

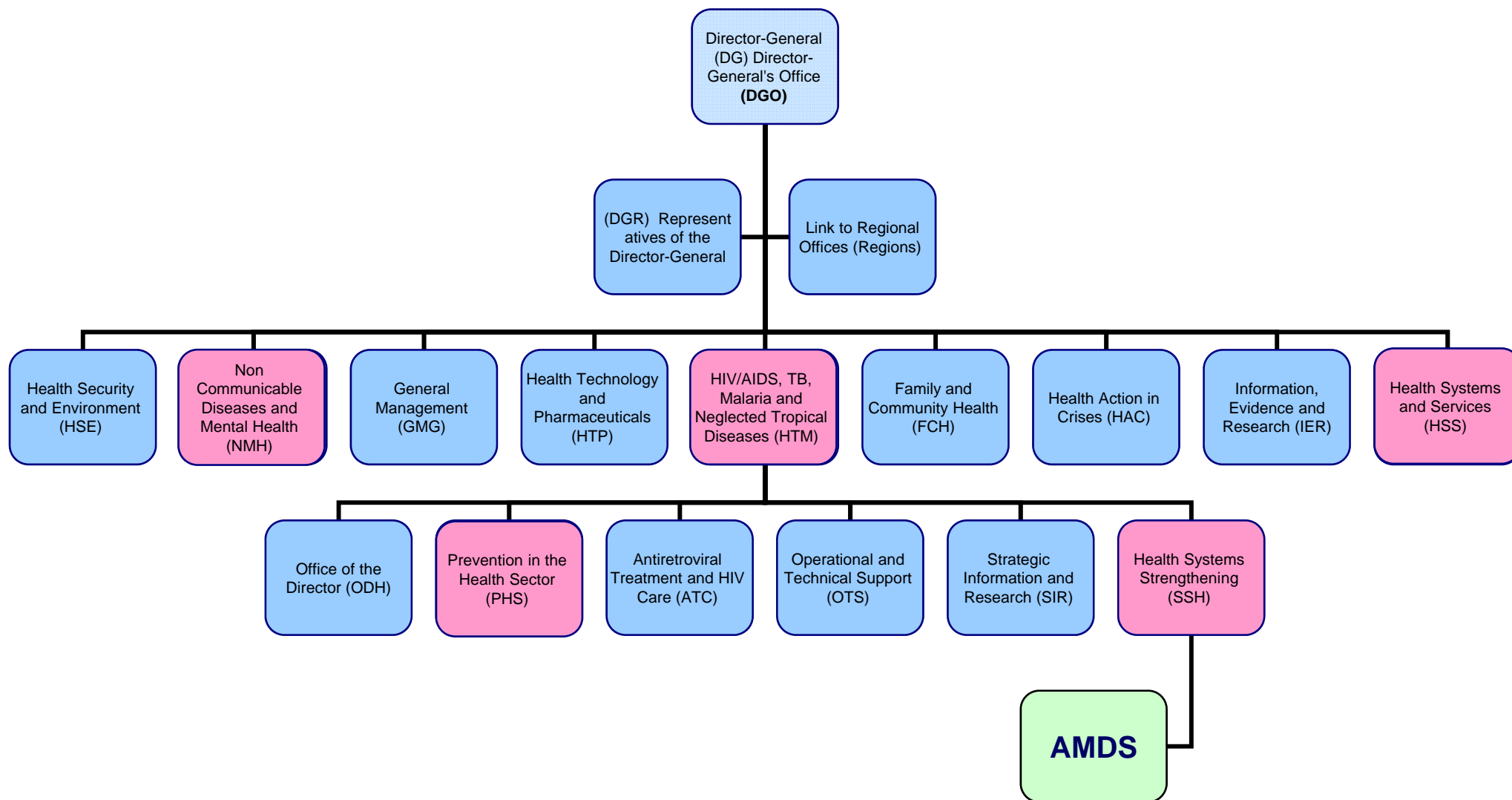
# WHO Controlled Medicines Database

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# Who is carrying out this project?



