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European Confederation of Pharmaceutical Entrepreneurs AISBL

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Pricing & Reimbursement / Market Access Working Group Meeting

Brussels, 4 June 2019

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Competition Law Compliance Policy

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- Current market conditions and issues, including industry pricing policies or patterns, price levels; capacity (including planned or anticipated changes regarding those matters), except where limited to the discussion of historical or public information;

[cont'd]

Competition Law Compliance Policy

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- Information as to future plans of individual companies concerning technology, capacity, marketing or sales; and
- Matters relating to individual suppliers or customers.

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Agenda (1/3)

I. **Welcome / Next Events / Meeting agenda**
Chairs

II. **UK Branded medicines pricing scheme**
David Thomson, Associate Director – NICE Commercial Liaison
Tamir Singer, Head of Commercial Development, Commercial Medicines Directorate, NHS England

Agenda (2/3)

III. **Innovative managed access agreements in EU with focus on Spain and Italy**

Vincent Cheney, Mariangela Prada, Berkeley Greenwood & Max Brosa Riestra, Medvance

IV. **BeNeLuxA – Insights from an industry perspective**

Information Sharing: Patient Registries and RWE

Sandra Paci, Argenx

Agenda (3/3)

V. **The Valletta Declaration: Objectives and Developments**
Patricia Vella Bonanno, Maltese Office of the Superintendance Public Health

VI. **EUCOPE Draft Discussion Paper on market access issues in the Netherlands**
Rob T.A. Janssen, Scalable Life Sciences B.V.

VII. **Country Update / AOB / Meeting conclusion**
Chairs

I.
Welcome / Next Events / Meeting agenda

Chairs

Upcoming Events

- 24 June 2019: EUCOPE Innovative Contracting Workshop, Brussels
- 25 June 2019: EUCOPE Members' Meeting, Brussels
- 26 June 2019: Gene & Cell Therapy Meeting, Brussels
- 3 July 2019: OMP Meeting (TC)
- 4 September 2019: Regulatory / PV / Medical Device Meeting, Brussels
- 10 September 2019: Pricing & Reimbursement / Market Access Meeting, Brussels
- 16 October 2019: EUCOPE Members' Meeting, Brussels

II.

UK Branded medicines pricing scheme

David Thomson, NICE, & **Tamir Singer**, NHS England

III.

Innovative managed access agreements in EU with focus on Spain and Italy

Vincent Cheney, Mariangela Prada, Berkeley Greenwood & Max Brosa Riestra, Medvance

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Innovative managed access agreements
in Italy and Spain

