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Cell and Gene Therapy Working Group
17 September 2018
12.00 – 16.00 CET

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Agenda (I)

I. **Welcome and introductions**

II. **Narrative – next steps**

III. **National market access updates**

- UK
- Germany

IV. **Priorities**

- Alternative funding models for one-time treatments
- Affordability challenges (including HTA, hospital exemption, horizon scanning, national market access issues)
- Cross-border healthcare directive and associated challenges

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Agenda (II)

V. EUCOPE Meetings with National Health Authorities

VI. European Consultations

- European Commission consultation on Good Clinical Practice for Advanced Therapy Medicinal Products closes
- EMA draft qualification opinion on Cellular therapy module of the European Society for Blood & Marrow Transplantation (EBMT) Registry.
- EMA upcoming consultation on (likely early 2019)

VII. Update on synergies with other initiatives

VIII. AOB/Next meeting/closure of meeting

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II. Narrative

- Version circulated incorporating member comments
- Images for possible inclusion:

- **Key questions:**
  - **Do we have the narrative designed as a brochure for wider circulation?**
  - **Is it circulated alongside moving forward other priorities or as a stand alone piece?**

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Autologous *ex vivo* gene therapy:
Genetic modification of the patient's own stem cells

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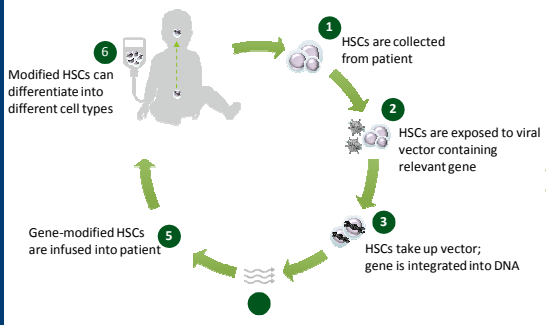

Autologous *ex-vivo* lentiviral gene therapy – correcting hematopoietic stem cells with the potential to:

- Deliver proteins systemically and to the brain
- Correct inherited immune, metabolic and blood disorders

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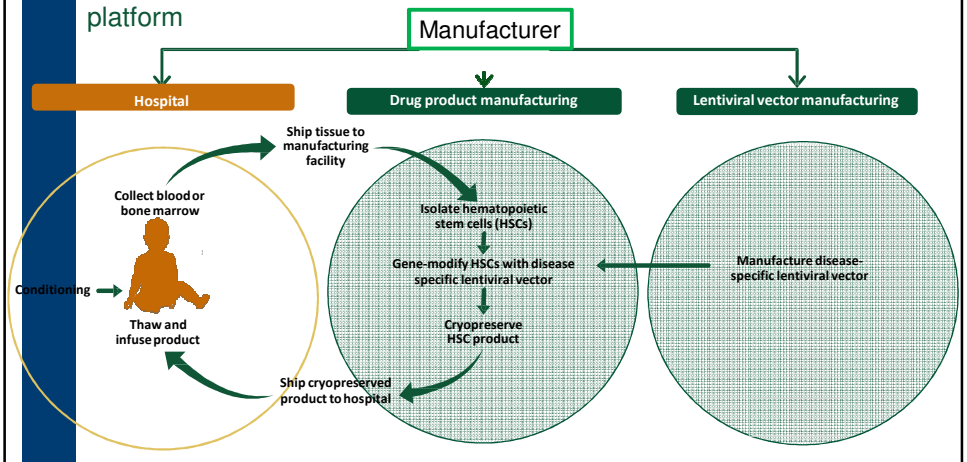
Global and scalable GMP manufacturing platform



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III. National Market Access Update: UK

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III National Market Access Issues – UK

- Current market access landscape
- Changes to NICE and NHSE processes
- Cell and gene therapies: the view from NICE
- Opportunities to influence

UK HTA and reimbursement landscape

Complex set of routes to access:

- England
  - NICE
  - NHS England
  - Regional Medicines Optimisation Committees
  - Clinical Commissioning Groups
- Scotland
  - Scottish Medicines Consortium
  - NHS Scotland
  - Health Boards
- Wales
  - All Wales Medicines Group
  - NHS Wales and Health Boards
- Northern Ireland
- UK wide Pharmaceutical Price Regulation Scheme or Statutory Scheme