# AMDS

## AIDS Medicines and Diagnostics Service (AMDS)



AMDS operates as a network. It maps and publicizes the capacity and availability of technical assistance of partner organizations to support capacity building for procurement and supply management, and brokers cooperation between technical partners, funding agencies, manufacturing companies and other organizations.

The AMDS also operates as a clearing house collecting and disseminating global level information on selection and use of antiretroviral (ARV) drugs and HIV diagnostics.

### AMDS INFORMATION

- :: [About AMDS](#)
- :: [AMDS e-library](#)
- :: [AMDS news](#)
- :: [Capacity building](#)
- :: [Country information](#)
- :: [HIV diagnostics](#)
- :: [Prequalification](#)

### PROCUREMENT SUPPLY MANAGEMENT

- :: [Forecasting](#)
- :: [Logistics Management and Information System \(LMIS\)](#)
- :: [Product selection](#)
- :: [Patents and registration](#)
- :: [Pricing](#)
- :: [Procurement](#)
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# WHO's Access to Controlled Medications Programme

To assist countries to improve access to controlled essential medicines

Activities:

- WHO Guidelines for pain management
- Training for estimates on need
- Update of Guidelines on Opioid availability
- Country support
- Policy and legislation analysis
- Procurement of controlled substances (advice)  
and much more....

[www.who.int/medicines under controlled substances](http://www.who.int/medicines_under_controlled_substances)



**World Health  
Organization**

# A new Project

WHO Controlled Medicines Database to improve access to

- morphine
- methadone
- buprenorphine



# Access to Morphine

- Of paramount importance at the late-stage of illness, e.g. cancer, HIV/AIDS
- Classified as 'controlled medicines'
- Access in low income countries is limited – despite low price
- 6 countries consume 79% of the world's morphine (2005 estimate INCB, 2007)
  - United States
  - Canada
  - France
  - Germany
  - Britain
  - Australia
- 80% of the world's population (in low and middle income countries) consume 6%



# Number of untreated HIV/AIDS pain patients

## HIV in developing countries:

- Terminal HIV/AIDS patients 2,866,000
- Near to no access to opioid analgesics
- 50% terminal stage AIDS patients suffer from moderate to severe pain
- → 1,433,000 HIV/AIDS patients will suffer from pain that can be treated, but will not be treated

Sources: based on cancer and HIV/AIDS deaths in 2001, WHR 2002 and INCB statistics



**World Health  
Organization**

# Number of untreated cancer pain patients

- 12 % of all death causes = 6.7 mln cancer deaths annually
  - 80% have no access to opioid analgesics
  - 80% terminal stage cancer patients suffer from moderate to severe pain
- 7.7% (=  $0.12 \times 0.8 \times 0.8$ ) of all people in the world will suffer from cancer pain that can be treated, but will not be treated (4.3 mln annually)

Sources: based on cancer and HIV/AIDS deaths in 2001,  
WHR 2002 and INCB statistics



**World Health  
Organization**

# Access to methadone and buprenorphine

- In 2005 added to *WHO Model List of Essential Medicines* list for use for opioid substitution therapy (OST)
- ± 60 countries with OST (methadone, buprenorphine, or both)
- 148 countries with IDU and 116 with HIV in IDUs
- OST most effective form of treatment for
  - opioid dependence
  - prevention of HIV transmission
  - adherence to HIV care, incl. ART
- Low overall global coverage



# Aims of this Project

- *Universal access to HIV prevention, treatment and care*
- Collect and share strategic information - transparency
- Provide a mechanism for price comparison
- Facilitate the procurement of these drugs



# The Procedure: 2007- to date

1. Search for companies on the Web
2. Creation of temporary database containing public domain information
3. Invite companies to confirm or correct the information and provide missing information (by email, fax, phone)
4. Construction of a database containing confirmed data
5. Publication on the AMDS website on 5 May 2008



# The Data Requested

- Name, address and country of manufacturer
  - Brand name of drug
  - Available forms and formulations
  - Brand name of drug
  - INN name (generic name)
  - Strength / concentration of drug
  - Production capacity of API in kg / annum
- Procurement issues
  - Country where specific formulations are registered for commercialization
  - Registration procedures
  - Export requirements
- Prices
  - Quoted unit price per smallest unit (mg / ml, mg or Kg) in original currency



