

BEST
SCIENCE
FOR THE MOST
NEGLECTED

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

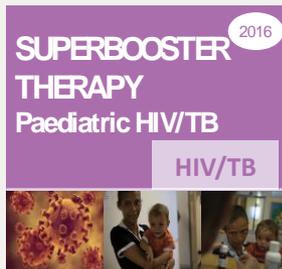
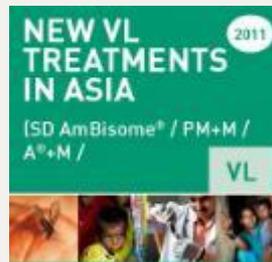
Knowledge Ecology International Meeting on Proposals to Delink R&D Costs from Drug Prices

Washington, DC

December 2, 2016

Rachel M. Cohen, Regional Executive Director, DNDi North America

7 New Treatments Delivered/Recommended



- ✓ Easy to use
- ✓ Affordable
- ✓ Field-adapted
- ✓ Non-patented

- **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

	Research			Translation			Development		Implementation
	Screen	Hit to Lead	Lead Opt.	Pre-clinical	Phase I	Phase IIa/PoC	Phase IIb/III	Registration	Access
HAT			SCYX-1330682* SCYX-1608210 oxaborole			SCYX-7158* oxaborole	Fexinidazole*		NECT Nifurtimox-Eflornithine Combination Therapy
Leishmaniasis	Screening	Leish H2L	DNDI-5421* DNDI-5610 oxaborole Amino pyrazoles* CGH VL Series 1*	DNDI-6148* oxaborole DNDI-0690* nitroimidazole	Fexi/MF Combination*		New Treatments for HIV/VL New Treatments for PKDL MF/Paromomycin Combo for Africa	New VL Treatments Latin America	SSG&PM Africa New VL Treatments Asia
Chagas	Screening	Chagas H2L	Chagas Lead Opt Biomarkers			New Benz Regimens +/- fosravuconazole* Fexinidazole*			Benznidazole Paediatric Dosage Form
Filaria	Screening		Macro Filaricide 3*	AbbV4083* TylaMac	Emodepside*				
Pediatric HIV					Two '4-in-1' LPV/r FDC granules		LPV/r pellets with dual NRTI		Superbooster Therapy Pediatric HIV/TB
HCV							Ravidasvir/ Sofosbuvir*		Malaria FDC ASAQ
Mycetoma							Fosravuconazole*		Malaria FDC ASMQ

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.)

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

blood

Prepublished online April 25, 2013;
doi:10.1182/blood-2013-03-490003

Price of drugs for chronic myeloid leukemia (CML), reflection of the unsustainable cancer drug prices: perspective of CML Experts

Experts in chronic myeloid leukemia



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Bernie Sanders

5 November at 14:25 · 🌐

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 be voters will embrace Prop. 61 on Tuesday and send a powerful signal across nation that the days of unchecked drug company greed are numbered.

SACBEE.COM

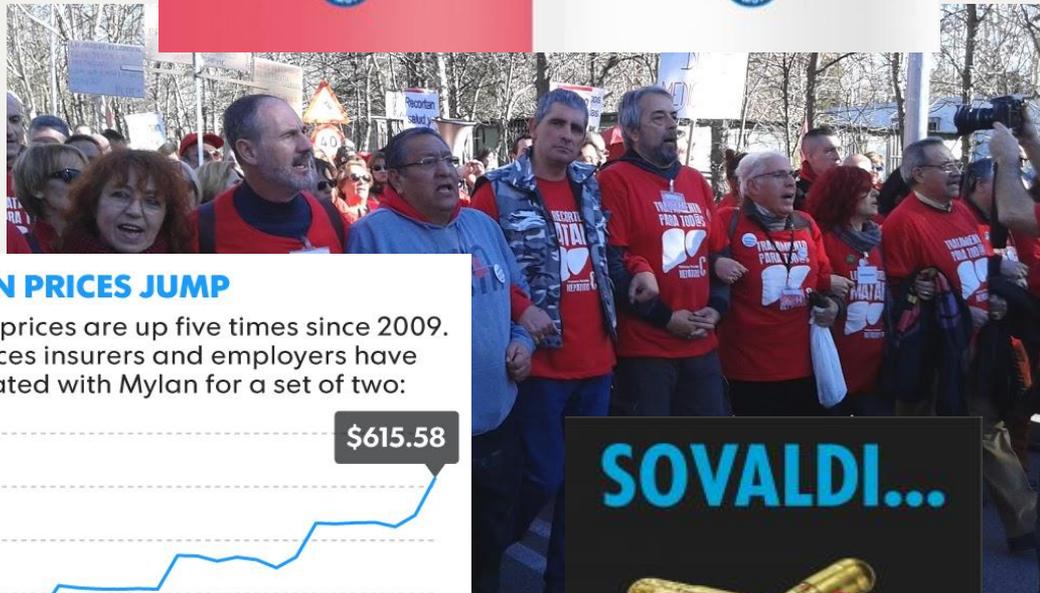


AVEC L'IMMOBILIER ET LE PETROLE, QUEL EST L'UN DES MARCHÉS LES PLUS RENTABLES? LA MALADIE.

Signez la pétition pour faire baisser le prix des médicaments sur www.leprixdelavie.com

SEUL 1% DES FRANÇAIS PEUT SE PERMETTRE D'AVOIR UNE HÉPATITE C.

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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:



SOURCE RX Savings Solutions
Jim Sergent, USA TODAY



SOVALDI...

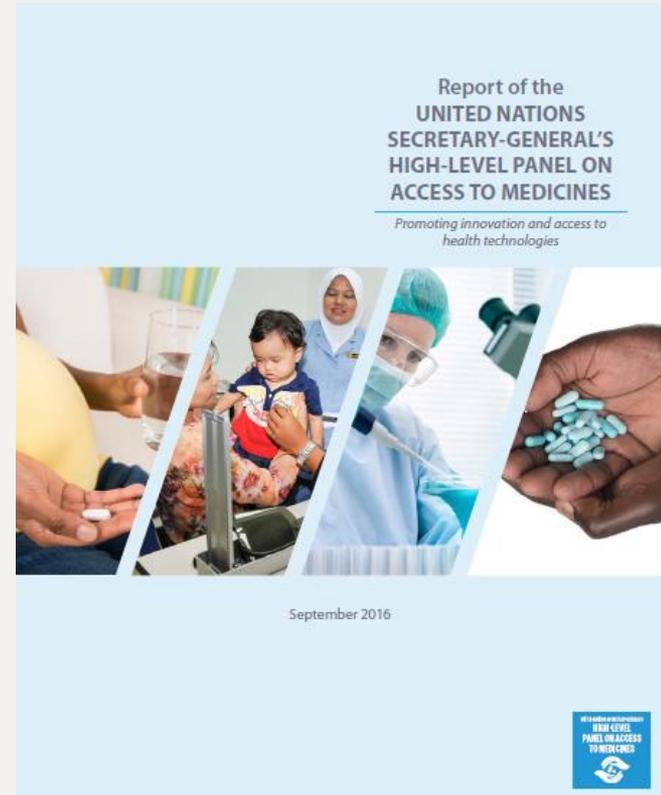
\$84,000

SO EXPENSIVE

INFLU + TAG

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