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Market Access / Pricing & Reimbursement Working Group

11 September 2018, Brussels

Agenda (I)

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I. **Welcome / Next Events / Working Groups**

II. **Update on the various Member States' Initiatives in the Health Care Sector** Scientific (Sven Jansen, MSD Europe)
- BeNeluxA collaboration
- Visegrad group
- Valetta declaration
- Nordic initiatives (joint tenders, Finosa)

III. **Economic compounding**
- Legal compounding "for personal use" in the Netherlands (Maarten Meulenbelt, Sidley)
- Report on the EUCOPE workshop on "economic compounding" (Zachary Burnside, FTI)

IV. **ATMPs in Italy** (Francesco Macchia, RareLab)

Agenda (II)

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V. Country Updates

- EUCOPE Check list The Netherlands: new rare diseases policy, measures to change the current reimbursement system & stronger cost control on medicines (Maarten Meulenbelt, Sidley)
- Germany: (Hans-Jürgen Seitz, IGES)
- France: Priorities of the French Government for year 2018-19 in the healthcare sector (Alexandre Regniault, France Biotech)

VI. Outcomes of EMA's accelerated scheme PRIME (Steve Norton and Christian Hill, MAP BioPharma)

VII. Patients' views on HTA and update on EPF's Access Campaign (Kaisa Immonen, European Patients' Forum)

VIII. AOB / Next Meeting Date / End of meeting

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I. Welcome / Next Events / Working Groups

Next Events

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- 17 September**: Gene & Cell Therapy WG Meeting, Brussels**
- 8 October**: EUCOPE 10-Year Anniversary**
- 9 October: **Members' Meeting, Brussels**
- 24 October: **Orphan Medicinal Products WG Meeting, Brussels**
- 13 November**: Regulatory / Pharmacovigilance / Medical Devices WG Meeting, Brussels**
- 20 November: **Market Access / P&R WG Meeting, Brussels**
- 30 November: **Legal Working Group, Berlin**

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Copenhagen: meeting with Medicinrådet on **7 December, 2-4pm**

The Danish Medicines Council (DMC)

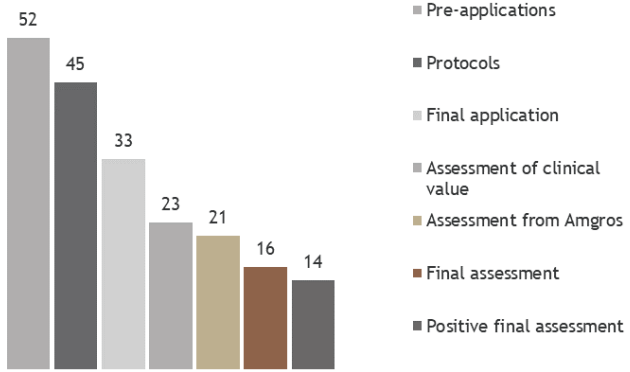
- New organization created on 1 Jan 2017 by the Board of Danish Regions
- It is an independent council that prepares recommendations and guidelines for medicines for the five regions.
- The Council is based on experiences from the Danish Council for the Use of Expensive Hospital Medicines (RADS) and the Coordination Council for the Enforcement of Hospital Medicine (KRIS).

The Danish Medicines Council (DMC)

DMC's role:

- Ensure fast and homogeneous use of new and existing medicines across hospitals and regions
- Impose stricter requirements for documentation to support that patients will benefit from new and existing medicines
- Enhance the basis for Amgros' price negotiations and calls for tenders.
  (Amgros = joint procurement service for the Danish regions, mostly concerned with procurement of medicines for hospital use)

52 pre-applications in the system by end May 2018 and 14 of these have positive final assessment.



Transparent process: ongoing reviews are published on the DMC's website.

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II. **Update on the various Member States' Initiatives in the Health Care Sector** (Sven Jansen, MSD Europe)

- BeNeluxA collaboration
- Visegrad group
- Valetta declaration
- Nordic initiatives (joint tenders, Finosa)

Introduction

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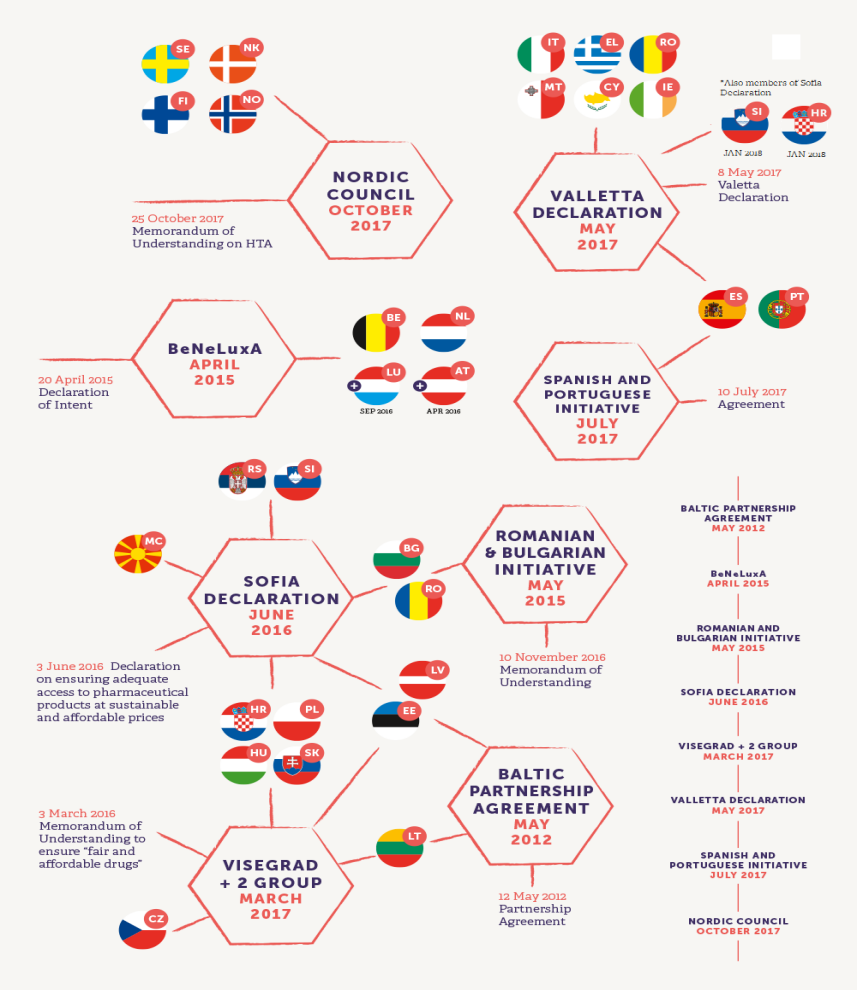

Cross – Country Collaborations could be focused on:

- Horizon Scanning
- Relative efficacy assessments
- HTA
- Information Sharing
- Joint pricing negotiations
- Joint procurement and contracting

(WHO policy brief 21, 2016)

And some or all of the above!

25 of 28 EU countries are involved in CCC initiatives

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Valletta – What is it about

- Start in May 2017
- Cyprus, Croatia, Greece, Italy, Ireland, Malta, Portugal, Rumania, Slovenia, Spain (Slovakia left, France and Estonia are/were observers)
- Technical committee:
  - Chair: Paola Testori Coggi (President of the AIFA Pricing and reimbursement Committee, Italy)
  - Vice-chair: Rui Santos Ivo (INFARMED - National Authority of Medicines and Health Products, Portugal)
- Joint negotiation (joint procurement, horizon scanning, HTA)
- Scope: New medicines

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Valletta – Update

- 2018: Slovenia and Croatia joined

- Last Technical Committee Meeting in Athens on 11 July
- Statement of Greek minister:
  - Roadmap
  - Legal Framework
- Greece announced cooperation on prices with Cyprus
- Next meeting in Bucharest in October 2018

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BENLUXAI (or iBeneluxa ?) – What is it about

- Started in April 2015
- Belgium and Netherlands (leads), Luxembourg, Austria, Ireland
- Joint Assessments (HTA), Pricing and reimbursement (joint negotiations), Information sharing, horizon scanning
- Scope: Orphan drugs, shift to expensive products

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BENELUXAI – Update

- Ireland formally joined on 22 June
- Announcement on 12 July: First reimbursement decision of Belgium and Netherlands after joint HTA and price negotiation (Biogen, Spinraza)
- Horizon Scanning:
  - 16-20 countries (EU and non-EU countries) met on invitation of Belgium government to discuss joint horizon scanning in March 2018
  - Call for tender for a supplier that can run the project expected for September

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Visegrad – What it is about

- Poland (lead), Slovakia, Hungary, Lithuania
- Observer: Czech Republic
- Croatia withdrew

- Joint negotiations for increasing access and „fair pricing“
- Joint acquisition and production of Vaccines

- Scope: Expensive / Orphan drugs, Vaccines

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VISEGRAD - Update

- Last (known) meeting in Bratislava, 2 March 2018
- Difficult to get information - details only over media or messages of officials from Poland or Hungary

- Elections in Hungary slowed down the process

- Joint statement of MoH‘s to strengthen their cooperation on non-communicable, chronic diseases, nutrition factors and childhood obesity in March

- Reportedly completed a legal framework (Source: Polish Head of HTA body on a congress in June)

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Nordic Collaborations – What it is about

Nordic tendering collaboration:

- Denmark (lead), Iceland, Norway
- Initiated by Nordic Council, Leadership by Danish payer organization AMGROS now
- Scope: Start with generic products. Innovative & Mature medicines

FINOSE:

- Finland, Norway, Sweden
- HTA – decision on P&R will remain national
- Non-reimbursed, innovative medicines
  - Preference on hospital products

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Nordic Collaborations Update

Nordic tendering collaboration:

- Danish purchaser AMGROS took leadership
- Tender for 2 off-patent products – starting in September 2018. Another tender with an off-patent should follow in April 2019
- Sweden and Finland are not part of the pilot

FINOSE

- Letter of intent signed in January
  - Joint evaluation process (incl. relative effectiveness and health economics elements)
- Finose Meeting on 27 March (incl EMA, EC, Industry)

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Summary

- European Commission support/involvement does not exist!
  - Declaration by Germany , June 2017: “There will be no coordination of the activities at a higher level, in particular by the Commission…There will be no involvement of European structures going beyond the competences provided for in the European Treaties.”
- There is a strong political will, but not matched at official/administrative level
- CCCs are difficult!

- Do we need EUCOPE activities?

