THE EXPERIENCE OF DNDi:
AN ALTERNATIVE “DELINKED” MODEL FOR NEEDS-DRIVEN R&D

Knowledge Ecology International Meeting on Proposals to Delink R&D Costs from Drug Prices
Washington, DC
December 2, 2016
Rachel M. Cohen, Regional Executive Director, DNDi North America
7 New Treatments Delivered/Recommended

- 30 projects, 8 disease areas
- 17 potential new chemical entities
- Over 160 partnerships, most in endemic countries
- 160 staff, half in endemic countries & 700 people working on DNDi projects
- ~ $450 million raised from public and private sources
- 4 regional disease-specific clinical trial platforms/networks and several technology transfers
DNDi R&D Portfolio (June 2016)
17 new chemical entities in the pipeline

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<thead>
<tr>
<th>Screen</th>
<th>Hit to Lead</th>
<th>Lead Opt.</th>
<th>Pre-clinical</th>
<th>Phase I</th>
<th>Phase IIa/PoC</th>
<th>Phase IIb/III</th>
<th>Registration</th>
<th>Access</th>
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<tbody>
<tr>
<td>HAT</td>
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<td>Fexinidazole</td>
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Leishmaniasis

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<tr>
<th>Screening</th>
<th>Leish H2L</th>
<th>DNDI-5421 DNDI-5610 oxaborole</th>
<th>DNDI-6148 oxaborole</th>
<th>DNDI-0690 nitroimidazole</th>
<th>CpG-D35 (CL)</th>
<th>Anfoleish (CL)</th>
<th>New CL Combination</th>
<th>MF/Paromomycin Combo for Africa</th>
<th>New VL Treatments Latin America</th>
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Chagas

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<tr>
<th>Screening</th>
<th>Chagas H2L</th>
<th>Chagas Lead Opt</th>
<th>Biomarkers</th>
<th>New Benz Regimens +/- fosravuconazole</th>
<th>Fexinidazole</th>
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Filaria

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<tr>
<th>Screening</th>
<th>Macro Filaricide 3</th>
<th>AbbV4083 TylaMac</th>
<th>Emodepside</th>
<th>Two ‘4-in-1’ LPV/r FDC granules</th>
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Pediatric HIV

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<th>Superbooster Therapy Pediatric HIV/TB</th>
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HCV

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<tr>
<th></th>
<th>Ravidasvir/Sofosbuvir</th>
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Mycetoma

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<th></th>
<th>Fosravuconazole</th>
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New Chemical Entity (NCE); Fexinidazole (for HAT, VL, and Chagas disease) = 1 NCE; Fosravuconazole = 1NCE
DNDi as Experiment in ‘Innovation for Access’: Practical Illustration of Delinkage

• ‘Delinked’ funding model does not require recouping R&D investments or financing future R&D through sales or revenues generated by IP

• IP policy ensures that treatments are affordable, access is equitable, and products are developed as public goods

• Public and private contributions pay for the cost of R&D upfront (grant approach), though open to exploring
  • 50/50 public/private
  • No single donors contributes >25% of overall budget (safeguards autonomy, scientific decision-making, etc.)

• Allows DNDi to independently identify needs, gaps, and priorities based on patient needs; promote sharing of research knowledge and data; and price products at ‘lowest sustainable price’
Key Pillars of DNDi Model (1/2)

1. Patients’ needs at the center of the R&D process
   - Therapeutic impact as most important driving force (role of founding partners, e.g. MSF, endemic countries)
   - Target product profiles (TPPs) drive R&D decision-making (ensuring that, by design, products are adapted to ‘field conditions’ and aim for maximum affordability)
   - Commitment to research capacity-strengthening
   - Continuous assessment of needs and landscape

2. Scientific access to data and knowledge and patient access to medicines essential
   - ‘Gold standard’ licensing terms
   - Use of IP flexibilities for research purposes and support for use of TRIPS flexibilities where IP barriers exist (e.g. HCV)
   - ‘Open source’ models for drug discovery (NTD Booster, etc.)
Key Pillars of DNDi Model (2/2)

3. Decreasing R&D costs through partnerships and collaboration

4. Strengthening and harmonizing regulatory mechanisms
Lessons for International Policy Negotiations?

• Establish globally agreed R&D needs, gaps, priorities linked to...

• Adequate, sustainable (public) financing (‘push’ funding and appropriately designed ‘pull’ incentives, e.g. prizes) linked to...

• Globally agreed norms based on principle of delinkage:
  • Accessibility (availability/affordability)
  • Openness, transparency, and access to knowledge
  • Pro-public health IP management and equitable licensing
  • Scientific and technological cooperation
  • Essential regulatory standards
Today no laws prevent drug companies from doubling or tripling prices. So they just do it—and get away with it. The soaring cost of medicine is a major crisis and a moral issue.

Here’s how to send a message to Big Pharma

Democratic presidential candidate Bernie Sanders: I am encouraged to see voters will embrace Prop. 61 on Tuesday and send a powerful signal across nation that the days of unchecked drug company greed are numbered.

**EPIPEN PRICES JUMP**

EpiPen prices are up five times since 2009. The prices insurers and employers have negotiated with Mylan for a set of two:

- $700
- $600
- $500
- $400
- $300
- $200
- $100
- $249
- $615.58

**SOVALDI...**

**$84,000**

**SO EXPENSIVE**

SOURCE RX Savings Solutions
Jim Sergent, USA TODAY
UN HLP on A2M

Key innovation policy recommendations:

- Initiate intergovernmental negotiations for a global R&D convention that delinks the cost of innovation from prices;
- Negotiate a Code of Principles to be adopted by all R&D players, ensuring innovation delivers affordable and accessible products;
- Require transparency from all R&D players, especially on R&D costs; and
- Ensure ‘public return’ on taxpayer-funded contributions to R&D.
From Rhetoric to Action: Opportunities for Concrete Change

• AMR, pandemic preparedness, NTDs: opportunities for new funding and/or approaches, application of progressive principles (G20)
• Implementation of specific recommendations at WHO, WTO, Human Rights Council
• Global Health and Foreign Policy resolution and future UN follow up
• National/regional initiatives and efforts at policy change
• In the meantime, development and voluntary adoption of progressive policy steps, incl Code of Principles by key R&D actors and funders