# The Outcome

- 214 companies contacted
- Response with information of producers/distributors of finished formulations and/or API so far
  - 28 and 12 of methadone
  - 16 and 7 of buprenorphine
  - 51 and 9 of morphine



# methadone

Manufacturer/Distributor	Generic Name	Brand Name	Dosage Form	Strength (Concentration of Drug)	Base Unit of Measure	Price Per Base Unit of Measure	price per smallest unit (mg)	Price Per Patient Per Year (PPPY) for a daily dose of 80 mg (price/mg x 80 x	
AH Cox & Company Ltd.	methadone hydrochloride	Methadone Tablets BP 5mg; Physeptone Tablets 5mg	5mg/tablet						
ALKALOID AD Skopje	methadone hydrochloride	METADON	tablets	5 mg/tab	20 tablets	N/A			
			oral drops, solution	10 mg/1ml	10 ml	€0.80	€0.0800	€233.60	
			oral solution	10mg/1ml	100 ml	€8.00	€0.0800	€233.60	
			oral solution	10 mg/1ml	1000 ml	€80.00	€0.0800	€233.60	
			solution for injection	10mg/1ml	5 ampoules	N/A			
					50 ampoules	N/A			
Biomed Ltd.	methadone hydrochloride	Biodone	oral liquid solution	2 mg/ml	200 ml	\$4.70	\$0.0118	\$343.10	
		Biodone Forte	oral liquid solution	5 mg/ml	1L	\$25	\$0.0050	\$146.00	
					200 ml	\$5.00	\$0.0050		
Biodone Extra Forte	oral liquid solution	10 mg/ml	1L	\$30.20	\$0.0030	\$88.20			
Dales Pharmaceuticals Ltd.	methadone hydrochloride	Methadone 5mg Tablets BP	tablet	5 mg/tab					
Dee Pharmaceuticals Ltd	methadone hydrochloride	Eptadone oral solution	oral liquid	1mg/ml	20 ml	£0.29	£0.0145	£423.40	
					40 ml	£0.5800	£0.0145	£423.40	
					60 ml	£0.87	£0.0145	£423.40	
					100 ml	£1.35	£0.0135	£394.20	
					1 L	£13.48	£0.0135	£393.62	
					5mg/ml	20 ml	£1.47	£0.0147	£429.24
						1L	£73.33	£0.0147	£428.25
Douglas Pharmaceuticals Ltd	methadone hydrochloride	PALLIDONE	tablet	5 mg/tab	10's	\$2.1300		\$245.28	
Ebewe Pharma GmbH Nfg. KG	methadone hydrochloride	Heptadon 10 mg ampoules	liquid in ampoules and Powder	10 mg/ml	10mg/ml x 10 ampoules	\$3.7100			
Extractum-Pharma Rt.	methadone hydrochloride	Metadon-EP	tablet	5 mg	200X	\$13	\$0.0130	\$379.60	
				20 mg	200X	\$54	\$0.0135		
					1 mg (estimation)	~\$0,013			
GlaxoSmithKline Australia Pty Ltd.	methadone hydrochloride	Methadone Syrup	oral liquid	5mg/ml	200 ml	\$16.91	\$0.0169	\$493.77	
			oral liquid	5mg/ml	1L	\$36.00	\$0.0072	\$210.24	
		Physeptone (analgesic)	tablet	10mg	packs of 20 tablets	\$15.47	\$0.0774	\$2,258.62	
			liquid (Injection)	10mg/ml	packs of 5	\$29.91	\$0.5982	\$17,467.44	