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III. Economic compounding

- Legal compounding “for personal use” in the Netherlands (Maarten Meulenbelt, Sidley)
- Report on the EUCOPE workshop on “economic compounding” (Zachary Burnside, FTI)

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Legal compounding "for personal use" in the Netherlands (Maarten Meulenbelt, Sidley)

Compounding: an update

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11 September 2018 - mmeulenbelt@sidley.com

SIDLEY
150 YEARS

Basics: magistral/officinal formula, special needs, manufacturing authorisation

- **Article 2(1) Directive 2001/83 ("Community Code")**: main rule
  - 1. This Directive shall apply to medicinal products (…) either **prepared industrially or manufactured by a method involving an industrial process**.
- **Article 3 Community Code**: magistral/officinal formula exceptions
  - 1. Any medicinal product prepared in a pharmacy in accordance with a medical prescription for an individual patient (commonly known as the **magistral formula**).
  - 2. Any medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question (commonly known as the **officinal formula**).
- **Article 5(1) Community Code**: exception to fulfil **special needs**
  - 'medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised health-care professional and for use by an individual patient under his direct personal responsibility.'
- **Article 40 (2) Community Code**
  - [A manufacturing authorisation] 'shall not be required for preparation, **dividing up**, changes in packaging or presentation where these processes are carried out, **solely for retail supply**, by pharmacists (…)'

Case law (1)

- C-185/10, *Commission/Poland* (importation 'competitive imported medicinal products')
  - 'Article 5(1) cannot be relied on to justify a derogation from the requirement for a marketing authorisation for reasons of a financial nature'
- C-535/11 *Novartis Pharma* (serial repackaging of Avastin)
  - MA requirement depends on whether repackaging activities 'result in a modification of the medicinal product concerned'
  - Key question under Art. 40 (pharmacy exception to manufacturing authorisation): 'whether the processes in question are carried out only on the basis of individual prescriptions that call for them to be carried out'
- C-276/15 *Hecht Pharma* (incense capsules ordered 'with proven frequency')
  - Article 2(1) (industrial process) not triggered if 'essential manufacturing steps … are carried out in a pharmacy as part of the normal pharmacy business producing in the course of one day up to 200 packages and intended for supply under the existing pharmacy licence'
    [subject to national court findings]
  - Member State may 'require pharmacists to comply with the pharmacopeia when manufacturing officinal formulae'

Case law (2)

- C-544/13 *Abcur* (130K boxes of Metadon APL, large scale serial production sites)
  - Article 2 (industrial process) covers ‘standardised production of significant quantities … to be stocked and sold wholesale’
  - Article 5(1) on special needs: cannot be invoked if there is another authorised product
  - Magistral formula (3.1) requires prior individual prescription for previously identified patient
  - Officinal formula (3.2) requires direct-to-patient delivery by preparing pharmacy
- A-G Opinion C-29/17 Novartis Farma SpA (*reimbursement* of repackaged Avastin)
  - [85] Company pointed out that pharmacies repackage Avastin on a large scale without having received a prior prescription; products are delivered to eye doctors in private practice, not to patients or hospitals
  - [86] A-G does not address these issues, considering that infringements would not be relevant for answering national court’s questions on reimbursesment
  - [87] Article 40 does not apply if there are individual prescriptions; no MA required for delivery of resulting products to hospitals
  - Article 5(1) exception (special needs) applies only to purely *therapeutic* reasons, does not justify off-label

Other applicable rules (1)

- Council of Europe Resolution CM/Res(2016)1, 1 June 2016 (replaces CM/ResAP(2011)1
- Added value of pharmacy preparations and responsibilities of HCPs
  - 'Pharmacy preparations are not advisable if a suitable pharmaceutical equivalent with a marketing authorisation is available'.
  - [HCPs] 'should take into account the medical need of the patient. A pharmacist should be able to refuse a prescription if a suitable pharmaceutical equivalent is available on the national market.'
- Specific CoE rules for pharmacy preparations include:
  - Preparation process, product dossier, labelling, import/export, GDP, risk assessment, …
  - A standard formula should be found in a national pharmacopoeia or nationally recognised formularies
  - Active pharmaceutical ingredients and excipients used for the pharmacy preparations, dosage forms and containers must comply with the relevant chapters and monographs of the European Pharmacopoeia, or in the absence thereof, a national pharmacopeia (…)
  - Where no (…) monographs exist, the quality of the starting materials should be fit for pharmaceutical use and be demonstrated on the basis of validated methods

Other applicable rules (2)

- European Pharmacopoeia – general monograph '*pharmaceutical preparations*' (Ph.Eur. 01/2018:2619)
  - Distinguishes between 'extemporaneous preparations' and 'stock preparations'
  - Ethical considerations and guidance
  - Acknowledgement that preparations constitute 'exemptions from formal licensing requirements' to 'meet the special needs of individual patients'
  - Duty of care to the 'special needs' patient receiving the preparation requires 'a suitable level of risk assessment', which is 'of special importance'
  - Person responsible for preparation must ensure, with a suitable level of assurance, that the pharmaceutical preparation is, throughout its shelf-life, of an appropriate quality and suitable and fit for its purpose

Dutch law

- Article 40(3) Medicines Act (Gnw): exception for ‘small scale’ preparations
- Article 2 Medicines Decree: pharmacy preparations must (i) comply with pharmacopoeia and (ii) be made with sound ingredients (‘deugdelijke bestanddelen’)
- Article 2 Dutch Healthcare Quality, Complaints and Disputes Act: obligation to provide ‘good care’
- Professional standards of Inspectorate (IGJ), pharmacists (KNMP), hospitals (NVZA)
  - Note in particular KNMP/IGJ guidelines for onwards delivery (‘doorlevering’): only if there is no registered alternative (e.g. new IGJ circular, 1 August 2018)
- GMP-Z (hospital pharmacists) e.g. no stocks; testing requirements for active ingredients
- Council of State, Regenboog Apotheek case (ECLI:NL:RVS:2013:BZ9066)
  - Preparation methylphenidate appropriate ‘where no suitable registered medicinal product is available’; intended for ‘own patients’
- 1.1.2019: new NZA guideline 19630: permits reimbursement for pharmacy compounds prepared when HCP has prescribed an authorized medicinal product
- Minister for Medical Care 15.06.2018: reference to pharmacy preparations as ‘alternative to registered medicines, when prices are excessively high’

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Report on the EUCOPE workshop on "economic compounding"
(Zachary Burnside, FTI)

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Compounding context

- The topic has not been discussed extensively at EU level but has gained significant prominence in certain EU countries.
- Over the past few years, Members have witnessed **a <u>trend of compounded products being used (in hospitals) instead of available licensed medicines as a way to save on healthcare costs.</u> We have also witnessed the use of unlicensed medicines as a comparator in HTA and P&R processes. We can call this economic compounding**.
- Examples of economic compounding in Europe include:
  - Paul Lebbink, a Dutch pharmacist was offering to compound a cheap variant of Vertex's Orkambi for the treatment of cystic fibrosis.
  - Orphacol, a Laboratoires CTRS product, approved by the EMA for the treatment of rare liver disorders. Compounded version of the product being used in Italy, despite Laboratoires CTRS having market exclusivity across Europe.
  - Orphan Europe product compared to an unlicensed medicine during HTA assessment by The Dutch National Health Care Institute (ZIN).
  - Leadiant's chenodeoxycholic acid (CDCA) a treatment for cerebrotendinous xanthomatosis (CTX), a rare disease. The Amsterdam Medical Center in the Netherlands is to manufacture a compounded version of the product.

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Work conducted to date on compounding:

- **In 2015 EUCOPE established a Working Group on the Use of Unlicensed Medicines**
  - Off-label use (Declaration on Good Off-Label Use Practices by Professor Marc Dooms – GOLUP and related activities);
  - Compounding.

- **Off label use and compounding have similar foundations** (budget constraints and high price of pharmaceuticals) and produce comparable effects: endanger patient safety, challenge EU regulatory system and internal market of medicines, disincentivize medical innovation.

- Actions taken in the area of compounding:
  - Definition of EUCOPE's position on compounding with the release of a position paper in June 2016 and a policy paper in November 2017.
  - Exploring stakeholders' perspective on compounding through a number of meetings, positioning EUCOPE as a key stakeholder in this area.

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Roundtable on pharmaceutical compounding – 10 July 2018

- 17 experts and representatives of European stakeholders – from pharmacists, to medical and patient organizations, as well as pharmaceutical companies discussed the safety & efficacy of compounded. Key points to come out included:
  - The need to ascertain whether there is a suitable medicinal product with a marketing authorization available, before undertaking the decision to conduct a pharmacy compounding operation.
  - Feeling that in some specific cases, newly authorized products replacing long used pharmacy preparation are becoming available an excessive price.
  - Value of product should be determined through early dialogue between all concerned stakeholders.
  - EUCOPE members argued that the EU regulatory framework must not be undermined by economic considerations.

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Roundtable on pharmaceutical compounding – next steps

- During the discussion, an initial consensus emerged around some **basic principles that are especially important when prescribing a compounded product**. Above all else, the **efficacy, safety and protection of the patient must come first.**

- EUCOPE is reaching out individually to participants to assess interest in reaching agreement on a policy document on compounding based on the discussion that took place on 10 July 2018.

- Such a document would help to overcome the different rules that apply across European countries, wile increasing patient safety, by providing guidance regarding the use of unlicensed medicines, and ensure a conducive environment for innovation.

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IV. **ATMPs in Italy** (Francesco Macchia, RareLab)

- Current state of play
- Market Access and funding issues

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Market Access / Pricing and Reimbursement working group meeting

ATMPs in Italy

Francesco Macchia, RARELAB

11th September 2018, Brussels

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Agenda

1 ATMPs in Italy

2 Access issues of ATMPs in Italy

3 Future challenges

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SCIENCE MEDICINES HEALTH

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EMA definition of ATMPs

Any medicinal products for human use which can be classified as **gene therapy** medicinal product, **somatic cell therapy medicinal** product and **tissue engineered product**.

Cells or tissues have been subject to **substantial manipulation** to achieve the biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement.

Specific guidelines on ATMPs classification were set in **2012**.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000296.jsp&mid=WC0b01ac058007f4bc
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2012/12/WC500136422.pdf

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Advanced therapies authorized:

Actually, in Italy, The ATMPs authorized are:

Ortho	Zalmoxis
Opthal	Holoclar
Onco	Imlygic
Immuno	Strimvelis
Immuno	Alofisel
Ortho	Spherox

Made in

EMA Approved in Q3 2018

- Kymriah
- Yescarta

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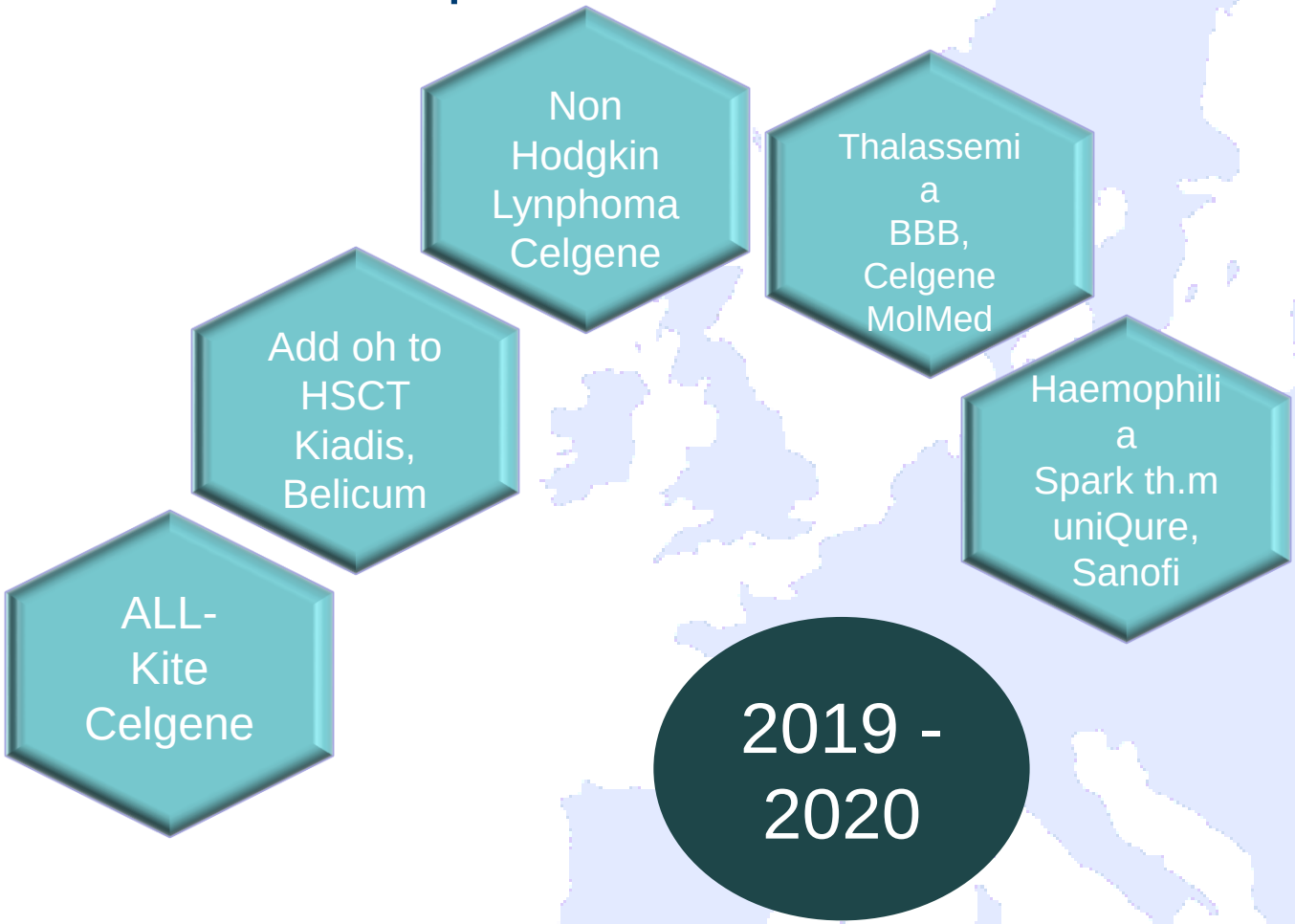
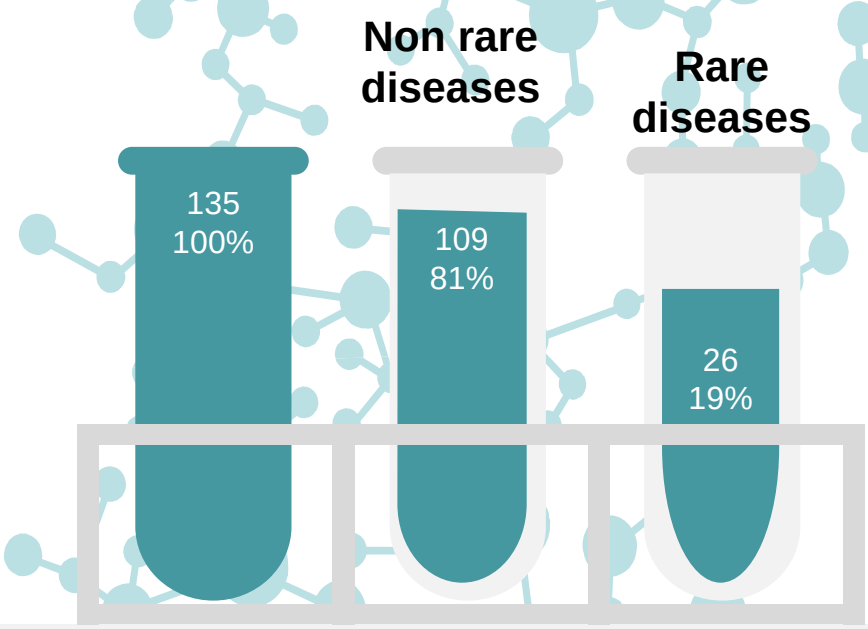
Advaced Therapies in future