June 4th

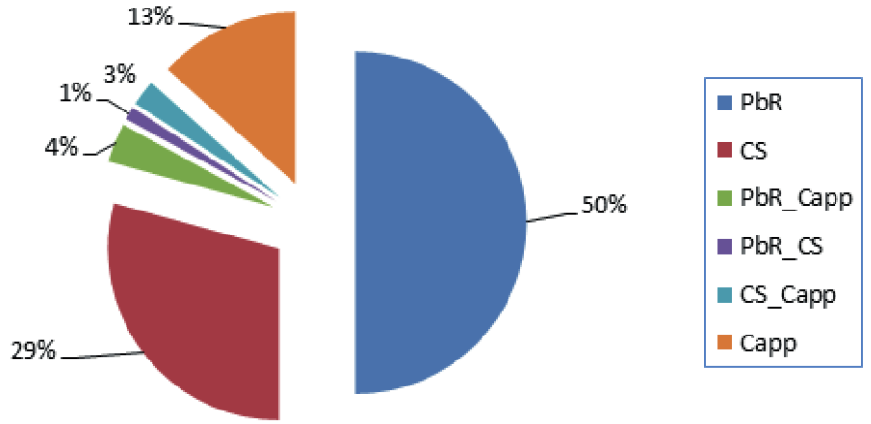
Italy

Mariangela Prada

Italy – Current Environment for Innovative Managed Access Arrangements

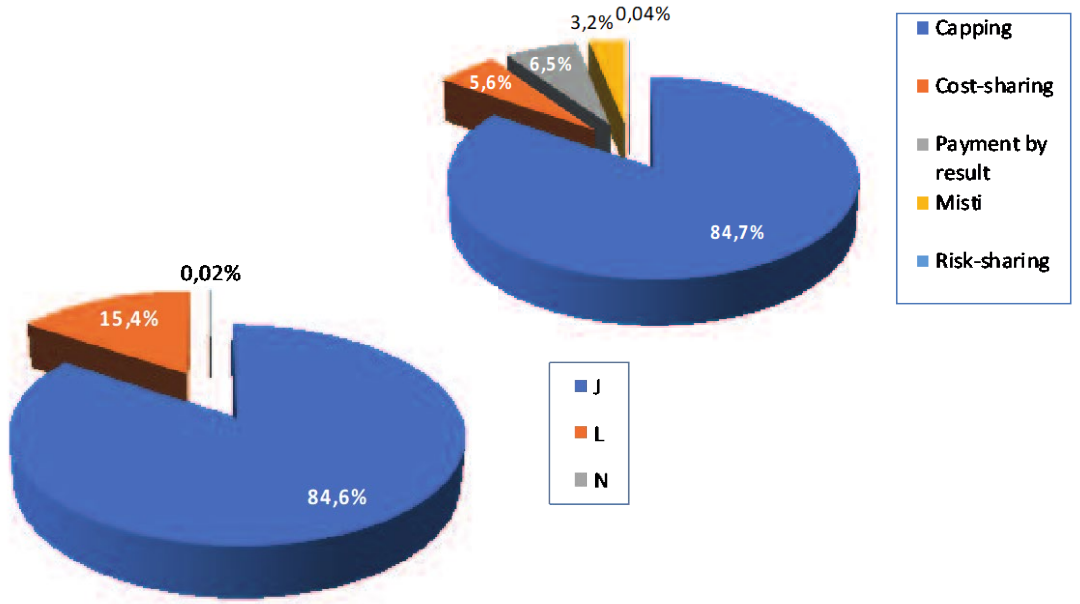
- The Italian NHS has adopted several instruments to manage budget impact, uncertain clinical outcome and appropriate use of medicines:
  - Hidden discounts
  - TP and AIFA Notes
  - **Performance-based risk sharing agreements** (cost sharing, risk sharing, payment by results) managed throughout Monitoring Registries

- The first AIFA MEA was adopted in **July 2006** and to date (May 2019) 44 outcome-based agreements on 163 AIFA Registries (148)/web-based Therapeutic plan (15) are active (108 drugs)
- Of the 44 outcome-based agreements, 10 were agreed before 2010, 11 in 2011-2013, 11 in 2014, 5 in 2015, 3 in 2016, 4 in 2017 and none in 2018-2019
- Outcome-based agreements stopped around 18 months ago, despite appearing to reduce the time to agreement and increase the efficiency of spending



Italy – MAAs and economic impact and time to market

Regione	Rimborsi ottenuti (€) 2017
Piemonte	35.270.452
Valle D'Aosta	663.725
Lombardia	83.929.270
PA Bolzano	1.481.717
PA Trento	2.701.309
Veneto	32.407.743
Friuli VG	6.153.463
Liguria	11.144.637
Emilia R.	39.566.797
Toscana	42.644.654
Umbria	4.678.161
Marche	9.500.191
Lazio**	38.531.189
Abruzzo	8.710.808
Molise	2.747.757
Campania	97.242.436
Puglia	45.373.481
Basilicata	4.037.527
Calabria	17.993.866
Sicilia	30.057.738
Sardegna	17.004.917
Italia	531.841.836



- An analysis of time to market of oncology drugs approved by the EMA between January 2013 and December 2015 showed that when products are authorized and reimbursed with an outcome-based MEA and a monitoring registry the resulting timeline for the reimbursement approval is strictly reduced.
- Products listed in our analysis and reimbursed with a monitoring registry (13) were associated with a mean shortening of the timing of approval (232 vs. 298 days for products not subjected to a registry).

Sources: AIFA OSMED Report, 2017; Prada et al., *Timeline of authorization and reimbursement for oncology drugs in Italy in the last 3 years*, Medicine Access @ Point of Care 2017; 1(1): e29-e36

Italy - Ready for future challenges…

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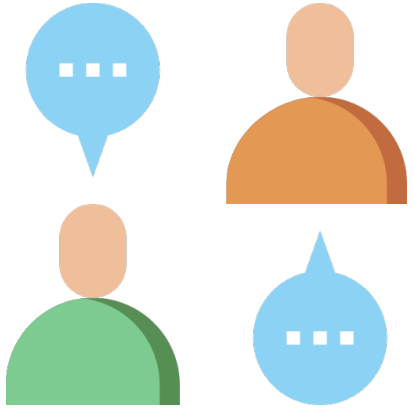
- Management and sustainability of ATMPs → can MAAs be the solution?

