

# India pharmaceutical profile 2017



## COUNTRY AT A GLANCE

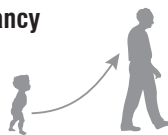
**1311051**

Population  
(in 000s)<sup>1</sup>



**68.3**

Life expectancy  
at birth  
(in years)<sup>2</sup>



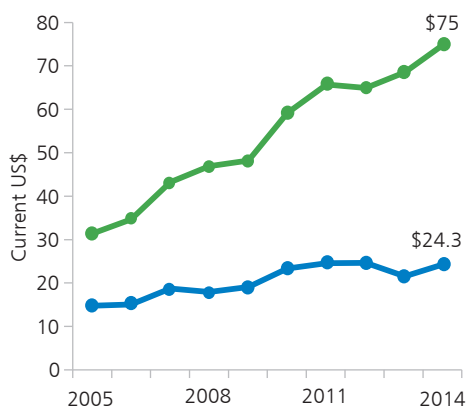
**1593**

GDP  
(per capita in  
current US\$)<sup>3</sup>



## OVERALL SPENDING ON HEALTH

Total per capita spending on health care (current US\$)<sup>4</sup>  
Total per capita spending medicines (current US\$)<sup>5</sup>

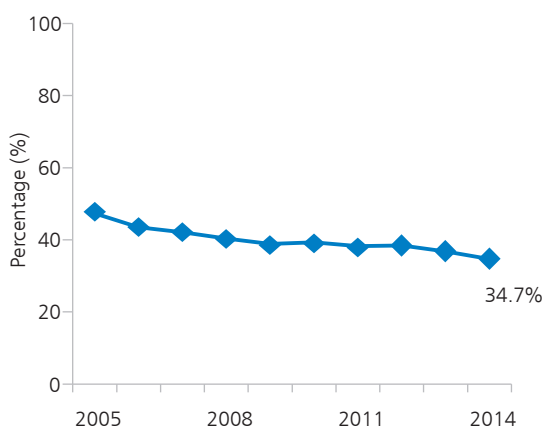


Share of government vs. out-of-pocket spending on health<sup>4</sup>

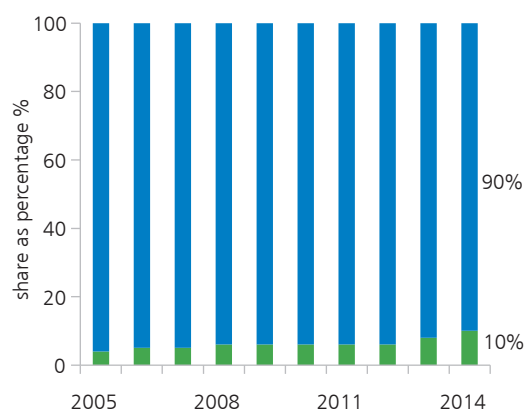


## SPENDING ON MEDICINES

Spending on medicines as share of total health-care cost<sup>5</sup>



Share of public and out-of-pocket spending on medicines<sup>5</sup>



## MEDICAL AND PHARMACY WORKFORCE



**7.3**  
Medical practitioners/10 000 population<sup>6,A</sup>



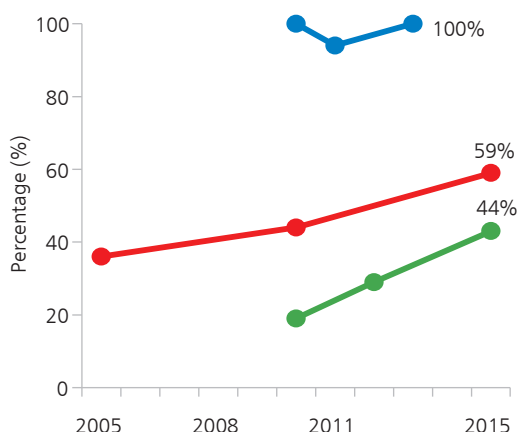
**<10**  
Pharmacists & pharmacy technicians/10 000 population<sup>7,B</sup>