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NICE: HTA processes

- Highly Specialised Technologies (HST) programme or Technology Appraisal (TA)?
  - Majority of cell and gene therapies will be TA (probably Single Technology Assessments (STAs)
  - HST only applies to very rare conditions or very small populations treated at a very small number of centres
    - See recent decisions about Duchenne Muscular Dystrophy and Spinal Muscular Atrophy products referred to STA
  - Decision criteria for routing technologies are ambiguous. NICE have indicated they may clarify interpretation of criteria at some point in the future.
- STA= £30k ICER (unless end of life care or other modifier)
- HST = £100-300k ICER
- Cancer Drugs Fund

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Recent changes at NICE I

- Budget Impact test - £20 million in any of first three years will trigger further negotiations with NHS England
  - Likely to lead to phased introduction
- Fast track appraisals for any product likely to have an ICER of £10k or lower
  - Unlikely for most gene and cell therapies but may be possible if high cost treatments already available and substantial savings may be achieve
- Managed Access Agreements to complement Patient Access Schemes
  - Can enable access but likely to have significant evidence generation and other additional requirements as well as price discounts

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Recent changes at NICE II

- Highly Specialised Technologies (HST) programme now has ICER thresholds:

Incremental QALYs gained (undiscounted, per patient, using lifetime horizon)	**Weight**
Les than or equal to 10	1
11-29	Between 1 and 3 (using equal increments)
Greater than or equal to 30	3

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NHS England – the real decision maker?

- New focus on **affordability** – even if cost effective, NHS England may challenge implementation
- Rules based negotiations
  - **Focus on ICER** and total cost
  - Limited flexibilities

NHS England increasingly important in reimbursement decisions

Major challenge for products without large off sets

Is a reimbursement getting harder?

Cell and gene therapies: the view from NICE I

- NICE mock appraisal of a CAR T therapy carried out by York CHTE in 2016
  - It asked if the STA methodology could be used. Not if it should be used.
- Recommendations:
  - The Technology Appraisals framework is applicable to regenerative medicines and cell therapy technologies.
  - NICE continues to further develop the ways in which uncertainty can be quantified and presented to decision makers.
  - NICE collaborates with other stakeholders to develop practical payment methods for managing and sharing financial risk, such as lifetime leasing.
  - NICE takes account of this study when reviewing the criteria for when the 1.5% discounting rate should be applied.

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Cell and gene therapies: the view from NICE II

- NICE stands by its Technology Appraisal methodology as fit for purpose:
  - Cell and gene therapies are not sufficiently "different" to require changes to standard NICE methodology
  - No case for taking rarity alone into account. NICE does not recognise evidential challenges for most rare diseases.
- NICE has committed to working towards greater consistency in decision making between Technology Appraisal committees with improvements to governance and formal regular discussion of key issues (e.g. discounting) to be established.

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Anticipated changes I

- Consultation on charging companies fees for appraisals
- New NICE commercial unit and NHS England taking formal responsibility for Patient Access Schemes
  - Likely to reinforce dominance of NHSE in decision making
  - Limited capacity makes significant increase in complex schemes unlikely
  - Potential for outcome based agreements when high value has been demonstrated
  - Potential for more guidance from NICE about what Appraisal Committees want to see from industry – what would be likely to lead to success

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Anticipated changes II

- UK-wide Pharmaceutical Price Regulation Scheme (PPRS) to be renegotiated in 2018. This is likely to dominate discussions with industry and the health system for the whole year. Industry is generally considered to be in a weak negotiating position but there may be opportunities for recognition of new technologies.
- Move towards “greater consistency” between approaches of different committees within NICE
- Methods reviews for TA and HST likely after PPRS

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Opportunities for influence?

- Increasing focus on NHSE as key decision-maker
  - Potentially more responsive to public and political influence than NICE
- PPRS – negotiations ongoing priority for Department of Health and key agencies
  - Influence is primarily through UK trade groups
  - Scottish model of earmarked funding for some new treatments not popular in England
  - Potential methods review for TA and HST
  - How much consultation will there be after failure of value based pricing?