Clinical Trials in Italy



Centre	Clinical Trial	Cell Factory
Papa Giovanni XXIII	9	yes
IRCSS Ospedale San Raffaele	5	No
Istituto ortopedico Rizzoli	5	Yes
Ospedale di Careggi	5	No
Università Carrolita Sacro Cuore	4	No
IRST IRCCS Meldola	4	Yes
IRCCS Policlinico San Matteo	3	Yes
Fondazione IRCCS Policlinico Milan	3	Yes
AOU Policlinico S.Orsola – Malpighi	3	No
AO San Camillo Forlanini	3	No
AO San Gerardo	3	Yes

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SCIENCE MEDICINES HEALTH

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Need to be prepared

The entry on market of these therapies will have a "disruptive" impact on the whole system.

Need for preparing an environment ready to absorb the big change which is about to affect Italy as well.

Dealing with these therapies with the old rules would compromise access to them by patients.

<u>Key areas for change:</u>

- **Reimbursement, market access;**
- **Regulatory convergence and sector-supportive initiatives;**
- **Industrialization and manufactoring.**

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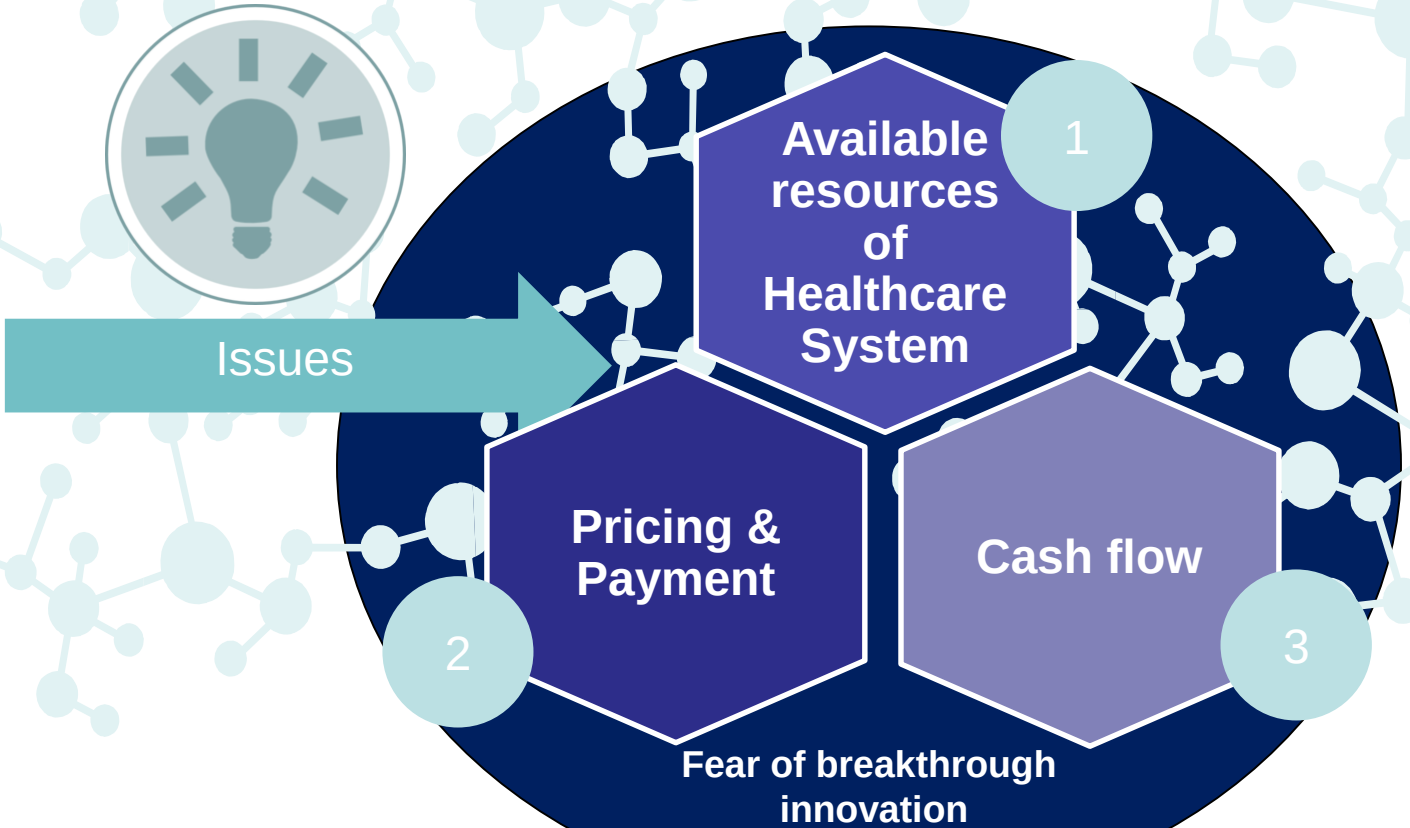
Issues

The growing number of ATMPs in the market could have a high impact on the whole NHS and it is necessary to respond promptly to avoid delaying the timely availability for patients or undermining the whole system.



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Cultural problems

1. **General fear of breakthrough innovation and population negative attitude versus science (i.e. vaccines)**

2. **Catholic reluctancy to genome editing (fear of next step on germinal lines)**

3. **Genetic Modified Organism (OGM) negative experience**

Need for **correct communication**

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Available resources of Healthcare System

ATMPs are often one shot therapies with high costs. In may case (for disease with no alternatives) they represent a pure Incremental Budget

We will have to deal with **scarce resources:** italian **innovative fund** that could reasonably **not be capacious to cover these therapies**, forcing the regions to take charge of them.

For **advanced therapies** will have very **few excellence centers at the national level and the whole burden may be only on those regions**

Clear need for a **dedicated fund**

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Pricing

high costs due (also) to high production costs

Core elements for P&R negotiation in Italy:

1. Funding (budget impact)
2. Innovation level (assessed through GRADE)
3. Comparator or production costs

A new system of evaluation of these technologies is needed which focuses on the patient and not on the product

Drug	US Price	ITA ex factory price	Revenue estimation in Italy*
Strimvelis		594 000 €	1 564 000 €
Zalmoxis		149.000 €	16 690 000€
Kymriah	475 000 $		26 536 324 €
Yescarta	373 000 $		260 474 965 €

** Based on estimated target population and assuming half of US price where ITA Price is not available*

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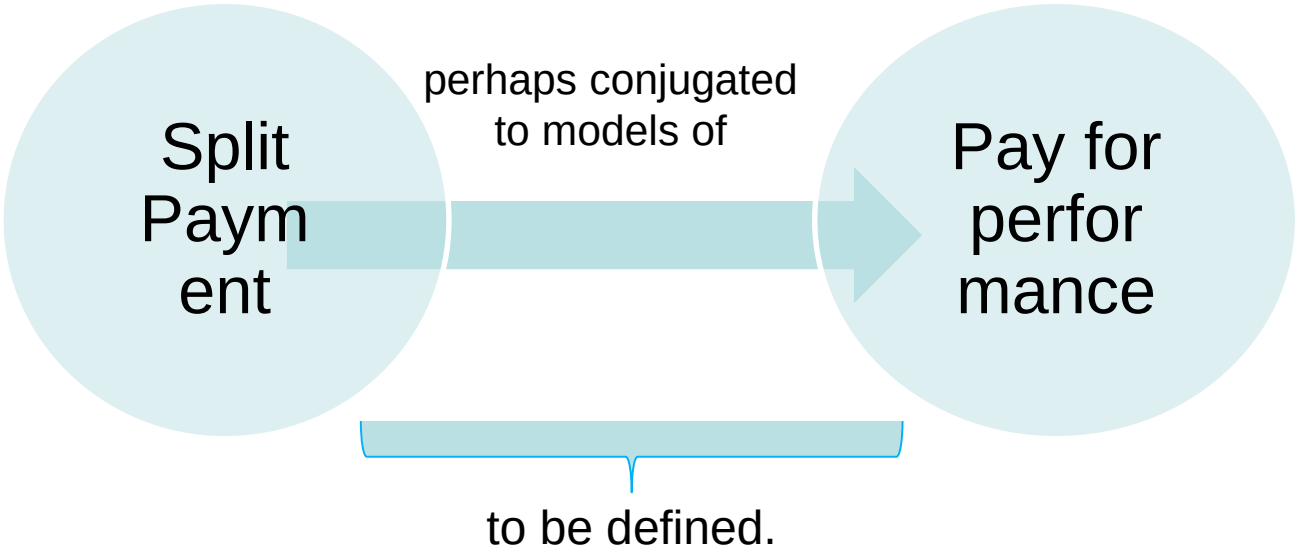
Payment

One shot treatment & long term benefit

It will be necessary to identify different **financial models** for the payment of these therapies as forms of :



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Cashflow –(1)

it is possible to foresee problems of **cash flow** or of the **financial availability of the supplier** both on an intra- and inter-regional level. In fact, these therapies require top-quality centers of excellence to be provided.

