulation**) or developing a new combined drug regimen, adding a new device or providing a new service (**drug combination**).

Can you give us more details and some examples?

- Drug Repositioning or repurposing is the process of finding a new therapeutic use for an already known medicine which had initially been developed for another indication.
  Examples: A very famous and classical example of a repurposed drug is Sildenafil. Originally developed as an anti-hypertensive, Sildenafil was later repositioned for the treatment of erectile dysfunction and pulmonary arterial hypertension. Other examples include:
  - Parkinson's to Alzheimer's (Memantine)
  - Cardiovascular to Oncology (Propranolol)
  - HIV infection to Oncology (Plerixafor)
  - Parkinson's to Diabetes type 2 (Bromocriptine)

- Drug Reformulation is the development of a different formulation for the same medicine, i.e. finding new ways to combine the different substances of a medicine, including the active ingredient, to produce a final medicinal product.
  Examples:
  - From standard release to quick release of the active substance (Bromocriptine)
  - From an intravenous to a subcutaneous injection (Trastuzumab)
  - From an injectable solution to a ready-to- use prefilled syringe (Methotrexate)
  - From a sublingual tablet to transdermal patches (Buprenorphine)

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What type of R&D efforts are needed to develop value added medicines?

Different types of value added medicines require different R&D efforts.

- Developing a new device requires considerable R&D investment to optimize the administration of the active substance.
- Certain changes to a medicine require a **clinical development programme** in order to collect new clinical data which are necessary to assess the safety and efficacy of the value added medicine:
    - New claims around safety or efficacy of the product such as different indications, an improved safety profile in case of repositioning or increased speed of onset in case of reformulation.
    - A change in the blood concentration profile of the medicine. This situation occurs when there is a change:
        - in dosing frequency,
        - in the strength per dose,
        - in the release profile,
        - in the route of administration,
        - for new formulations,
        - where it is difficult to demonstrate the pharmacokinetic equivalence.
    - A new combination product containing active substances that have not previously been used together
    - In certain circumstances, to support safety/efficacy in children in accordance with the requirements of the European paediatric regulation.

Can you give an example of a therapeutic area where value added medicines can add benefit?

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

Despite the availability of efficacious molecules to treat asthma and COPD, evidence shows that low adherence to treatments contributes to poor patient outcomes[2] associated with an increased risk of hospitalisations, medical visits, and administration of antimicrobials or oral corticosteroids[3].

There are convincing health benefits in investing more time and resources to understand and address this situation.

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What are their benefits for the healthcare community?

The benefits of value added medicines are expected to impact healthcare systems through increasing treatment options, preventing therapeutic escalation or increasing rational use of medicines. They will as a consequence reduce the use of healthcare resources and improve cost-effectiveness, and therefore contribute to the efficiencies of the healthcare system and better patient health and access.

What benefits will value added medicines bring to patients?

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

With this in mind, the Value Added Medicines Group is developing a framework to provide new opportunities to help patients in their healing process, offering more adapted medicines to those who need it.

What benefits will value added medicines bring to healthcare professionals?

Value added medicines provide healthcare professionals with unprecedented flexibility in therapy choices to target better outcomes for patients, whose needs remain unaddressed and unmet by existing therapies. Healthcare professionals will be able to choose from a wider range of treatment options using well known active substances, but allowing for a more tailor-made, patient centric approach, increasing patient and professional satisfaction.

Value added medicines offer a well-known safety and tolerability profile based on existing molecules, creating confidence in using alternatives which are more adapted to some patients' lives and needs. Fewer side effects, better modes of administration, new dosage forms or easier to handle medicines are among the benefits that value added medicines offer to healthcare professionals so that patients can be treated more effectively without resorting to expensive next line therapies.

What benefits will value added medicines bring to payers?

Several healthcare inefficiencies are impacting the sustainability of healthcare budgets, such as suboptimal use of drugs The WHO has notably estimated that more than 50% of all medicines globally are prescribed, dispensed or sold inappropriately and that 50% of all patients fail to take their medication as prescribed or dispensed[4]. The cost of non-adherence in Europe is estimated to cost European governments 125 billion euros per year[5].

Value added medicines provide an opportunity to tailor treatment to specific patient subgroups and therefore to reduce misuse of medicines which can lead to therapeutic failure and which are unnecessarily consuming resources for payers.

[4] WHO, Health systems financing: the path to universal coverage (2010)

[5] €125bn/year is an A.T. Kearney estimate based on US avoidable cost data

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Why is our industry developing value added medicines?

Value added medicines represent a form of R&D, merging a pharmacological approach of known molecules with a well-known safety and tolerability profile together with more patient and/or healthcare professional insight, leveraging new technologies to transform existing molecules to address specific needs that could not have been tackled 20 years ago.

Working with proven compounds whose toxicity and other effects have been studied, the pharmaceutical industry can reduce development times, but considerable R&D investment and effort are still required to reposition, reformulate or combine new technologies with known molecules. Our aim is to bring innovation continuously through the entirety of a molecule's lifecycle, particularly those molecules no longer protected by patent, without impacting patient access.

What objective is the Value Added Medicines Group aiming for?

Our aims are to establish, in collaboration with patients, healthcare professionals and payers, a sustainable market model that incentivises R&D, notably when the molecules come off patent, and to enable access to value added medicines in Europe.

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value added medicines

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

- Price escalation and budget constraints
- Underuse of cheaper options
- Suboptimal use of drugs
- Need for improvement in identification of cost-effective drugs

50% OF PATIENTS

FACE CHALLENGES WITH MEDICATION ADHERENCE

IMPACT OF NON-ADHERENCE

DISEASE WORSENING → THERAPEUTIC ESCALATION → 125 BN € EXTRA COSTS PER YEAR

VALUE ADDED MEDICINES

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

IMPROVEMENTS

- New therapeutic uses
- Better efficacy
- Better safety
- Better tolerability
- Better ease of use
- Better way of administration

HOW

DRUG REPOSITIONING
Finding new indications

DRUG REFORMULATION
New delivery system

COMPLEX COMBINATION
New regimens or adding technology

WHAT'S IN IT FOR...

PATIENTS
BETTER ADHERENCE AND QUALITY OF LIFE

HEALTHCARE PROFESSIONALS
IMPROVED SAFETY AND EFFICIENCY

INCREASED TREATMENT OPTIONS

PAYERS
IMPROVED BUDGET EFFICIENCY

RESEARCHERS
INNOVATION THROUGHOUT A MOLECULE'S LIFECYCLE