	Outcomes-based Agreements	Reinsurance	Consumer Loan	Third-Party Financing	Manufacturer Managed Financing	Government Financing
Features	Payment for results	Payer purchases reinsurance to reduce financial risk of having to pay extremely high costs for individual patients	Patient obtains a personal loan to enable upfront payment for the treatment outside of regular health insurance and repays the loan in periodic instalments. Payments stop if the patient dies or the treatment fails	Payer receives a loan from a financial institution to enable upfront payment to the manufacturer, with loan repayment in periodic instalments. Payments stop if the patient dies or the treatment fails	Manufacturer offers an instalment payment option allowing the payer to pay the cost of treatment in periodic instalments. Payments stop if the patient dies or the treatment fails	Payer receives a loan from the government to enable upfront payment and repays the loan in annual instalments. Payments stop if the patient dies or the treatment fails
Strengths	Addresses uncertainty about clinical benefits Can be combined with amortization methods	Relieves short term budget pressure	Addresses uncertainty about clinical benefits Moves upfront payment to annual fee for performance	Addresses payer uncertainty about clinical benefits Moves upfront payment to annual fee for performance	Addresses payer uncertainty about clinical benefits Moves upfront payment to annual fee for performance	Addresses payer uncertainty about clinical benefits Moves upfront payment to annual fee for performance
Weaknesses	Difficulty of measuring outcomes Difficulty of agreeing criteria for "success"	May be substantial premiums to pay Spreads the risk, but does not address long term sustainability	Untested mechanism Many people unable to afford payments Patient is taking on financing costs unless manufacturer offers a lower price	Untested mechanism Need to address patient switch of health insurer Payer is taking on financing costs	Untested mechanism Needs to address patient switch of health insurer Negotiation of responsibility for financing costs	Untested mechanism Need to address patient switch of health insurer Payer is taking on financing costs

What this means for you…



- A big challenge is AIFA's approach to MAAs, despite the fact that Italy is one of the countries that started early with these kind of agreements

- In the next few months, once the P&R negotiations of the first ATMPs and gene therapies are concluded, the new direction for innovative payment schemes and managed access agreements will become clear.

- In the meantime, companies can be proactive in proposing innovative reimbursement scheme, starting, ideally, an early discussion with AIFA, in order to build, together and on time, a shared access scheme.

Spain

Max Brosa Riestra

Spain – Current Environment for Innovative Managed Access Arrangements

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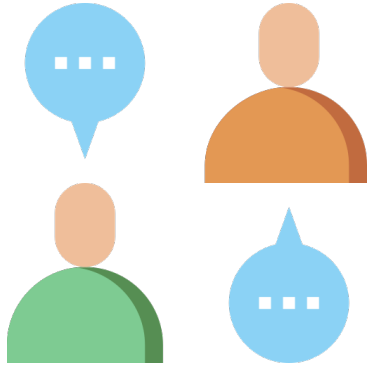
- In 2011 the first payment-by-results scheme was signed in Spain between a regional health service (Catalan Institute of Oncology/Catsalut) and AstraZeneca for the introduction of gefitinib in the treatment of EGFR-positive NSCLC patients.
- Managed Access Agreements available for highly specialised therapies (mainly high cost oncology drugs) from ~2013:
  - At national level, sales cap where agreed during P&R negotiations
  - At regional and, in most cases, hospital level, outcomes-based payment models are used as entry agreements

In the Spanish NHS, the implementation of innovative managed entry agreements has been mainly at local level, lead by hospital pharmacists.

Potential Future Direction of Managed Access in Spain

- [Some] Regions to use MEAs as (almost) mandatory access pathways (e.g. oncology drugs in Catalonia)
- The Ministry of Health has recently introduced a new reimbursement model for high cost drugs that combines different innovative elements (at National level):
  - Nusinersen (2018): restricted use through a clinical protocol, stopping rule, sales cap, patients' registry, … and lifetime free of charge supply to patients in expanded/compassionate uses.
  - CAR-T (2019): instalment payment + outcomes guarantee (50% at treatment and 50% at 18 months for patients in complete response).
- Increasingly willing to gather RWD to allow both outcomes based RSA and price revisions.
- **Potential new role of regional health services in the P&R decisions may further increase the importance of MEAs to achieve a reimbursed price.**

What this means for you…



- The current P&R criteria and procedures are under review in Spain, and a new role for cost-effectiveness information, RWD and outcomes based agreements will probably defined.