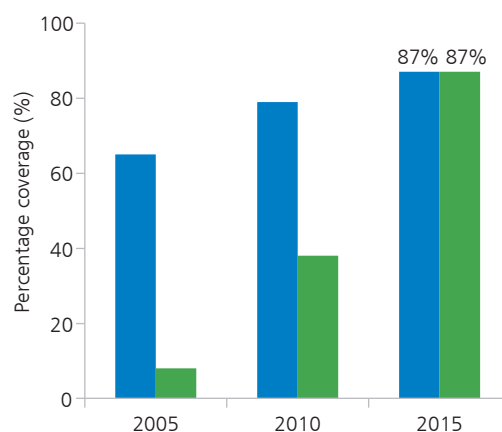
**5.2**  
Registered pharmacists/10 000 population<sup>8</sup>



**HIV/AIDS, Malaria and Tuberculosis treatment coverage** <sup>9,10,11</sup>



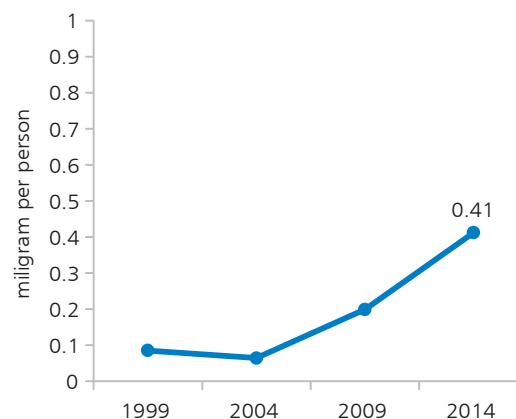
**Diphtheria-tetanus-pertussis (DTP3) and Hepatitis B3 immunization coverage** <sup>12</sup>



**Hypertension and Diabetes Mellitus treatment coverage**

Data insufficient to analyse

**Access to palliative care: Opioid consumption in Morphine Equivalence (ME) minus Methadone** <sup>13</sup>



Morphine Equivalence minus methadone represents country capacity to deliver palliative care, because it excludes treatment for drug dependency



**Key Pharmaceutical Legislation** <sup>14</sup>

Drugs and Cosmetics Act, 1940 and Rules 1945 as amended up to 31 December 2016

**National Medicine Policy** <sup>15,16</sup>

Pharmaceutical Policy 2002  
National Vaccine Policy 2011

**National Essential Medicines List** <sup>17</sup>

National List of Essential Medicines (NLEM)-2015

**National Standard Treatment Guidelines** <sup>18,19,c</sup>

Both individual disease and state-level standard treatment guidelines exist

**INTELLECTUAL PROPERTY RELATED POLICIES & PRODUCTION**

**Number of Local pharmaceutical manufacturers** <sup>20</sup>

4900 for formulations and 1500 for active pharmaceutical ingredient

**Least Developed country status** <sup>21</sup>

No

**Member of World Trade Organization since** <sup>22</sup>

1995

**TRIPS flexibilities used** <sup>23</sup>

Yes

# Pharmaceutical system flowchart

## Medicine



**National Regulatory Authority:** Central Drugs Standard Control Organization (CDSCO)

**Regulated products<sup>24</sup>:** [www.cdsc.org.in](http://www.cdsc.org.in)

**Medicines:** YES    **Vaccines:** YES    **Medical devices:** YES    **Traditional medicines<sup>25</sup>:** YES

**Medicine Quality Control Laboratory<sup>26</sup>:** Total 8: 1- Indian Pharmacopoeia Commission (IPC) Ghaziabad; 5-central drug testing laboratories and 2-regional drug testing laboratories

**ISO 17025 certified<sup>27</sup>:** YES    **WHO prequalified<sup>28</sup>:** YES (IPC, Ghaziabad)

**Number of registered medicines:** Not available



**Agency responsible for selection<sup>17</sup>:** Core Committee on National List of Essential Medicines, Ministry of Health & Family Welfare