In the best scenario, this center are one by region, in the worst case there **are only three or four centers concentrated in very few region of excellence**, which have to receive **patients from regions that do not guarantee immediate solvency.**

**For example, centers of excellence*

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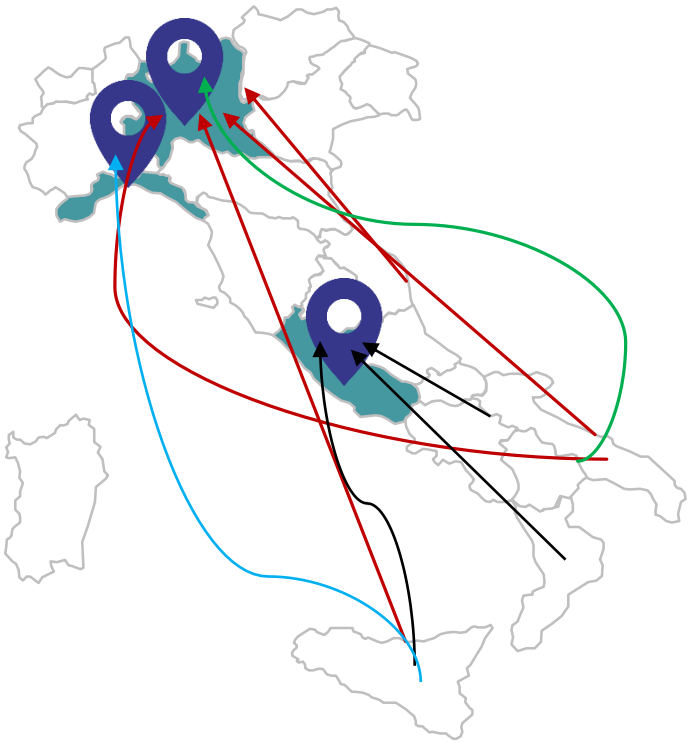
Cashflow – (2)



Infact, the expenditure for health services offered to non-residents is 1) **initially charged to the regions providing the services**; only at second time 2) **are repayments of the other regions of residence of the assisted**, paid into the final balance and after a compensation operation which, given its complexity,

is **governed by specific guidelines approved by the Conference of Regions and Autonomous Provinces.**

CONFERENZA DELLE REGIONI E DELLE PROVINCE AUTONOME

**For example, interegional mobility*

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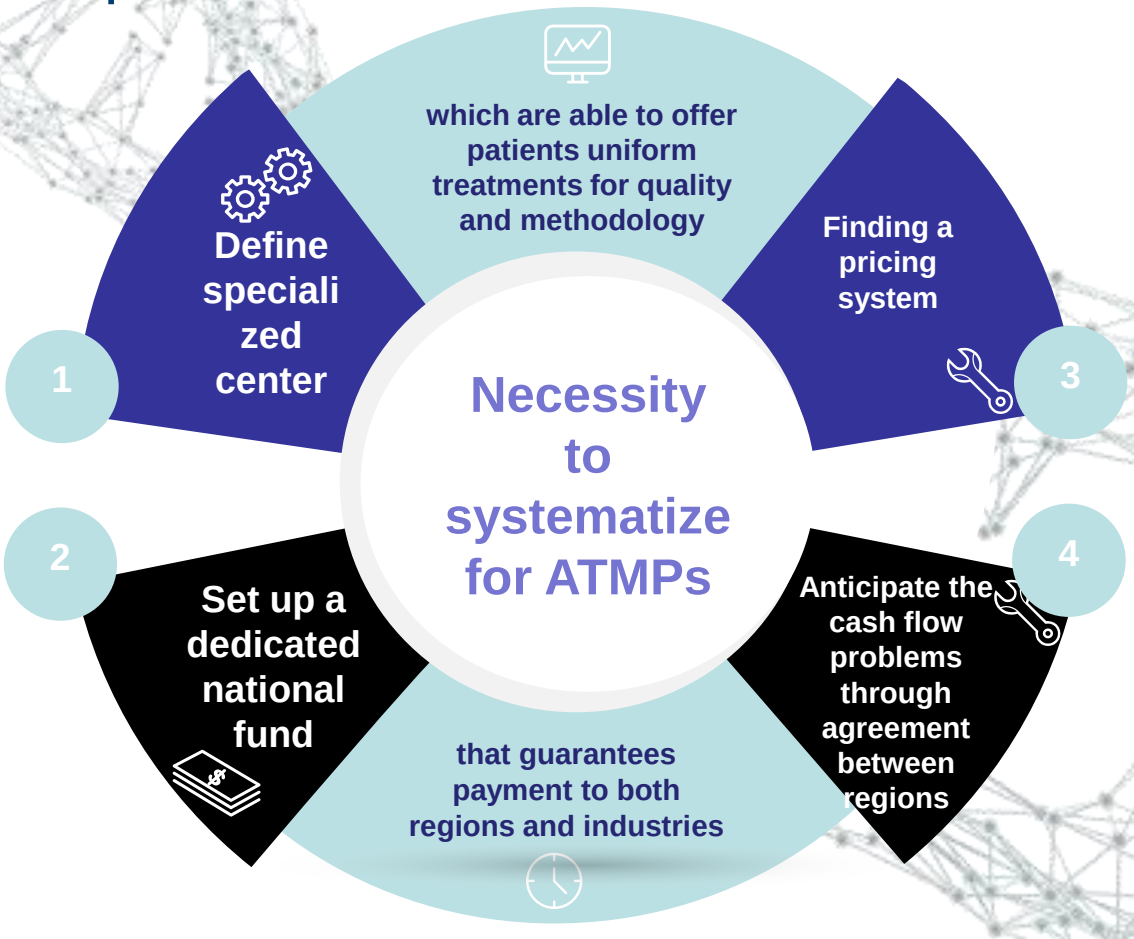
Future steps



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Final remarks

There are many issues to be addressed, involving the multiple floor either **regulatory, operational and of access** to innovative therapies.

A **joint effort is needed between companies, institutions, scientific societies and the hospital network** for bringing to patients the sescientific innovations, which have the potential to heal and change the history of certain diseases.

After the OMG experience in Italy, we are aware there a crucial need for **correct information & communication.**

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GENOME EDITING AND TARGETED THERAPIES THINK TANK

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Thanks for your attention

Francesco Macchia,

Managing Director, RARELAB
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Different technological platform

- **Advanced cells:** modified T-celles;Hematopoietic stemcells; iPSCS; MSCs; adultprogenitor cells(neural, liver, cardiac); etc.
- **CellsbasedImmunotherapies**: T-cells; CAR-T; TCR; NK cells; TILs; MILs; Gamma delta cells; Dendritics vaccines; etc.
- **Noveland syntheticgenesdelivery vehicles**: AAV; RV; LV; AD; etc.
- **Genomeediting:** CRISPRS/Cas; next-genCRISPR test; TALENs; ZFNs; Homologous Recombination; etc.
- **Next-genexpressionconstructs**: novel capsids; innovative regulatory elements, including synthetic promoters that enable specificity, strenghtand improve capacity; inducible elements to regulate gene expression temporally or in response to external stimul; molecular kill switches to improve safety; etc.

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V. Country Updates

- The Netherlands: new rare diseases policy, measures to change the current reimbursement system & stronger cost control on medicines (Maarten Meulenbelt, Sidley)
- Germany: (Hans-Jürgen Seitz, IGES)
  - Recent court ruling on mixed prices
  - Update on developments regarding physician information system (AiS)
- France: Priorities of the French Government for year 2018-19 in the healthcare sector (Alexandre Regniault, France Biotech)

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The Netherlands: new rare diseases policy, measures to change the current reimbursement system & stronger cost control on medicines (Maarten Meulenbelt, Sidley)

Netherlands update

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11 September 2018 - mmeulenbelt@sidley.com

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150 YEARS

Recent legal and policy developments - Netherlands

- Recap from presentation on compounding:
  - 1.1.2019: new NZA guideline 19630: permits reimbursement for pharmacy compounds, prepared when HCP has prescribed an authorized medicinal product
  - Minister for Medical Care 15.06.2018: pharmacy preparations are an ‘alternative to registered medicines, when prices are excessively high’
- 1 July 2018: entry into force of Decree on ‘sluis’ (‘lock’), Stb. 2018, 131
  - no reimbursement pending negotiations if budget EUR 40 million, certain >€50K treatments with > €10M annual costs
- Ongoing measures (e.g. TK 29477, 510, 11 July 2018)
  - Replace high-priced countries in Maximum Prices Act as of 1.1.2020
  - Compulsory licensing: awaiting report Dutch Federation of Universities Q1 2019
  - Roundtable announced October 2018 to discuss ‘medical need’ when switching
  - Bundling purchasing power (reference to international cooperation)
  - Discussion with VIG (EFPIA member) to achieve more transparency

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Germany (Hans-Jürgen Seitz, IGES)

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Topics

- **AMNOG-Mixed Prices: Recent Court Ruling**
- **Physician Information System (AIS): Update**

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AMNOG-Mixed Prices: Ruling of Federal Social Court

Background

- AMNOG benefit Assessment
- Price Negotiations
- Arbitration Board
- Objection of GKV-SV to Decision of Arbitration Board on Mixed Prices regarding (Eperzan ® (albiglutid; Glaxo-Smith-Kline) and Zydelig ® (idealisib; Gilead) and the mixed price system in general
- Germany has “one” reimbursed price for a product (pack), irrespective of the indication or patient subgroup (area of application) it was prescribed for
- Mixed prices are relevant, when G-BA has separated several patient Subgroups (AoA) with different comparative therapies and different additional benefits

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One „mixed price“ for all populations

Comparator costs and added benefit may differ between patient populations

Reimbursement price applies to all populations

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AMNOG-Mixed Prices: Ruling of Federal Social Court

Urgent resolution of Social Court Berlin-Brandenburg

- Mixed price system is unlawful if G-BA has allocated different AoAs with different comparators and different additional benefit

Judgement of Social Court Berlin-Brandenburg

- Some critical aspects on lawfulness of mixed prices

Federal Social Court (FSC) Judgement

- Ruling of Social Court Berlin-Brandenburg was lifted and objection of GKV-SV was rejected
- 3 areas of implications

Source:
http://www.gerichtsentscheidungen.berlinbrandenburg.de/jportal/portal/t/a0n/bs/10/page/sammlung.psml?pid=Dokumentanzeige&showdoccase=1&js_peid=Trefferliste& ocumentnumber=1&numberofresults=1&fromdoctodoc=yes&doc.id=JURE170026175&doc.part=L&doc.price=0.0&doc.hl=1%20-%20focuspointhttp://www.lsg.berlin.brandenburg.de/media_fast/4417/l9kr213-16kl.pdf

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AMNOG-Mixed Prices: Ruling of Federal Social Court

1. No general objections against current mixed price system in Germany

- Confirmation of one price and one reimbursed price (§ 78 abs. 3a Drug law, § 130 b SGB V)
- Mixed prices are imperative in case G-BA has allocated different AoAs with different comparators and different additional benefit
- Mixed prices are in line with regulations on economic efficacy law ("Wirtschaftlichkeitsgebot") and constitutional law ("Verfassungsrecht")
- Dependent on subpopulations the mixed prices are sometimes too high, sometimes too low. This will balance out, provided allocation of drug to indications in AMNOG and pricing process is correct

Sources:https://www.bsg.bund.de/SharedDocs/Verhandlungen/DE/2018/2018_07_04_B_03_KR_20_17_R.html (28.08.2019)
https://www.bsg.bund.de/SharedDocs/Verhandlungen/DE/2018/2018_07_04_B_03_KR_21_17_R.html(28.08.2019)

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AMNOG-Mixed Prices: Ruling of Federal Social Court

2. Position of Arbitration Board (AB) was confirmed/strengthened

- AB decides on reimbursed price (in case no initial agreement has been achieved) according to § 130 b Abs. 2 SGB V)
  - Considering all relevant aspects of the individual case, including, indication, annual therapy cost of comparable drugs, European prices of the product and other topics (frame agreement on § 130 b Abs. 9 S 1-3 SGB V)
- High degree of freedom of AB to decide
- Degree of freedom of AB the higher, the lower the quality/validity of the data basis is
- AB is not obliged to publish details of its calculation algorithm for its pricing decision
- It is justified to assume, that prescribers will use drugs according to the allocated additional benefit (i.e. is line with G-BA ruling)

The system as a whole provides an appropriate framework to prevent AB decisions based on arbitrariness

Sources:https://www.bsg.bund.de/SharedDocs/Verhandlungen/DE/2018/2018_07_04_B_03_KR_20_17_R.html (28.08.2019)
https://www.bsg.bund.de/SharedDocs/Verhandlungen/DE/2018/2018_07_04_B_03_KR_21_17_R.html(28.08.2019)

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AMNOG-Mixed Prices: Ruling of Federal Social Court

3. Mixed Prices & Regress System of Physicians

- Prescribers have to follow economic efficacy law (“Wirtschaftlichkeitsgebot”), i.e. to prescribe the most economic drug