- Companies should explore and anticipate potential MEAs including outcomes based RSA to be used during access pathways at different levels (also at national level).

- Early conversations with the Spanish Medicines Agency and the MoH have proved to fasten the inclusion of MEAs within the P&R conditions in recent negotiations.

Thank you!
Questions?

Medvance – Group members

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IV.

BeNeLuxA – Insights from an industry perspective

Sandra Paci, Argenx

V.

The Valletta Declaration: Objectives and Developments

Patricia Vella Bonanno,
Maltese Office of the Superintendance Public Health

THE VALLETTA DECLARATION

The Valletta Declaration

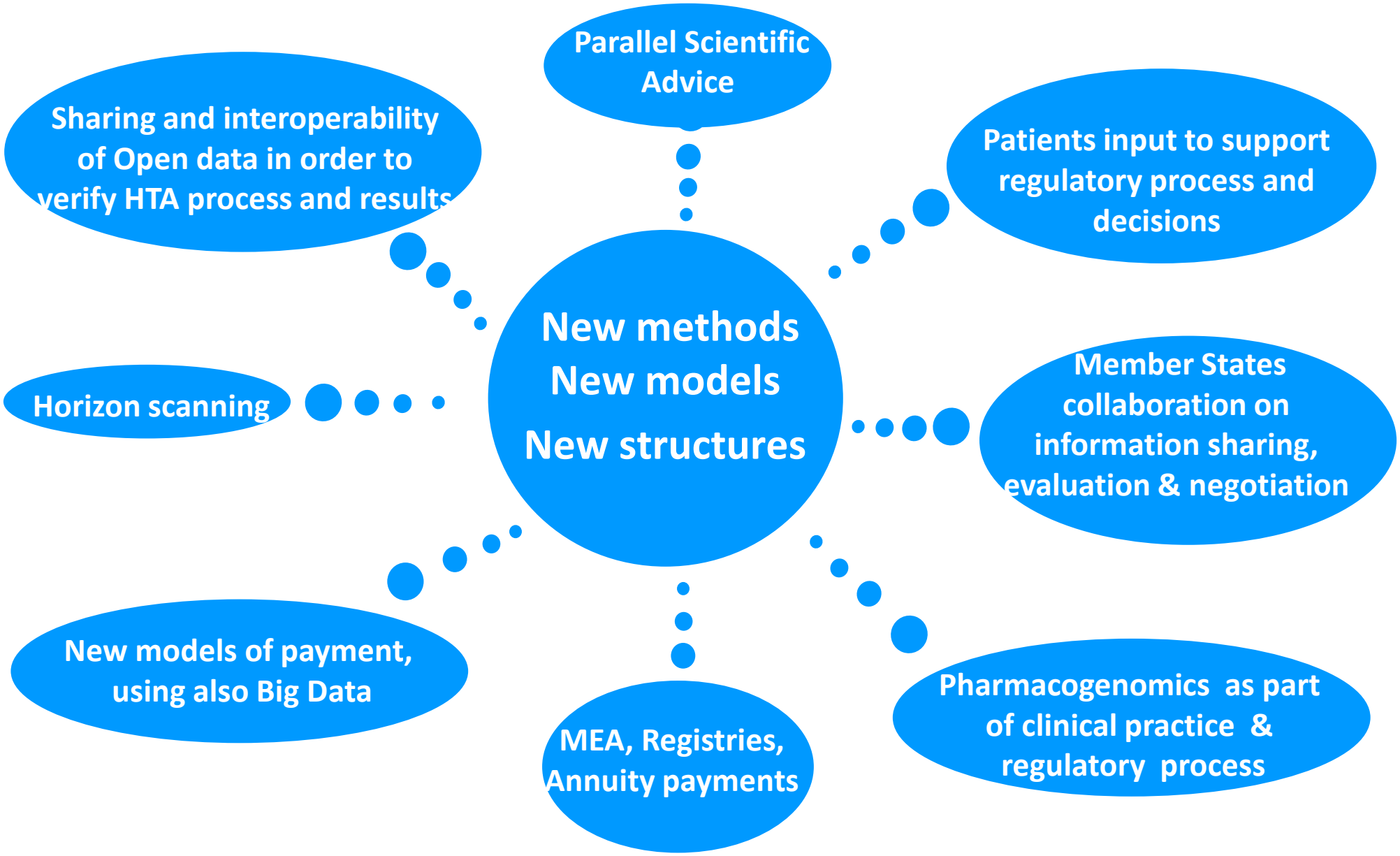
EUCOPE, Brussels

4th June 2019

Patricia Vella Bonanno

Member of the Valletta Technical Committee

How to deal with the ever-increasing spending on pharmaceuticals ?