**Number of products on essential medicines list<sup>17,D</sup>:**

**By active ingredient:** 376    **By dosage form:** Approximately 1000

**Traditional medicines products included in essential medicines list<sup>29</sup>:** YES

**Medicines availability is indicated by health facility level:** YES

**Number of products in National Formulary<sup>30</sup>:** National Formulary 2016, Products – 521



### Public sector

**Agency responsible for public procurement<sup>31</sup>:** Ministry of Health and Family Welfare (Central Medical Services Society)

**Procurement done at Central**  **State**  **Facility**

**Commonly used procurement methods:** Competitive tendering (Two bid system)

### Private sector

**Number of wholesalers:** Not available



### Public sector

**Price control:** YES

**Agency responsible:** National Pharmaceutical Pricing Authority<sup>32</sup>

**Price mechanism<sup>31,33</sup>:** Lowest procurement price considered

**Patient prices for essential medicines in public sector:**

**Free medicines<sup>34</sup>:** YES

**Fixed price<sup>35</sup>:** YES (Jan Aushadhi Scheme)

### Private sector

**Agency responsible for price control<sup>32</sup>:** National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers

**Pricing mechanism:** Market Based Pricing<sup>36</sup>

**Manufacturer**  **Wholesale**

**Retailer<sup>E</sup>**

**Mark-ups regulated:** YES

**Fixed or regressive<sup>37,F</sup>:** Fixed. Ceiling of drug prices based upon Market Based Pricing (MBP)



### Public sector

**Agency responsible for distribution<sup>31,33</sup>:** Centralized/decentralized at central/state or local government level