- The ruling of the FSC does not comment on relationship between mixed prices and regress system of physicians

The mixed price system is a regress neutral system

Sources:https://www.bsg.bund.de/SharedDocs/Verhandlungen/DE/2018/2018_07_04_B_03_KR_20_17_R.html (28.08.2019)
https://www.bsg.bund.de/SharedDocs/Verhandlungen/DE/2018/2018_07_04_B_03_KR_21_17_R.html(28.08.2019)

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PHYSICIAN INFORMATION SYSTEM (AIS)

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Physician Information System (AIS)

AMVSG: March 2017

- Prerequisites for the use of electronic programmes in the delivery of care (§ 35 abs. 3a; § 73 Abs. 9 SGBV)
- G-BA decisions need to be integrated
- Decisive: “Guideline” from MoH (Ministry of Health)
  - Regulations range and framework
  - Medical Information, Economic Information, Interoperability with other systems….
  - to be expected soon…. (May/June 2018), to be expected in about 3 weeks …. (August 2018)
- New AIS is to be seen in the context of e.g.
  - early benefit assessment, IQWIG assessment, Hearing, G-BA Decision
  - Drug-Guidelines (AMR), Guidelines (Leitlinien, etc.) Congresses

? **General question: Information supporting autonomous therapy decisions or (generally) binding information**

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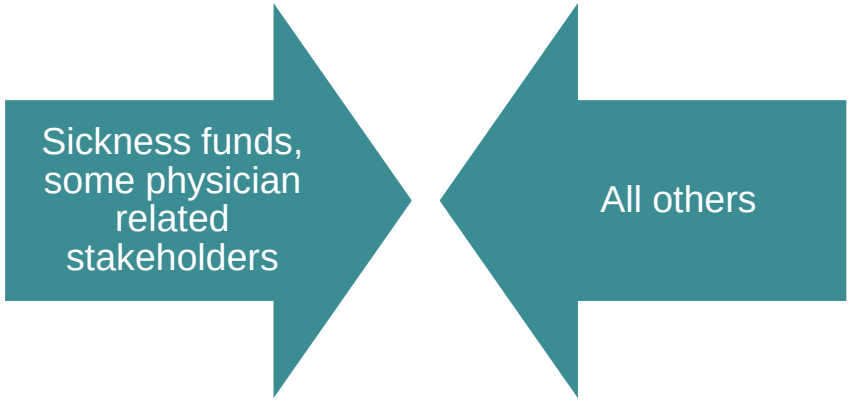
Physician Information System (AIS)

Do we move towards a traffic light system ?



Broad Spektrum of Stakeholder interests ranging from pure medical information via inclusion of economic information to a system directing prescribing behaviour of physicians for products after having passed early benefit assessment

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Physician Information System (AIS)

State of Play:

- **Framing guidelines of MoH further delayed, so no details available yet**
- **Likelihood for "soft system" increases but uncertainty remains**

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France: Priorities of the French Government for year 2018-19 in the healthcare sector (Alexandre Regniault, France Biotech)

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Priorities of the French Government for healthcare (2018-19)

Alexandre Regniault
France Biotech / Simmons & Simmons LLP
alexandre.regniault@simmons-simmons.com

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Priorities of the French Government for healthcare (2018-19)

- Social affairs and health
- A plan for hospital reform
- Health products: background
- Health products: measures announced at CSIS on 10 July 2018
- Timeline

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Social affairs and health

- Remit of Ms. Minister Agnès Buzyn is wide: “solidarities (social affairs) and health”
- Parliamentary committees also cover both social affairs and health in both chambers
- Following months will be very busy on social affairs
  - Plan to fight poverty (to be announced mid-September)
  - Opening negotiations on unemployment benefits reform
  - Resuming discussions on pensions (Government officer to outline reform by Dec.18 / Jan.19)

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A plan for hospital reform

- Plan for hospital reform to be announced “mid-September” 2018 – should be articulated around 5 work streams
  - Improving quality and relevance of healthcare (“we should pay for what works”)
  - Methods for financing and regulation
  - Professional education and quality of working conditions for HCPs
  - Digital transformation
  - Territorial organisation of healthcare

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Health products: background

- French Government had difficulty anticipating the financial impact of the current “wave” of therapeutic innovation (started with hep. C therapies in 2014)
- Cost of health products [outside hospital] has grown by € 9.9 bn over 2010-2017
- Pharmaceutical companies have contributed an effort to control spending, through various mechanisms:
  - Price cuts
  - Capping annual revenue
  - Sharp increase in clawbacks paid to the social security system

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CSIS 2018: 1) “Faster access to innovation for patients”

- **Measure 1: Speeding up procedures for clinical trial authorisation**
  - Target for ANSM (competent authority): 45 days (medicinal products, MD/IVD) or 110 days (ATMP)
  - Target for ECs (“CPPs”): 60 days

- **Measure 2: Speeding up procedures for market access**
  - Target: 180 days by 2022
  - CEPS staff to be reinforced (+6 FTE)
  - Tighter frame for negotiation with CEPS
  - New “letter of orientation” + new Leem-CEPS framework agreement

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CSIS 2018: 1) “Faster access to innovation for patients” (ctd.)

- **Measure 3: Extending early access to innovation (ATU)**
- **Measure 4: Extending the scope of the medico-economic evaluation of health products**
- **Measure 5: Developing mechanisms for early reimbursement of medical devices**

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CSIS 2018: 2) “Research, education: public and private sectors together to meet tomorrow’s challenges”

- **Measure 6: Improving implementation of a “single agent” to manage patents co-held by public entities**
- **Measure 7: Developing research through public-private partnerships (staff exchanges, mutual laboratories)**
- **Measure 8: Assisting companies and their employees in their digital transition**
- **Measure 9: Creating “Health Data Hub”, “one of the largest health databases in the world”**

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CSIS 2018: 3) “Bringing momentum to branches to prepare the future”

- **Measure 10: Encouraging a dedicated branch for ATMPs**

- **Measure 11: Creating a “worldwide centre of excellence” for biotech in France (with a dedicated “fund for innovation”)**

- **Measure 12: Developing public and private financing specific to the various stages of maturity of a health product company’s project**
  - VC fund “Innobio II” will aim at raising € 150-250m
  - “FABS” funds to be dedicated to health tech by € 170m

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CSIS 2018: 4) “A more stable and predictable dialogue” between Government and industry

- **Measure 13: Making drug regulation simpler and more predictable**
  - A “floor” of minimal growth for healthcare spending, to be set at 0.5% of global turnover for next 3 years

- **Measure 14: Redefining guidelines to the CEPS, prioritising regulation through agreements**

- **Measure 15: Reforming current HTA tools (SMR / ASMR to be replaced by a new, single assessment tool: VTR)**

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Timeline 2018-2020

Date	Event
Sept. 2018	Government to present health budget bill (“PLFSS”) for 2019 OPECST, Conseil d’Etat and CCNE opinions on bioethics law reform
Oct./Nov. 2018	PLFSS to be discussed in Parliament
Dec. 2018	PLFSS 2019 published
Dec. 2018	End of M.P. Planel’s term as head of drug pricing authority (CEPS)
H1 2019	Bioethics bill to be presented / discussed in Parliament
May 2019	European Parliament elections *(watch for any change in Gov’t)*
Dec. 2019	PLFSS 2020 published
Q2 2020	“Municipales” elections (mayors) *(watch for any change in Gov’t)*

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VI. Outcomes of EMA's accelerated scheme **PRIME** (Steve Norton and Christian Hill, MAP BioPharma)

PRIME update and conditional/approval under exceptional circumstances

Developed for

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by MAP BioPharma 11th September 2018

PRIME from launch in 2016 aimed to support companies with 'potential' to facilitate earlier access

- PRIority MEdicines scheme, launched in March 2016
- Early Access
- Enhanced scientific and regulatory support

Medicines must show potential to:

"Significantly address patients' unmet medical needs"

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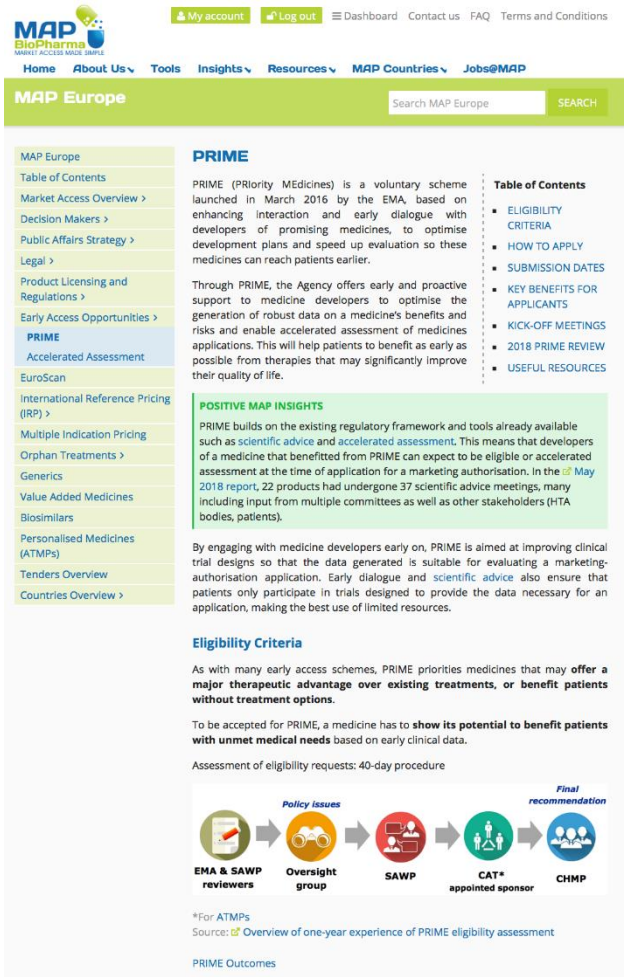
Two years are summarised in the EMA report (7th May 2018) and we track key indicators for PRIME on MAP Online (www.mapbiopharma.com)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PRIME: a two-year overview



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Support for early and broad engagement offered by PRIME, aiming to manage uncertainty from limited data/population

- Single point of contact at EMA assigned early on
- Rapporteur from CHMP/CAT assigned early on
- Scientific advice on development plans, milestones and key issues
- Confirmation of potential for accelerated MA assessment
- Kick-off meeting with CHMP/CAT, experts from scientific committees and EMA staff

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PRIME eligibility requires one of two elements AND potential – it's not easy in comparison to UK PIM, but could be worse!