The Valletta Declaration

Member States expressed their political will to cooperate in full trust, loyalty, solidarity and transparency for better access to medicines, 8 May 2017 in La Valletta

Objectives

- Guaranteeing patients' access to new and innovative medicines and therapies
- Ensuring sustainability of national health systems
- Achieving collaboration between the Member States leading to synergy between these countries

➢ Permanent Technical Committee (**Valletta Technical Committee**):

IT Chair and PT Vice-Chair, Secretariat in La Valletta, Malta

➢ Meetings of the Valletta Technical Committee held, on a rotation basis, in the participating countries, some of which with a joint Ministerial session

➢ Confidentiality agreement signed by VTC Members

The Valletta Declaration

- Croatia
- Cyprus
- Greece
- Ireland
- Italy
- Malta
- Portugal
- Romania
- Slovenia
- Spain

over 160 million citizens

31,5% of EU population

as one aggregated joint market

open to other EU Member States

The Valletta Declaration

- It is a political and administrative agreement between governments of participating Member States
- Different procedures and timing of assessment and negotiation at national level
- The joint assessments should be harmonized and rapid in order not to introduce delays in the access to medicines, and must start at an early stage so as to ensure that no reimbursement dossier is submitted in any country
- Joint output is to be implemented in each country in accordance with its respective legal framework.
- Which price has to be jointly negotiated ? Fixed price? Maximum price? Range of prices?
- Industry is concerned about possible uncertainty in the implementation of joint outcomes at national level
- Need to guarantee confidentiality during the whole process and for the final agreed prices

The Valletta Declaration: activities

- ❑ Structured exchange of information on specific medicines or categories of medicines with significant therapeutic value and high financial impact, in view of:
  - *Input in the negotiation phase*
  - *Renegotiation of contractual arrangements*
- ❑ Strengthening the exchange of comparable information on prices of medicines
- ❑Exchange of information and good practices on policies and on pricing & reimbursement of medicines e.g. for biosimilars
- ❑ Sharing of pharmaco-therapeutical/effectiveness assessments of medicines
- ❑ Horizon scanning of innovative therapies

The Valletta Declaration: activities

- Work on candidate products
  - Selecting new medicinal products for joint work
  - Performing joint clinical assessment and economic evaluation
  - Running joint price negotiations

➢ Choice of medicines
- *Medicines without MA or at early phase of MA*
- *Innovative medicines, including orphans*

➢ Criteria for prioritization of products
- *Interest of the therapeutic indications*
- *Unmet medical need*
- *Cost of therapies*
- *Expected volume of use and prevalence of the disease*
- *Alternative treatments already approved for these indications*
- *Level of cooperation with the marketing authorization holder*

The Valletta Declaration: experiences so far

- Seven meetings of the Valletta Technical Committee (some included a Ministerial meeting)
- Discussion and exchange of information to facilitate the access to medicines and address the challenge of high prices of medicines e.g. approaches for the assessment and use of CAR T cell therapies by National Health Systems; sharing of information on key policy developments such as reference price mechanisms, medicines shortage and availability
- Establishment of strategic collaboration on pricing & reimbursement of medicines amongst national authorities
- Exchange of policy solutions on key issues relating to the access of medicines e.g. Italian delegation presented their intitiative on a draft Resolution submitted to the WHO “Improving the transparency of markets of drugs, vaccines and other health-related technologies”
- Sharing of information and best practices relating to the access of medicines of relevant therapeutical value and/or high financial impact
- Work for joint assessment and negotiation of candidate products is continuing
- Discussion on a proposal for an Institutional Framework to enhance Member State cooperation

Thank-you

VI.

EUCOPE Draft Discussion Paper on market access issues in the Netherlands

Rob Janssen, Scalable Life Sciences B.V.