**Public sector facilities<sup>38</sup>:**

Total hospitals: 210998

District hospitals: 1251    Sub-district hospitals: 2724

Community health centres: 1146

Primary health centres: 31824    Sub centres: 164053

### Private sector

**Number of retail outlets<sup>20</sup>:** 800000

**Licensed retail pharmacies per 10 000 population:** Not available

**Number of traditional medicines outlets:** Not available

## Patient

# References

1. United Nations, Department of Economic and Social Affairs, Population Division. World Population Prospects, the 2015 revision. New York, 2015. <https://esa.un.org/unpd/wpp/> -accessed 12 May 2017.
2. World Health Organization. Global Health Observatory (GHO) data: life expectancy. Geneva. [http://www.who.int/gho/mortality\\_burden\\_disease/life\\_tables/en/](http://www.who.int/gho/mortality_burden_disease/life_tables/en/) - accessed 12 May 2017.
3. The World Bank. World development indicators 2016. Washington DC. <http://databank.worldbank.org/data/reports.aspx?source=world-development-indicators> - accessed 12 May 2017.
4. World Health Organization. Global Health Expenditure Database (GHED): total health expenditure. Geneva. <http://apps.who.int/nha/database/Select/Indicators/en> - accessed 12 May 2017.
5. World Health Organization. National Health Accounts, India. World Health Organization. Geneva. Internal communication, April 2017.
6. World Health Organization. World Health Statistics 2017. Geneva. 2017. <http://apps.who.int/gho/cabinet/uhc.jsp?lang=en> -accessed 24 May 2017.
7. World Health Organization. Global Health Observatory (GHO) data: health workforce pharmaceutical density. Geneva. [http://www.who.int/gho/health\\_workforce/pharmaceutical\\_density\\_text/en/](http://www.who.int/gho/health_workforce/pharmaceutical_density_text/en/) - accessed 24 May 2017.
8. Data taken from SEAR health workforce survey April 2016.
9. United Nations Programme on HIV/AIDS. Estimates of coverage of people receiving ART. <http://aidsinfo.unaids.org/> - accessed 12 May 2017.
10. World Health Organization. World malaria reports. Geneva. [http://www.who.int/malaria/publications/world\\_malaria\\_report/en/](http://www.who.int/malaria/publications/world_malaria_report/en/) - accessed 12 May 2017.
11. World Health Organization. Global Health Observatory (GHO) data. Geneva. <http://apps.who.int/gho/data/view.main.57060ALL?lang=en> -accessed 12 May 2017.
12. World Health Organization. WHO/UNICEF estimates of national immunization coverage. Geneva. [http://apps.who.int/immunization\\_monitoring/globalsummary](http://apps.who.int/immunization_monitoring/globalsummary) -accessed 21 June 2017.
13. Pain & Policy Studies Group. Country Profiles: Opioid consumption in Morphine Equivalence (ME) minus Methadone. University of Wisconsin, USA. 2015. <http://www.painpolicy.wisc.edu/countryprofiles> -accessed 12 May 2017.
14. Central Drugs Standard Control Organization. Ministry of Health & Family Welfare, India. Acts and Rules. <http://www.cdsc.nic.in/forms/contentpage1.aspx?lid=1888> -accessed 24 May 2017.
15. Department of Pharmaceuticals. Ministry of Chemicals & Fertilizers. Pharmaceutical Policy 2002. India. <http://pharmaceuticals.gov.in/policy> -accessed 24 May 2017.
16. Ministry of Health & Family Welfare. India. National vaccine policy 2011. [https://www.nhp.gov.in/sites/default/files/pdf/NATIONAL\\_VACCINE\\_POLICY.pdf](https://www.nhp.gov.in/sites/default/files/pdf/NATIONAL_VACCINE_POLICY.pdf) -accessed 24 May 2017.
17. Central Drugs Standard Control Organization. Ministry of Health & Family Welfare, India. National List of Essential Medicines 2015. India. 2015. <http://cdsc.nic.in/WriteReadData/NLEM-2015/NLEM,%202015.pdf> -accessed 24 May 2017.
18. National Institute for Health & Family Welfare, Ministry of Health & Family Welfare. National health Portal. Ministry of Health & Family Welfare. India. [https://www.nhp.gov.in/standards-and-protocols\\_pg](https://www.nhp.gov.in/standards-and-protocols_pg) -accessed 24 May 2017.
19. Ministry of Health & Family Welfare. The Clinical Establishments Act, 2010: Standard Treatment Guidelines. Ministry of Health & Family Welfare. Delhi. <http://clinicalestablishments.nic.in/En/1068-standard-treatment-guidelines.aspx> -accessed 24 June 2017.
20. World Health Organization, Regional Office for South East Asia. Promoting Cooperation for regulation in trade of medical products: Report of the regional meeting WHO-SEARO, New Delhi, India. September 2015. [http://www.searo.who.int/entity/health\\_situation\\_trends/report\\_regional\\_meeting\\_22to24\\_september\\_2015.pdf?ua=1](http://www.searo.who.int/entity/health_situation_trends/report_regional_meeting_22to24_september_2015.pdf?ua=1) -accessed 24 May 2017.
21. United Nations, Department of Economics and Social Affairs, Development Policy and Analysis Division. LDC list. 2016. [http://www.un.org/en/development/desa/policy/cdp/ldc/ldc\\_list.pdf](http://www.un.org/en/development/desa/policy/cdp/ldc/ldc_list.pdf) -accessed 12 May 2017.
22. World Trade Organization (WTO). Members and Observers. World Trade Organization. Geneva. 2016. [https://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm) -accessed 21 June 2017.
23. World Intellectual Property Organization. Statistical Country profiles. World Intellectual Property Organization. Geneva. [http://www.wipo.int/ipstats/en/statistics/country\\_profile/](http://www.wipo.int/ipstats/en/statistics/country_profile/) -accessed 21 June 2017.
24. Central Drugs Standard Control Organization. Ministry of Health & Family Welfare, India. <http://www.cdsc.nic.in/forms/Default.aspx> -accessed 24 May 2017.
25. Ministry of AYUSH. Government of India. <http://ayush.gov.in/> -accessed 24 May 2017.
26. Central Drugs Standard Control Organization. Ministry of Health & Family Welfare, India. <http://www.cdsc.nic.in/forms/contentpage1.aspx?lid=1425> -accessed 24 May 2017.
27. National Accreditation Board for Testing and Calibration Laboratories. Quality Council of India. <http://cercenvis.nic.in/PDF/NABL-2016.pdf> -accessed 24 May 2017.
28. World Health Organization. List of Medicine quality control laboratories. Geneva. 2016. <https://extranet.who.int/prequal/content/medicines-quality-control-laboratories-list> -accessed 24 May 2017.
29. Ministry of AYUSH. Government of India. Essential Drug Lists of AYUSH. <http://ayush.gov.in/tenders-vacancies-and-announcements/publications/essential-drugs-list-ayurveda-siddha-unani-and-homeopathy> -accessed 24 May 2017.
30. Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare. India. 2016. <http://ipc.nic.in/showfile.asp?lid=589&EncHid> -accessed 24 May 2017.
31. Central Medical Services Societies, Ministry of Health & Family Welfare. Government of India. <http://www.cmss.gov.in/> -accessed 24 May 2017.
32. National Pharmaceutical Pricing Authority, Ministry of Chemicals & Fertilizers. Government of India. <http://nppaindia.nic.in/> -accessed 24 May 2017.
33. Singh PV, Tatambhotla A, Kalvakuntla R, et al. Understanding public drug procurement in India: a comparative qualitative study of five Indian states. *BMJ Open* 2013;3:e001987. doi:10.1136/bmjopen-2012-001987. <http://apps.who.int/medicinedocs/documents/s20032en/s20032en.pdf> -accessed 24 May 2017.
34. Ministry of Health & Family Welfare. Government of India. Operational Guidelines for Free Drugs Service Initiatives. Ministry of Health & Family Welfare. India. [https://www.mpphsc.in/Files/PDF/b731acad-ed-43b6-b286-99aea308b1fb\\_0\\_Free\\_Drugs\\_Service\\_Initiative.pdf](https://www.mpphsc.in/Files/PDF/b731acad-ed-43b6-b286-99aea308b1fb_0_Free_Drugs_Service_Initiative.pdf) -accessed 24 May 2017.
35. National Pharmaceutical Pricing Authority, Ministry of Chemicals & Fertilizers. Government of India. <http://nppaindia.nic.in/nppaprice/newmedicinepricesearch.aspx> -accessed 24 May 2017.
36. National Pharmaceutical Pricing Authority, Ministry of Chemicals & Fertilizers. Government of India. Drug Price Control Order 2013. [http://nppaindia.nic.in/DPCO2013\\_03082016.pdf](http://nppaindia.nic.in/DPCO2013_03082016.pdf) -accessed 24 May 2017.
37. National Pharmaceutical Pricing Authority, Ministry of Chemicals & Fertilizers. Government of India. <http://www.nppaindia.nic.in/frequent.html#4> -accessed 24 May 2017.
38. Ministry of Health & Family Welfare. Health Management Information System, National health Mission. Ministry of Health & Family Welfare. Government of India. [https://nrhm-mis.nic.in/hmisreports/firmstandard\\_reports.aspx](https://nrhm-mis.nic.in/hmisreports/firmstandard_reports.aspx) -accessed 24 June 2017.