- To qualify for PRIME, a product should:
  - Offer a major therapeutic advantage, or
  - Treat patients for whom other options are not available

- Medicine's potential must be demonstrated
  - *"Clinically meaningful improvement of efficacy, such as… prevention, onset or duration of the condition"*

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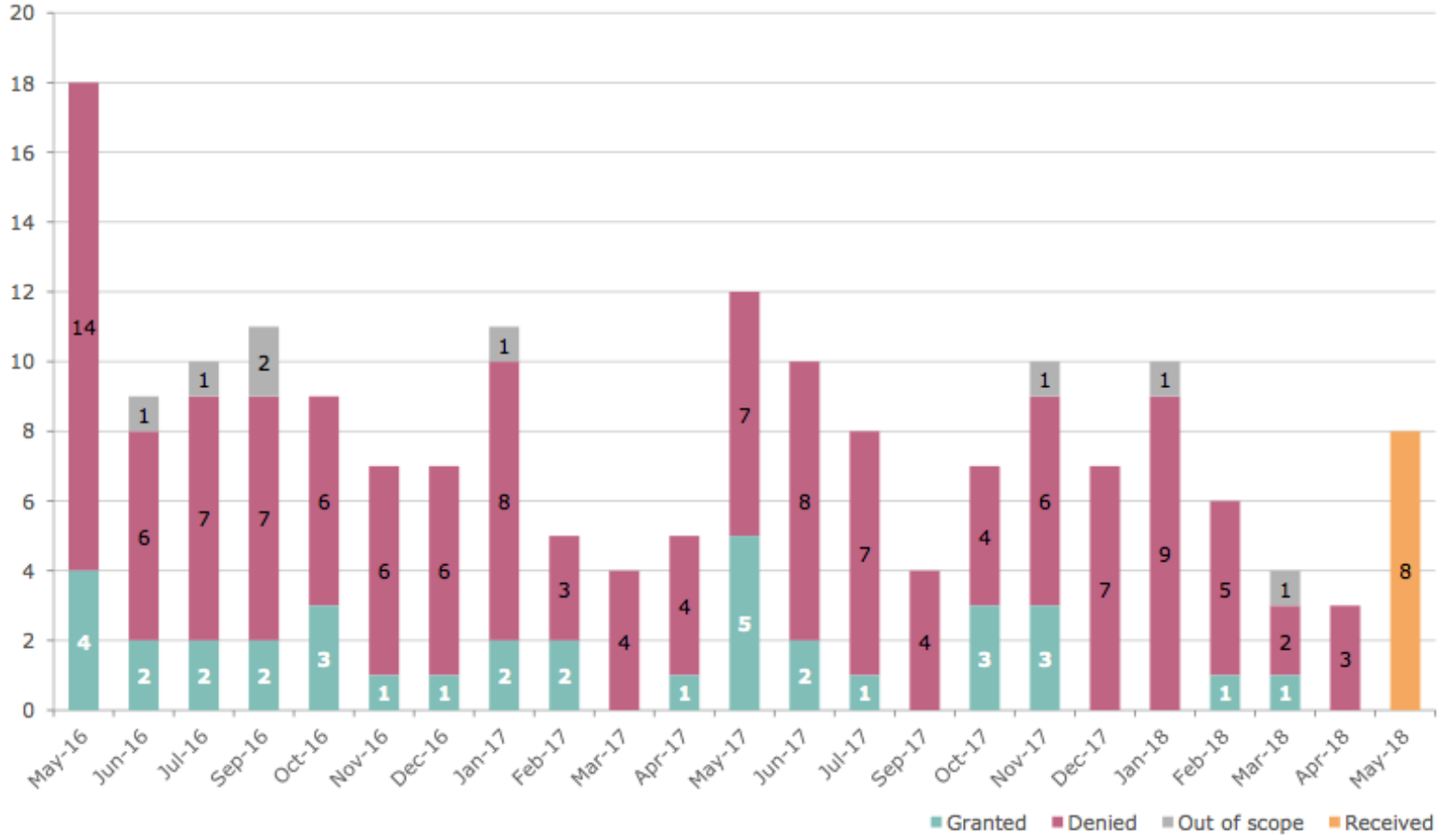
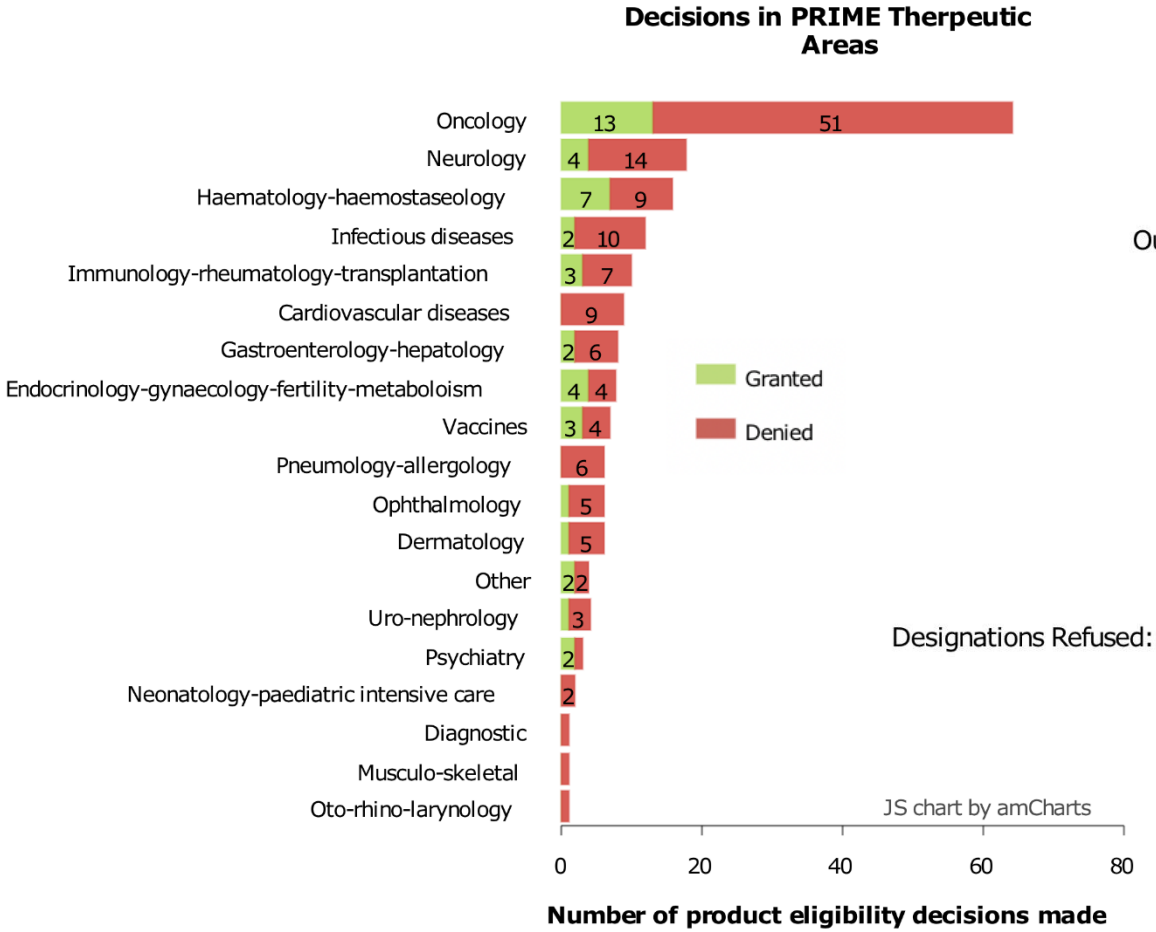
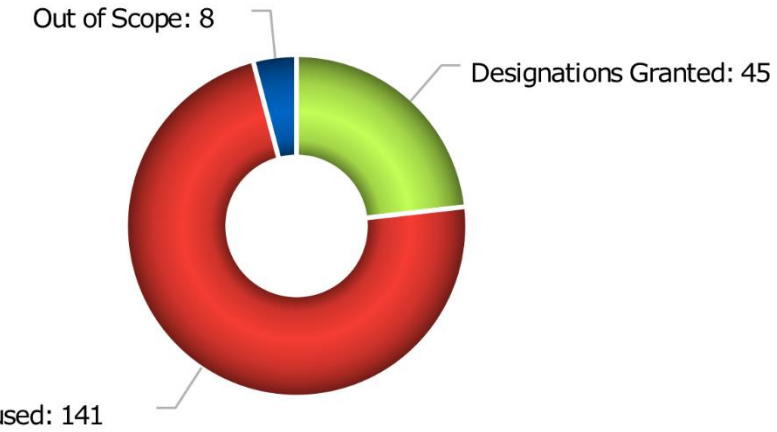
3-12 applications per month, virtually all in scope. EMA is satisfied the community understand eligibility for PRIME



Relatively low success rate across all fields of medicine, more applications in oncology. Approximately 23% successful

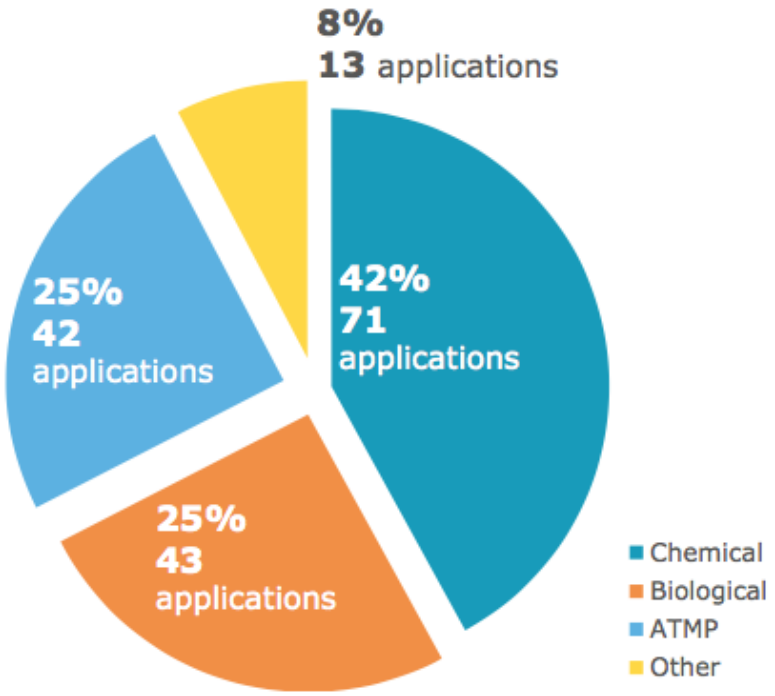




Product areas have not grown equally, many ATMPs

Some trends, coincidental or otherwise

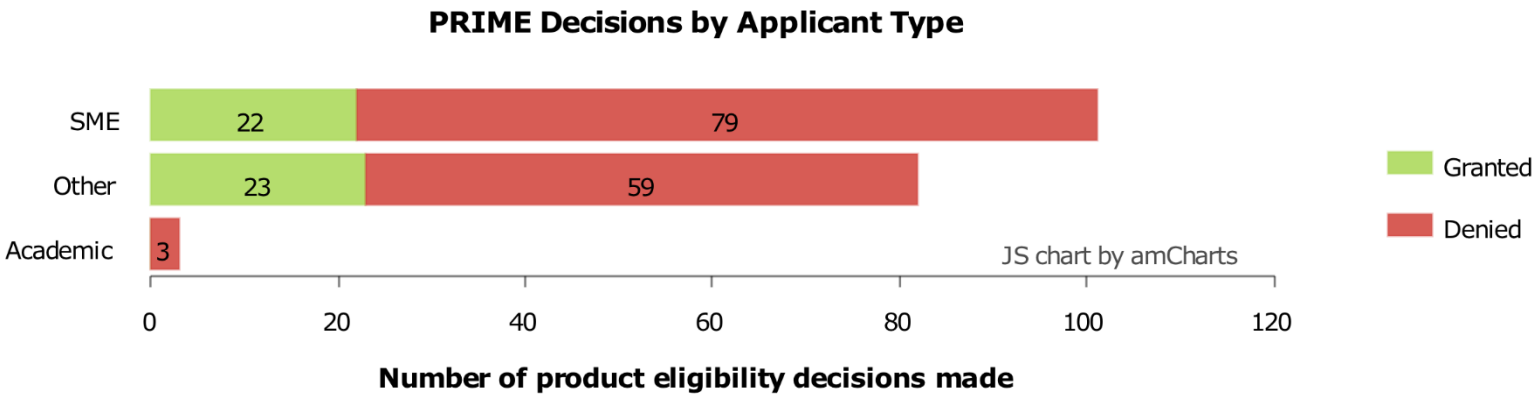
- Year two saw a sharp increase in infectious diseases/vaccines
- High number for ATMPs



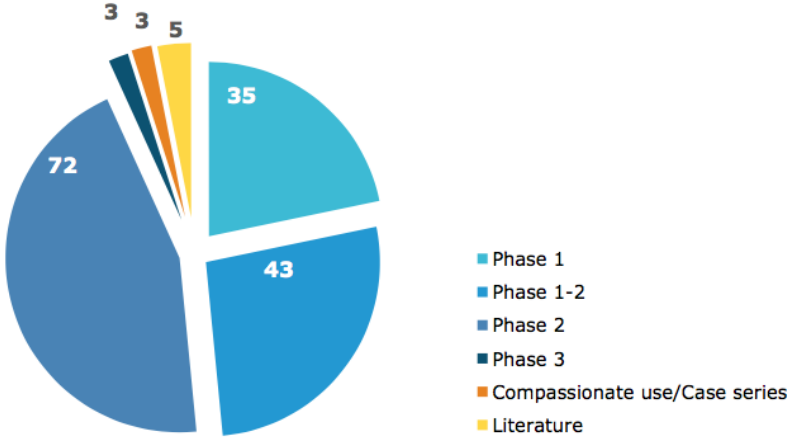
36 products eligible to PRIME since launch

30 in rare diseases | **16** for paediatric patients | **15** advanced therapy medicinal products

All companies apply at Proof of Concept stage, SMEs and academics may apply earlier (Proof of Principle); on average 3 yrs pre MA



- 3/8 Proof of Principle application by SMEs were granted
- Clinical trials usually needed for Proof of Concept applications
- Yr 1 saw more products rejected (14) for being too advanced in development than yr 2 (3)



Outcomes – quite early, which prompted us to resurrect our review of conditional approval or approval in exceptional circumstances

- CHMP recommends first two CAR-T cell medicines for EU use
- Kymriah (tisangenlecleucel) and Yescarta (axicabtagene ciloleucel) went through PRIME (June/May 2016) to EMA approval (June 2018)
- Kymriah announced as funded by NHS England 05 September 2018

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Experience of PRIME

Deuchar and McGettigan, Regulatory Rapporteur – Vol 14, No 10, October 2017

- *"clear guidance with well-defined pathways relating to how a product will procedurally navigate through the application stage to successful designation and beyond, with the key benefits of each scheme being well described"*
- ***"The rejection was based on a single perceived… related to their interpretation of the nonclinical to clinical relationship of a particular parameter not considered to be a primary assessment criterion as per the published guidance"***
- *"it would be extremely helpful if the EMA could publish a rolling list of conditions that they have already concluded, through previous PRIME and PIM applications, do not meet the "unmet medical need" criteria"*

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Two products completed PRIME and CHMP, some interesting trends emerging. What is of interest and we will report back?