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III. Gene Therapy reimbursement in Germany

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Reimbursement issues: CAR T-cells

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- As gene & cells therapies are **in-patient products** the main focus should be on DRGs and NUBs
- The **NUB is the main market access tool** as the AMNOG process sets the price only out-patient while DRGs / NUBs reimburse the in-patient use
- Positive NUB status (1 or 4) is usually needed as the reimbursement by DRGs is limited – **see slide 10**
- **For CAR T-cells used in hematology NUB 4 status already exists**
- **GBA is likely to consider the products as eligible for AMNOG** as apheresis is well known and as the transfusion itself is rather standard practice as well (the process in between is rather complex but seems not relevant for GBA to consider the product a method) to be discussed with GBA
- **In case of low out patient turnover: company could claim for AMNOG waiver**
- **BUT: a positive AMNOG outcome (which for OMPs is likely) might help significantly for the uptake in hospitals**

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NUBs for ATMPs for 2017

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- **NUB status 1 difficult to obtain for ATMPs** due to limited patients numbers, few data and limited usage in hospitals prior to the InEK application
- **Most ATMPs have obtained NUB status 4 again for 2017** which allows for reimbursement in individual cases such as:
  - Talimogen Laherparepvec (Imlygic), position 654 (**117 hospitals**);
  - Alipogene tiparvovec (Glybera), position 671 (**4 hospitals**) and
  - Ex vivo expanded autologous human corneal epithelial cells (Holoclar), pos. 670 (**5 hospitals**)
  - **And for the 1st time in 2017: CAR T-cells, position 656 (84 hospitals)**

Panel outcomes:

- **More than 90% of the university hospitals negotiate on NUB 1, less so on NUB 4.**
- **NUB 4 status is not necessarily negative if: GBA, GKV-SV (AMNOG) backing, negotiation support and disease awareness in unmet need exists.**
- **Hence, it is of utmost importance to raise disease awareness at payer level.**
- **A public statement by GKV-SV and positive GBA assessment (AMNOG) backing the reimbursement will likely help** like in the case of Glybera which has been reimbursed.

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NUB list InEK

§ 6 (2) KHEntgG: Informationen für 2017

lfd. Nr.	Verfahren	Status 2017	Information bezüglich § 137h Abs. 1 Satz 1 SGB V	Anzahl der anfragenden Krankenhäuser
656	Gabe von CAR (Chimärer Antigen Rezeptoren) T-Zellen zur Behandlung hämatologischer Erkrankungen[2]	4	D	84
657	Intraaortaler Katheter mit parakorporaler Membranpumpe zur Kreislaufunterstützung des linken Ventrikels	4	A	63
658	Zungen- und Gaumen-Geweberetraktoren zur Behandlung der obstruktiven Schlafapnoe	4	A	40
659	Intermittierende druckkontrollierte Katheter-Okklusion des Koronarvenensinus	4	A	31
660	Transkatheter-Implantation einer interatrialen Shunt-Vorrichtung für die Behandlung von Herzinsuffizienz	4	A	26
661	Gezielte Lungendenervation bei symptomatischer COPD	4	B	17
662	Kabelloses kardiales Stimulationssystem des linken Ventrikels zur kardialen Resynchronisationstherapie	4	A	17
663	Donor-Lymphozyten mit in-vitro-Aufbereitung bei schweren Infektionen nach Stammzelltransplantation[2]	4	D	15
664	Implantation gentechnisch charakterisierter Chondrozyten	4	D	12
665	Autologes Zelltherapeutikum mit modifizierten dendritischen Zellen im Rahmen der Behandlung von Glioblastomen[2]	4	D	11
666	Perkutane cavale Klappenstentimplantation	4	A	10
667	Permanentes extra-aortales Herzunterstützungssystem mittels Gegenpulsation	4	A	8
668	Stammzelltherapie bei pAVK und diabetischem Fußsyndrom	4	D	7
669	Adoptiver T-Zelltransfer zur Therapie viraler Infektionen nach allogener Stammzelltransplantation[2]	4	D	5
670	Ex-vivo expandierte autologe, menschliche Hornhaut-Epithelzellen[2]	4	D	5
671	Alipogentiparvovec	4	D	4

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Predictable P&R procedures…

…but few experience in gene therapy for all stakeholders:

- Glybera just announced that it would withdrew from EU markets
- Payers are not used to pay high 600.000 EUR or more (approx. price Strimvelis)
- In-patient: InEK usually grants NUB 4 status
- But procedures are clear: NUB application and AMNOG (very likely if not claimed for an exemption)

What needs to be done:

- **Need to convince KOLs, payers and hospital controlers to use product and negotiate NUB**
- **Get clarity at GBA on AMNOG (method vs pharmaceuticals)**
- **Market conditioning through discussions with payers, InEK, MDKs**
- **Translating product value and prices for one time treatments**
- **Show willingness on pay for performance of deferred payments**

ToDos for pharma companies:

- **Get clarity about AMNOG filing, organize payer panels, prepare payers and hospitals to negotiate on existing NUB status for CAR T-cells (position 656)**

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Scope of AMNOG: gene therapy

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AMNOG is applicable for medicinal products containing a new API launched after 1.1.2011 - but this is often not clear:

Fixed dose combinations = New API?
Gene therapies: pharmaceuticals or methods?

- **Glybera:** http://www.english.g-ba.de/downloads/91-1028-146/Alipogene%20tiparvovec_ENG_2015-05-21.pdf (english GBA report)
  https://www.g-ba.de/informationen/nutzenbewertung/146/#tab/dossier (OMP)
- **Imlygic:** https://www.g-ba.de/informationen/nutzenbewertung/243/ (not finalized yet; non-OMP)
- **Provenge:** https://www.g-ba.de/informationen/nutzenbewertung/143/#tab/dossier (withdrawn from market; non-OMP)

Hence, companies need to be sure about the eligibility for AMNOG of their products early on and seek scientific advice to set up clinical trials in the right manner (right comparator, endpoints).

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Gene therapy: method or drug?

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According to GBA, the role of the physician is the decisive factor for the demarcation based on 4 criteria: (referring to the Federal Social Court case of 19.10.2004 - BSG, B 1 KR 27/02 R – Verteporfin)

- Could the treatment be considered an established practice?
- Is a special capability of the involved physician needed?
- Could the treatment be seen as a normal application of a pharmaceutical by a physician?
- **Is the physician's treatment at least equally important if compared to the pharmaceutical effect of the product itself?**

The distinction between ex vivo and in vivo therapy is one but not the only factor; GBA (Müller): "in gene therapy there is some discretion reg. demarcation", "we know apheresis"

GBA might likely argue that apheresis and transfusion is known, hence: pharmaceutical = AMNOG

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IV Working Group Priorities

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Priorities (I)

- Three overarching priorities were agreed:
  1. Alternative funding models for one-time treatments
  2. Affordability challenges (including HTA, hospital exemption, horizon scanning, national market access issues)
  3. Cross-border Healthcare Directive and associated challenges
- We need to agree how to take each of these forward. We could propose the following:
  1. Alternative funding models
     - Map examples of innovative models in key markets - members will have some experience here that they might be willing to share.
     - Host national level roundtables to move forward discussions on these issues

IV. Priorities (II)

2. Affordability challenges (including HTA, hospital exemption, horizon scanning, national market access issues)
   - Narrative has incorporated high-level concerns regarding HTA and hospital exemption
   - Identify any short-medium term EC level actions
   - Identify which markets will use hospital exemption as a price comparator and consider targeted actions
   - Link in to other EUCOPE groups (e.g. OMPs) and identify if any actions required on horizon scanning
   - Inform/draft EUCOPE responses to relevant consultations

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IV. Priorities (III)

   - National market access issues: "deep dive" discussions to be led by external experts:
     - This meeting: Germany and UK
     - Meeting 3: France and Spain
     - Meeting 4: Italy

3. Cross-border HCD and associated challenges
   - WG members suggested this should be led by EURORDIS group and be less of a priority for the WG.
   - Proportionate activity could include mapping key CBHCD challenges in key markets to feed in to EURORDIS group along with any highlights of good practice. Members will have some insights they may be willing to share otherwise external expertise may be required to undertake brief mapping exercise.
   - Identify core messages for individual company engagement and to feed in to EURORDIS discussions

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V. EUCOPE Meetings with National Health Authorities

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Outcome of EUCOPE's meetings with HAS (France) and GBA (Germany)