# buprenorphine

	A	B	C	D	E	F	G	H	I
4	<b>Buprenorphine Price and Cost</b>								
5									
6	<b>Manufacturer/Distributor</b>	<b>Generic Name</b>	<b>Brand Name</b>	<b>Dosage Form</b>	<b>Strength (Concentration of Drug)</b>	<b>Base Unit of Measure</b>	<b>Price Per Base Unit of Measure</b>	<b>price per smallest unit (mg)</b>	<b>Price Per Patient Per Year (PPY) for a daily dose of 16 mg ( price/mg x 16 x 365)</b>
7	<b>ARROW Génériques</b>	buprenorphine hydrochloride	BUPRENORPHINE ARROW cp subling (Subutex generic)	sublingual tablets	0.4 mg/tab	7 tablets	\$3.7940	\$1.3550	\$7,913.20
8					2 mg/tab	7 tablets	\$8.8900	\$0.6350	\$3,708.40
9					8 mg/tab	7 tablets	\$25.4660	\$0.4548	\$2,655.74
10	<b>Bedford laboratories</b>	buprenorphine hydrochloride	Buprenorphine Hydrochloride injection (Buprenex)	liquid (injection)	0.3 mg/ml	10x1ml			
11	<b>CTS Chemical Industries LTD</b>	buprenorphine hydrochloride	Nopan	sublingual tablets	0.2 mg/tab	2x10 tablets			
12						5x10 tablets	\$8.02	\$0.8020	\$4,683.68
13	<b>Essex pharma GmbH</b>	buprenorphine hydrochloride	TEMGÉSIC	sublingual tablets	0.2mg/tab	20 tablets	24.65 €/20 tab.	€ 6.16	€ 35,989.00
14			TEMGÉSIC forte	sublingual tablets	0.4mg/tab	20 tablets			
15			TEMGÉSIC ampullen	solution for injection	0.3mg/ml amp.				
16	<b>Hospira, Inc</b>	buprenorphine hydrochloride	Buprenorphine Hydrochloride 0409-2012-32 - Carpuject	liquid (injection)	0.3mg/ml	1mlx10	£2.49/ml £24.90	£8.30	£48,472.00
17	<b>Merck Génériques</b>	buprenorphine hydrochloride	BUPRENORPHINE MERCK	sublingual tablets	0.4 mg/tab	7 tablets	\$3.00	\$1.0714	\$6,257.14
18					2 mg/tab	7 tablets	\$6.00	\$0.4286	\$2,502.86
19					8 mg/tab	7 tablets	\$17.00	\$0.3036	\$1,772.86
20	<b>Mundipharma Pty Ltd.</b>	buprenorphine	Norspan	transdermal patch	5 mg/patch	2 patches	\$25.97	\$2.5970	\$15,166.48
21					10 mg/patch	2 patches	\$30.70	\$1.5350	\$8,964.40
22					20 mg/patch	2 patches	\$30.70	\$0.7675	\$4,482.20
23	<b>Narcotics Control Division</b>	buprenorphine hydrochloride	Temgesic	sublingual	0.2 mg/tab		~0.60 baht	3.0 baht	17,520 baht
24		buprenorphine hydrochloride	Temgesic	injection	0.3 mg/ml		~3.33 baht	11.10 baht	64,824 baht
25	<b>Warszawskie Zakłady Farmaceutyczne Polfa SA (Polfa Warszawa SA)</b>	buprenorphine	Bunondol	sublingual tablets	0.2 mg/tab	60 tablets	7.50	\$0.6250	\$3,650.00
26				liquid (injection)	0.3 mg/ml	5x1ml	2.36	\$1.5667	\$9,149.33
27				sublingual tablets	0.4 mg/tab	30 tablets	7.50	\$0.6250	\$3,650.00
	<b>Reckitt Benckiser</b>	buprenorphine	SUBOXONE	sublingual tablets	2mg		\$0.40 - \$2.00		

# What is most relevant to us here?

- Great variation in prices being paid, ranges
  - methadone 29 - 26.000 USD for 80mg daily dose per patient/yr
  - buprenorphine 1.775 - 65.000 USD for 16mg daily dose per patient/yr
- More expensive than ART



# What we did not do

- No process of quality assurance or quality control
  - No regulatory approval of compounds
- No endorsement or recommendation of products or companies by WHO



# What Next?

- We
  - will update when information becomes available and make it into a searchable database
- You
  - could influence your market
    - Identify 'best buys' in your country
    - Increase nr of registered companies in your country
    - Increase offer of products
- Companies to send their information to [amds@who.int](mailto:amds@who.int)

# Thank you!

- <http://www.who.int/hiv/amds/en/>
- <http://www.who.int/hiv/idu/en/index.html>