Product Name	Therapeutic Indication - Summary	Accelerated Review?	Authorisation type	Orphan (time of CHMP op.)	PRIME?	Active Time Elapsed	Clock Stop Elapsed	MA?	MA Holder	NICE decision date	Lag MA to NICE	SMC Decision date	Lag MA to SMC
Kymriah	Paediatric and young adult patients up to 25 years of age with B-c	Y	awaiting publication	Y	Y			CHMP: 28/06/18	Novartis Europharm Limited				
Yescarta	Yescarta is indicated for the treatment of adult patients with relap	Y	awaiting publication	Y	Y			CHMP: 28/06/18	Kite Pharma EU B.V.				
Vemlidy	treatment of severe vernal keratocon											03/09/2018	59
CRYSVITA	treatment of X-linked hypophos												
Jorveza	Jorveza is indicated for the t											None	
Bavencio	Bavencio is indicated as m										05	07/05/2018	231
Vosevi	Vosevi is indicated for th										0	09/04/2018	257
Maviret	Maviret is indicated for t											13/11/2017	110
OXERVATE	treatment of neurotroph											None	
Brineura	treatment of neuronal c											None	
Spinraza	Spinraza is indicated for											07/05/2018	342
Qarziba	Qarziba is indicated for											Under review	
Natpar	Natpar is indicated as a											09/04/2018	350
Alecensa	Alecensa as monothera											08/05/2017	81
OCALIVA	OCALIVA is indicated for											12/06/2017	182
Venclyxto	Venclyxto monotherapy											07/08/2017	245
NINLARO*	NINLARO in combinatio											09/07/2018	595
Lartruvo	Lartruvo is indicated in c											13/11/2017	369
CABOMETYX	CABOMETYX is indicate											12/06/2017	276
Kisplyx	Kisplyx is indicated in co											10/10/2016	46
Zalmoxis	treatment in haploident												
Epclusa	Epclusa is indicated for											07/11/2016	124
Darzalex	DARZALEX is indicated i											09/10/2017	507
Pandemic influ	prophylaxis of influenza												
Empliciti	Empliciti is indicated in											08/08/2016	89
Coagadex	Coagadex is indicated fo												
Tagrisso	TAGRISSO as monother											13/02/2017	377
blincyto	BLINCYTO is indicated a											13/06/2016	203
Praxbind	Praxbind is a specific re											12/09/2016	297
Kyprolis	Kyprolis in combination											07/08/2017	627
Strensiq	Strensiq is indicated for												
Kanuma	KANUMA is indicated fo												
Lenvima	LENVIMA is indicated as											10/10/2016	501
Zykadia	Zykadia as monotherapy										5	07/12/2015	215
Holoclar	Treatment of adult patie												
Ofev	Ofev is indicated in adult										1	12/10/2015	270
Viekirax	Viekirax is indicated in com										290	08/06/2015	144
Exviera	Exviera is indicated in combi											08/06/2015	144
Scenesse	Prevention of phototoxicity in adu											Under review	
Ketoconazole H	Ketoconazole HRA is indicated for the treatment of endogenous	Y	STANDARD	Y	N			19/11/2014	Laboratoire HRA Pharma			07/09/2015	292
Harvoni	Harvoni is indicated for the treatment of chronic hepatitis C	Y	STANDARD	N	N			17/11/2014	Gilead Sciences Ireland	01/11/2015	349	09/03/2015	112
Daklinza	Daklinza is indicated in combination with other medicinal	Y	STANDARD	N	N			22/08/2014	Bristol-Myers Squibb Pharma EEIG	01/11/2015	436	10/11/2014	80
Sylvant	SYLVANT is indicated for the treatment of adult patients with	Y	STANDARD	Y	N			22/05/2014	Janssen-Cilag International NV				

Summary in numbers

28 accelerated

22 standard

4 exceptional

15 conditional

2 pending

29 orphan

NICE reviewed 23, 8 positive, 7 restricted, 6 CDF, 2 withdrawn

SMC reviewed 28, 14 positive, 9 restricted, 5 negative

NICE/SMC guidance colour coding:

Red – negative

Amber – restricted

Yellow – CDF (NICE)

Green – recommended

Grey - withdrawn

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Thank you for your attention

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VII. **Patients' views on HTA and update on EPF's Access Campaign** (Kaisa Immonen, European Patients' Forum)

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EPF Access Campaign - Universal Health Coverage for All

EPF & Access

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2018 – New WG on Universal Access to Healthcare

"How we can achieve universal health coverage for all"

2017 – Roadmap to achieve Universal Health Coverage for All by 2030

"These are our claims: we need to take action"

2017 - Campaign on Universal Health Coverage

"This is the situation we face"

2016- EPF Report on Access

"This is what Access means to us"

2015 - EPF Definition of Access: "the 5 As"

UN SDGs

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- **Goal 3**: Ensure healthy lives and promote well-being for all at all ages
- **Key target**: achieve **universal health coverage by 2030**, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all

"If we don't get it right in the SDG on health, then there is a risk that the other SDGs will fail" Nicola Bedlington

SUSTAINABLE DEVELOPMENT GOALS

EPF Roadmap to Achieving Universal Health Coverage for All by 2030

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EPF 2017 Campaign on Access to Healthcare: with related advocacy tools, including a toolkit for EPF members and a petition which was signed by 571 signatories.

Articulating our vision: with a Roadmap entitled 'Taking Action – A Roadmap to Achieving Universal Health Coverage for All by 2030'

The campaign set out with the aim to contribute to making **universal access a reality for EU patients by 2030**, through **defining and promoting concrete actions, in concert with the health community**, to which decision makers need to commit, to ensure we achieve the **Health SDG by 2030.**

Universal Health Coverage For All. #Access2030

"WHILE UNIVERSAL HEALTH COVERAGE IS A WELL-RECOGNISED GOAL FOR ALL HEALTHCARE SYSTEMS IN THE EU, THIS BASIC RIGHT IS NOT YET A REALITY FOR ALL PATIENTS IN THE EU, AND FOR THIS REASON, SUCH A ROADMAP IS NEEDED."

STANIMIR HAZARDHIEV (BULGARIAN NATIONAL PATIENT ORGANISATION)

Taking Action – A Roadmap to Achieving Universal Health Coverage for All by 2030

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What is it about?

Leading the way to Universal Health Coverage – a reality where ***everyone***, ***everywhere*** can access essential quality health care and services without facing financial hardship

- Identifying outstanding **challenges**, **patients' concerns** and **unmet needs**
- Providing **recommendations** on how to achieve UHC and what **actions** that need to be taken
- Encouraging more **EU cooperation** and **inclusive approach** to **SDG implementation** to improve access to health

Why does the Roadmap matter?

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While **universal health coverage** is a well-recognised goal for all healthcare systems in the EU, this basic right is **not yet a reality** for all patients in the EU.

For this reason, such a Roadmap is needed.

Universal Health Coverage For All. #Access2030

- This Roadmap opens the way to achieving Universal Health Coverage for All, to ensure the rights of all patients are respected, to fight the inequalities that persist in health across the EU, and to make health a priority in all policies at national and EU levels.

*"Access to healthcare is a **basic human right** and should never be withheld in our society. Without equality in healthcare, we cannot obtain longer-term sustainable development" "Accessing quality healthcare is a problem for a large segment of the population and no longer a "minority" issue"*
Katherine Wheeler, Vice-chair Lupus Europe

What is EPF advocating for?

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- ✓ A **transparent, inclusive** and **collaborative** implementation of the UN SDGs;
- ✓ **Intersectoral action for health**;
- ✓ **Key elements and actions** described in the recommendations which reflect in their entirety the needs that are considered by patients to be **essential in attaining UHC**

SUSTAINABLE DEVELOPMENT GOALS

#Access2030

3 GOOD HEALTH AND WELL-BEING

What do we want to achieve?

- ***Inspire*** and ***motivate*** decision makers and stakeholders to commit to UHC
- ***Guide*** EU and MS when developing SDG implementation strategies and related policies

Who is this Roadmap intended for?

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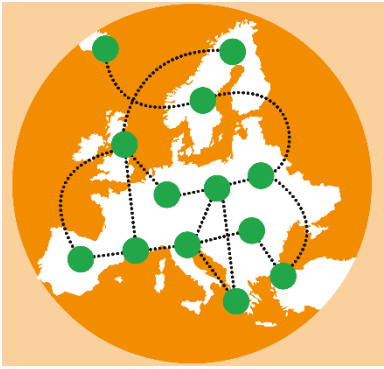
EPF will use this roadmap as a reference document for all our activities on access to health.

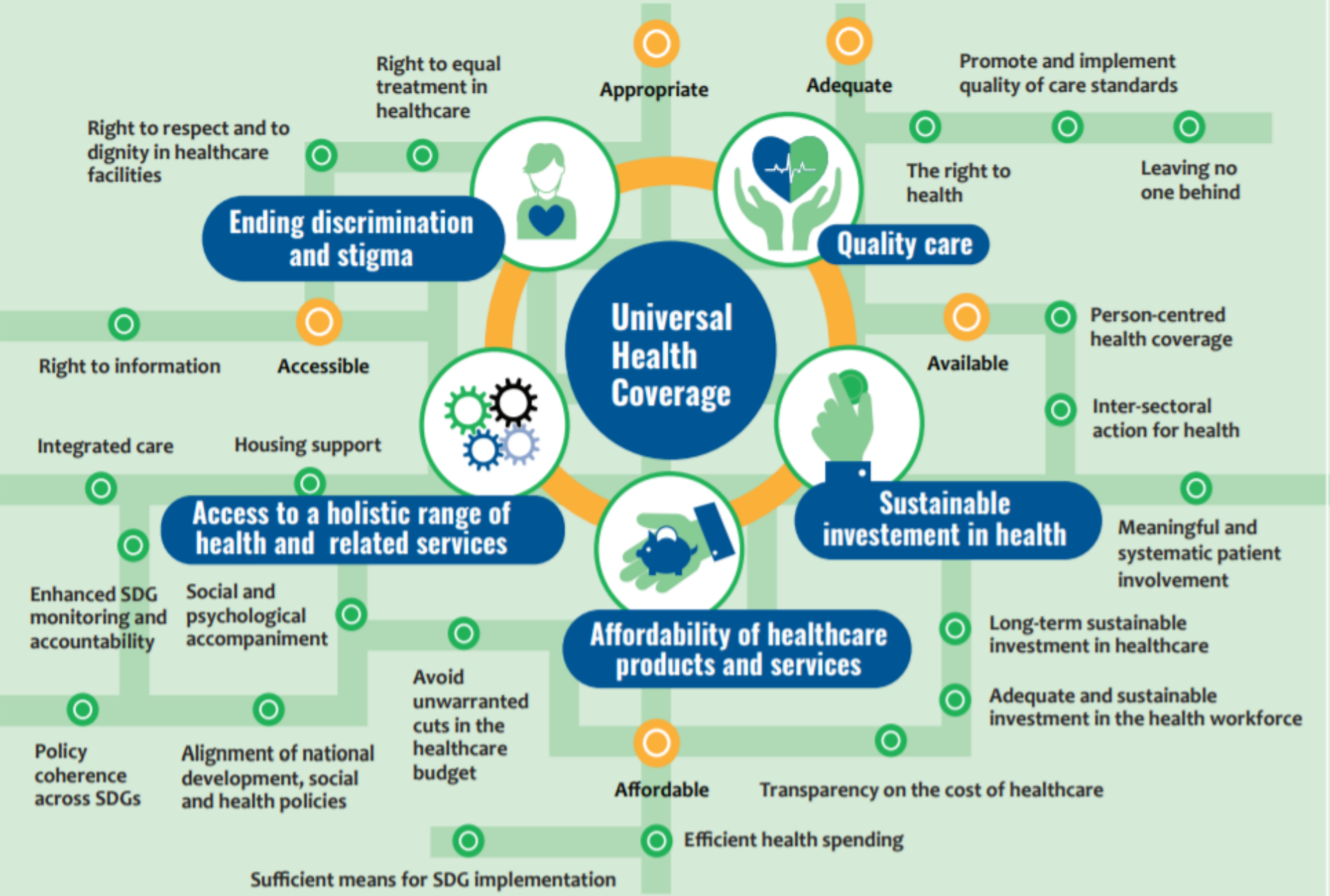
EPF invites **EU and Member State decision makers** to consider this roadmap and its recommendations when developing related policies and UN SDG implementation strategies.