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GBA meeting – 30 March 2017

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- **GBA does benefit package for:** ambulatory and hospital care, dental care and psychotherapy
- GBA provides for:
  - Diagnostic & therapeutic procedures and intervention
  - Quality assurance
  - Disease management programs for chronic diseases
  - Assessment of Pharmaceuticals
- **GBA tools:**
  - Reference price groups
  - Exclusion from reimbursement ('lifestyle' drugs)
  - Applications procedures for OTC-exemptions list and medical devices with CE-certification
  - Therapeutic advice for economical prescribing
  - Restriction of exclusion of drugs ('late' Benefit Assessment)
  - Off-label use
  - **Early Benefit Assessment**

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GBA meeting – 30 March 2017

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- **Early Benefit Assessment :** additional benefit over the appropriate comparator (according to GBA 's code criteria's) regarding patient relevant endpoints (mortality, morbidity, quality of life)

Costs of the treatment, the number of patients and the quality requirements are considered for the publication of a **resolution**, which is the basis for price negotiations.

- **National Early Scientific Advice** is increasing (204 in 2016, 10 at the EMA in 2016) related to the extent of the additional benefit

- **Orphan Drugs** have the highest rate of additional benefit/benefit assessment

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HAS meeting with Francois Meyer – 27 April 2017

- Background: From October 2013 to August 2015, the HAS ran an international project titled SEED (Shaping European Early Dialogues for health technologies)
  - The aim of this project was to conduct **pilots on early dialogues between its member HTA agencies and developers of health products** whose products were in the development stage. This collaborative approach to HTA Early Dialogue involved 14 partners across the EU and led to the successful completion of 11 SEED EDs.
- After the project came to an end, it was decided by the HAS to consider cooperation in the field of HTA Early Dialogues within the framework of the EUnetHTA Joint Action 3 running from 2016 to 2020. Such cooperation recently started in 2017, with the launch of the Work Package 5a (WP5a) activities, for which deliverables consist in the following:
  - Develop and establish an organizational structure for Early Dialogues
  - Evaluate how the collection of fees from industry and the redistribution among partners could best be implemented
  - Evaluate how the actual agreement between industry and EUnetHTA partners could be set up
  - Deliver 33-35 Early Dialogues
  - Develop and implement a financially sustainable system for delivering EDs

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HAS meeting with Francois Meyer – 27 April 2017

- Led by the HAS, this project was kicked off with the publication of the call for Expression of Interest to participate in the EUnetHTA JA3 Early Dialogues on 26 January 2017, with the rationale of first proposing Early Dialogues involving only HTA bodies, and then introducing a parallel procedure with regulators.
- A few statements from the April meeting:
  - Alignment between HTA bodies will increase with the number of Early Dialogues completed
  - Patient involvement should help to reduce divergences between countries in the future
  - The European Commission will organise a meeting between members of EUnetHTA and the pharmaceutical industry representatives on Joint Action

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The Netherlands – 21 September 2017: Zorginstituut Nederland

Zorginstituut Nederland

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Discussed Questions

- Is it possible for ZiN to consider an “oral hearing” from a company as part of their response to ZiN report on drug assessment, in particular in case of high impact diseases?
- How do you see the instrument of ‘special consultations’ develop, going forward?
- Can ZiN comment on the role of Companion Diagnostics?
- Does ZiN have a view on a new trend (developed also in the US) which comprises clinical extrapolation from in vitro data?
- Comparator in phase 2/3 clinical trials for an orphan drug: What is ZiN’s general guidance for comparator choice where there are no licensed alternatives?
- Could you please provide us with an update on the status of alignment and collaboration with Belgium, Lux and Austria as it relates to HTA assessment and pricing/reimbursement negotiations/decisions?

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Austria – 28 March: Main Association of Austrian Social Security Institutions

Österreichische Sozialversicherung

- Meeting Mr. Robert Sauermann, Deputy Head of Department of Pharmaceutical Affairs and his team, for a cross-discipline exchange
- Recent changes in the legislation affection pricing & reimbursement
- BeNeLuxA – what progress has been made?