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Discussion Paper on the Netherlands

Prepared by Alnylam with Scalable Life Sciences

Request for Input

- Analysis of the Dutch situation
  - General description of the system
  - Key issues

- Work in progress

- Does the analysis include the most important issues correctly?

- What should Eucope's position be on this?

Background: The Dutch System

- Mandatory private health insurance with public social conditions

- Outpatients (GVS)
  - Pharmaco-economic evaluation obligatory if budget impact of over € 10 million per year (indications) within the next 3 years

- Inpatients
  - ‘Diagnose treatment combinations’ for less expensive treatments (usually under € 1.000 per treatment)
  - ‘Add-on’ for more expensive drugs
  - Assessment for drugs over € 2.5 million and added value

Background: The Dutch System

- Lock procedure for drugs deemed too expensive
  - Expected annual total costs exceed € 40 million
  - Expected treatment costs per patient over € 50.000 per year *and* expected annual total cost projection exceeds € 10 million

Overall Trend to Increasing Hurdles for Expensive Drugs

- Overall trend to increasing hurdles for expensive drugs
  - Inpatient orphan drugs in particular
  - National negotiations *and* negotiations with insurers

- Following slides: the key issues

Key Issue 1#: More Orphan Products in the ‘Sluis’

- A growing list of orphan products have been put into the ‘sluis’
- Savings limited (?), but politically important
- Result: additional delays
- How do we view this?

Key Issue #2: Uncertainty of Inclusion in the “Lock” Damaging

- While horizon scan process is very transparent and allowing for dialogue, criteria for inclusion in lock are unclear
  - What combination of efficacy data, price, costs and other relevant information will get you into lock?
  - Better timelines needed
  - Early alignment needed on products that certainly can be excluded

- For borderline products formal process should be set-up to get clarity and alignment asap

Key Issue #3: Current Decision Criteria for the Lock (ICER Threshold) Negative for Access

- For products assessed by ZiN there is a threshold
- ICER thresholds reference value stratified for burden of disease The higher the burden, the higher the reference value
- Report shows a negative impact on access decisions:
  - Threshold can result in a reduction of reimbursed drugs
  - If applied, only 33% of pharmaceuticals would be reimbursed
  - Highest reduction of positive advice in high BoD group
- What solutions do we see?

Key Issue #4: Insurers Use "Add-on" Process Increasingly to Force Negotiations (1)

- To obtain the add-on status to be requested by at least one insurance company and one care provider

- Reportedly, some manufacturers experienced that private insurers would use the process to force pharmaceutical companies into negotiations with insurers

- Obtaining an add-on status must be dealt with separately for drugs dealt with nationally determined reimbursement

Key Issue #4: Insurers Use "Add-on" Process Increasingly to Force Negotiations (2)

- If ZiN waives further assessment insurers and buyers are officially responsible for the appropriate use and cost-effective purchasing of these products

- How to ensure that insurers do not hinder access unnecessarily?
  - Transparency?
  - Specific legal criteria that limit the criteria that healthcare insurers can use to refuse supporting the application for an add-on?
  - …?

Key Issue #5: Increasing Collaboration and Centralization Insurers Cause Additional Problems

- A “Joint Buyer” working group of the national association of healthcare insurers (ZN) identifies drug candidates for National Agreement or “multilateral agreements”
  - No transparent, objective and verifiable criteria for identification and process
  - More fragmentation of the pricing and reimbursement pathways and possibly unfair competition between competitors

- Is it enough to push for transparency, timeframes and criteria as in EU’s Transparency Directive (Council Directive 89/105/EEC)?

Key Issue #6: Assessment ZiN Not Well Attuned to Orphan Drugs

- The Current Assessment Procedure of ZiN is not well attuned to the specifics of orphan drugs
  - Low patient numbers, disease variation and fairly unknown disease progression

- The long expected policy paper on this is still not published by Ministry of Health

- What do we want to share and / or propose?

Underlying Issue: Political focus on costs

- Dutch political focus: are drug prices reasonable from a cost perspective?
  - ‘Not value based medicine but costs plus’
    - Cost savings not really taken into account
  - Industry easy target

- Solutions?
  - Building trust by giving insight into average development costs for specific product groups on a sectoral level?
  - ‘R&D costs not essential for drug price’

VII.

Country Updates / AOB / Meeting conclusion

Thank you for your time