EPF urges **patient organisations and civil society** to use this roadmap to engage with their governments, holding them to account for the implementation of UHC.



- ❑ EU and National SDG Implementation Strategies
- ❑ European Semester Country-Specific Recommendations
- ❑ Delivering on the EU Pillar of Social Rights

The illustration below depicts 5 goals as well as complementary and interconnected key actions to accomplish in order to achieve UHC. These recommendations are described in further detail in the Roadmap.



Next Steps

Subsequent to our 2017 campaign, **equity of access** continues to be a **high priority** for EPF:

- New internal **working group on Universal Access to Healthcare;**
- Focus on the **implementation** of the **political steps and actions** highlighted in our Roadmap;
- **Collaboration** with **organisations representing patients subject to vulnerability and exclusion** to ensure our work reflects the needs of **all** patients
- Continue to raise awareness of **unmet needs and barriers** patients face in accessing healthcare;
- Support the **2030 Agenda** (SDG Watch Europe);
- While advocating for a **transparent, inclusive and collaborative implementation** of the UN SDGs and
- **Intersectoral action for health**
- **Milestones:** three events between now and 2030

'EPF's Roadmap Towards Achieving Universal Health Coverage for All by 2030, will feed into the Commission's broader reflection 'towards a sustainable Europe by 2030', EU Commissioner for Health Vytenis Andriukaitis

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Health Technology Assessment

What is HTA?

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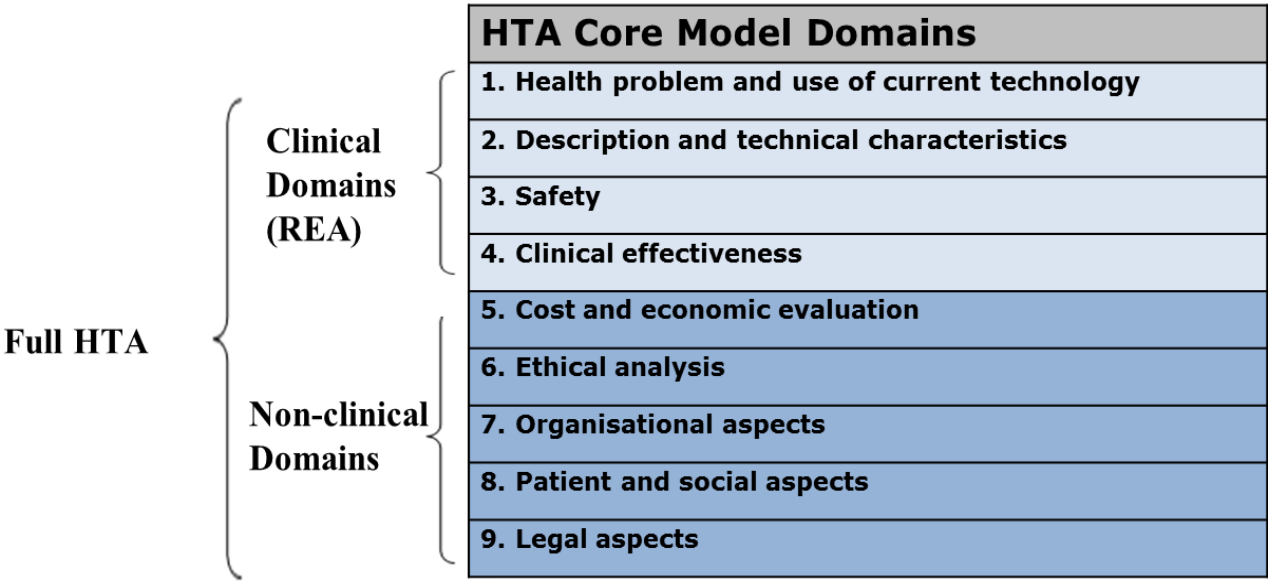
*HTA = "a multidisciplinary **process** that summarises **information** about the **medical**, **social**, **economic** and **ethical** issues related to the use of a **health technology** in a systematic, transparent, unbiased, robust manner. Its aim is to **inform the formulation of safe, effective health policies** that are patient focused and seek to achieve **best value**" (as defined by EUnetHTA JA).*



Why HTA matters to EPF

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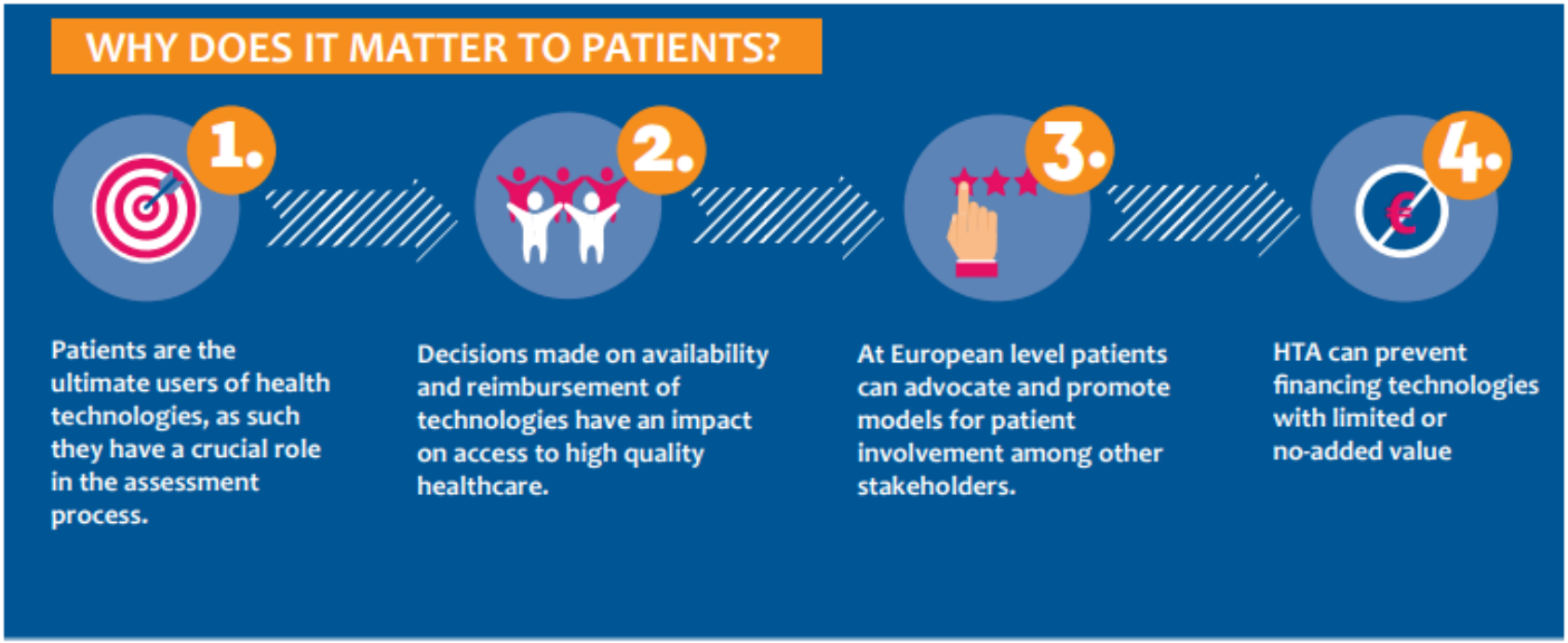
HTA has the potential to contribute to the achievement of "***equitable access to sustainable and high-quality healthcare*** designed and delivered to meet *patients' and informal carers' needs* at all levels of care, *embracing innovation in all its forms*"

EPF Goal #2



How we advocate on HTA

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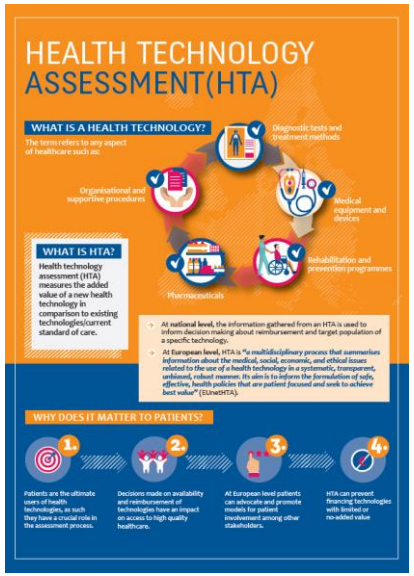
- Consultations with members
- Study on Patient involvement in HTA (2013)
- Webinars and online sessions (check YouTube for our Breakfast Briefings)
- Factsheet
- Briefing on HTA
- Position Paper on HTA proposal
- Open dialogue and exchange of views with other stakeholders



EPF Position on the EC Proposal for a Regulation on HTA

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- Overall proposal 

It responds to a clear need from the patient community to reduce discriminatory effects of different HTA methodologies and divergent results

- Scope of the proposal 

Pragmatic and balanced approach- focus on clinical aspects – based on global evidence. EPF wants medical devices included

- Patient involvement 

COM foresees patient involvement throughout, including in horizon-scanning, joint scientific advice and joint clinical assessment…

EPF Position on the EC Proposal for a Regulation on HTA

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- Patient involvement

- BUT EPF wants patients on the Coordination Group
- Distinction between patient involvement in governance and in assessments
- EP introduced restrictions

- Rules and *modus operandi* of the Stakeholder Network

- Stronger Network with meaningful contribution to the work of the CG
- Guidelines and funding for patient involvement needed

Transparency: lay summaries of all HTA reports should be published

Medical Devices

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EPF supports keeping MDs “in” to reduce the fragmentation of the MDs market and facilitate accessibility to the best (safer, more efficient etc) technologies to the benefit of patients

EPF supports the identified selection criteria (unmet medical needs, potential impact on patients, public health, healthcare systems significant cross-border dimension, EU-wide added value, available resources) as long as it is clarified that “**unmet medical need**” and “**impact on patients**” must be developed with the involvement of patients and patient organisations

EPF understand MDs require a specific approach to HTA

Conclusion

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We are engaging in dialogue with policymakers and stakeholders on this proposal, advocating for stronger and better resourced patient involvement

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VIII. AOB / Next Meeting Date / End of meeting

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Market Access / Pricing & Reimbursement Working Group

11 September 2018, Brussels