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Sweden – TLV: 13 April in Stockholm

TLV
TANDVÅRDS- OCH LÄKEMEDELSFÖRMÅNSVERKET

- The Dental and Pharmaceutical Benefits Agency, TLV, is a central government agency whose remit is to determine whether a **pharmaceutical product, medical device** or dental care procedure shall be **subsidized by the state**.
- TLV also determines retail margins for all pharmacies in Sweden, **regulates the substitution of medicines at the pharmacies** and supervise certain areas of the pharmaceutical market.
- **Registry**: TLV is managing a pricing database

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United Kingdom – NICE Office for Market Access: 3 May in Manchester

NICE National Institute for Health and Care Excellence

- **OMA helps the life sciences industry engage with NICE and the healthcare system to speed up market access**
- Meeting with Meindert Boysen (Center Director, Centre for Health Technology Evaluation) Carla Deakin (Associate director) and Fay McCracken (Adviser)
- **Brexit** – what main aspects will change for import to the UK? Timeline?
- **In-depth therapeutic market access advice - OMPs, Cell & Gene therapies**

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Italy – AIFA: 16 May in Rome

Agenzia Italiana del Farmaco
AIFA

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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).

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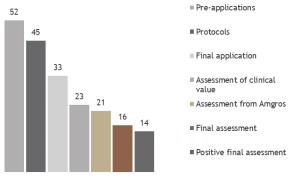
Danish Medicines Council (DMC)

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[44]

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VI. European Consultations

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European Consultations

- Current consultations:
  - European Commission consultation on Good Clinical Practice for Advanced Therapy medicinal Products.
  - Closes 28 October 2018
- Planned Consultations:
  - EMA consultation on the EMA Guideline on Investigational ATMPs (in development, publication may be Q4 2018 or Q1 2019)
  - Consultation likely to last 6-12 months
  - Focus on common standards for clinical trials and assessment of novel products – details unlikely to be shared ahead of formal consultation
- Does the Working Group want to develop/inform a EUCOPE response to the consultation?

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VII Update on synergies with other initiatives

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Update on synergies with other initiatives

- Update from EUCOPE and members on engagement with key initiatives, including:
  - ARM
  - EURORDIS

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Possible synergies with other initiatives

	EUCOPE Cell and Gene Therapy Working Group	ARM (including Market Access initiative)	FIPRA "Multi Stakeholder Initiative on Patient Access and RWE"	EURORDIS Rare Impact Initiative	High-Level Group on Innovation and Provision of Medicines	European Haemophilia Consortium Roundtables
Areas of Interest	Access issues Payment models Developing industry position for policy makers and co-ordination of input into multi-stakeholder initiatives	Identifying Member State readiness for cell and gene therapy (policy, HTA and payer readiness) Potential to develop policy recommendations	Identifying key uncertainties and RWE requirements for complex/rare conditions. Likely to include cell and gene therapies.	Developing policy recommendations to address access issues	Alternative payment models for 'breakthrough', curative, high budget impact medicines	Economics and Access, Health Care Systems and Novel Therapies Switching from Standard Therapies: Where do Novel Therapies Fit In
Participants	Industry only EUCOPE members	ARM – European membership	Multi-stakeholder meetings planned	Multi-stakeholder meetings	Member State government representatives, industry (including EUCOPE)	MEP sponsors, EHC Members, industry representatives, clinical and other stakeholders invited to attend
Timing	Ongoing – first meeting held 20 February 2018	Market access mapping exercise underway	2018	2018-2019 Next meeting: 25 September 2 year project	Ongoing	Regular series of EU Parliamentary roundtables.
Comments	Input in to EURORDIS work Potential to collaborate with other initiatives	Potential interest in collaborating with other initiatives	Focus on outputs from two roundtables	Scoping meeting held Jan 2018 with project to run for approximately 2 years	Need explicit consideration of cell and gene therapies – narrative may help with this	Politically active disease specific group – could be influential and have relevance beyond haemophilia

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VIII. AOB/Next meeting/close of meeting

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Next meeting dates

- Face to face meeting: **confirmed 22 November 2018**
  - Debriefing from national meetings
  - Focus on France and Spain
  - Engagement and advocacy plan
  - Work programme
- Face to face meeting 2: **February 2019** (to be confirmed)
  - Focus on France and Spain ·
- Face to face meeting 3: **April 2019** (to be confirmed)
  - Focus on Italy

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