## Notes:

- A. 0.725 physicians per 1000 population.
- B. Less than 1 pharmaceutical personnel per 1000 population.
- C. Other sources:
  - 1) [http://pbhealth.gov.in/AMR\\_guideline7001495889.pdf](http://pbhealth.gov.in/AMR_guideline7001495889.pdf)
  - 2) <http://icmr.nic.in/guidelines/treatment%20guidelines%20for%20antimicrobial.pdf>
  - 3) <http://www.tb.cindia.nic.in/index1.php?lang=1&level=1&sublinkid=4571&lid=3176>
  - 4) <http://clinicalestablishments.nic.in/WriteReadData/93.pdf>
  - 5) <http://clinicalestablishments.nic.in/WriteReadData/448.pdf>
  - 6) <http://nvbdcp.gov.in/iec.html>
- D. By self-calculating all the strengths listed.
- E.  $P(c) = P(s)(1+M/100)$ , where  $P(s)$  = Average Price to Retailer for the same strength and dosage of the medicine ;  $M$  = % Margin to retailer and its value = 16.
- F. A Manufacturer, distributor or wholesaler shall sell a formulation to a retailer, unless otherwise permitted under the provisions of this order or any order made thereunder, at a price equal to the retail price, as specified by an order or notified by the Government, (excluding excise duty, if any) minus sixteen per cent thereof in the case of Scheduled drugs.