

# Medicines for All

## Unexceptionable Recommendations

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The recommendations on access to medicines, vaccines and technology made in the report of the Planning Commission's High Level Expert Group on Universal Health Coverage for India are welcome and should go a long way towards rectifying many existing problems. Yet, it would have been reassuring if a few more details had been spelled out. Given the array of vested interests that stand to lose out if they are implemented, it also remains to be seen if they will be accepted in full.

This piece is dedicated to the memory of my father who passed away soon after I finished writing it, and who was one of the persons who motivated me to public life, such as it is. The author is grateful to Anant Phadke and Renu Khanna for careful comments on an earlier draft. Omissions are the author's.

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There can be no two opinions about the recommendations on access to medicines, vaccines and technology made in the Planning Commission's High Level Expert Group (HLEG) report<sup>1</sup> on Universal Health Coverage (UHC) for India. Broadly speaking, the recommendations are in tune with demands that have been made by groups such as the All India Drug Action Network, the Jan Swasthya Abhiyan and the Medico Friend Circle for a number of years. While welcoming these recommendations, we point out that unless some crucial details are also spelled out, they are likely to be implemented in a way that their objectives are not realised.

We comment on the recommendations (see the box) even as we are aware that a report like this is normally a golden mean of sorts, trying to strike an acceptable path amidst a welter of opinions and degrees of emphasis.

### Public Spending on Drug Procurement

The HLEG report recommends, "Increase public spending on drug procurement to 0.5% of the gross domestic product (GDP) and provide free essential medicines to all". The provision and availability of medicines for all is, techno-managerially speaking, the "easiest" thing to do in the run-up to a UHC system. It will increase the number of users and the faith ordinary citizens have in the public system. This has been the experience in states such as Assam and Bihar where National Rural Health Mission (NRHM) funded medicines have added to the supply at the last level, leading to long queues at primary health centres (PHCs). Much of the confidence that this can be done comes from the experience of the Tamil Nadu Medical Services Corporation (TNMSC), which has had a remarkably successful run for 15 years. An exercise done by Anant Phadke and the author, extrapolating from

the TNMSC and the Chittorgarh-Nagaur experience in Rajasthan, gives a figure of Rs 22,000 crore per year for free medicines to all patients attending both private and public health facilities.<sup>2</sup> The HLEG recommendation of 0.5% of the GDP translates to Rs 30,000 crore, as mentioned in the report. (With the new GDP estimates, it would amount to Rs 45,000 crore.)<sup>3</sup> Unfortunately no details of this estimate of Rs 30,000 crore are given and it can be turned down by officials.

One understands that the authors of the report followed the international "norm" that expenditure on medicines be 15% of the total health allocation. From this, it would follow that the health budget is taken to be Rs 2,00,000 crore or 3.3% of the GDP (if Rs 30,000 crore is 0.5% of the GDP as given in the report). According to recent reports, the health budget is proposed to be 2.5% of the GDP. With current GDP taken to be Rs 89.8 lakh crore, 15% of 2.5% of it works out to 0.375%, which is Rs 33,750 crore. As and when the health budget increases to, say, 6% of the GDP (the international "norm" is 6% of GDP), should the budget for medicines be Rs 81,000 crore? Or more likely, if as a result of parliamentary debate or coalition "dharma", the government increases it to 3%, should the medicine budget be Rs 40,500 crore at 0.45% of the GDP? Or if the GDP estimate of Rs 89.8 lakh crore (or trillion) per se is

#### High-level Expert Group's Recommendations

- 1 Increase public spending on drug procurement to 0.5% of the gross domestic product and provide free essential medicines to all.
- 2 Enforce price regulation and apply price control on all formulations in the Essential Drug List.
- 3 Ensure drug and vaccine security by strengthening the public sector and protecting the capacity of Indian private sector companies to produce low-cost drugs and vaccines needed for the country.
- 4 Strengthen institutional mechanisms for procurement and distribution of allopathic and AYUSH drugs.
- 5 Promote rational use of drugs through prescriber, patient and public education.
- 6 Strengthen central and state regulatory agencies to effectively perform quality and price control functions.
- 7 Protect the safeguards provided by the Indian patents law and the TRIPS Agreement against the country's ability to produce essential drugs.
- 8 Transfer the Department of Pharmaceuticals to the Ministry of Health.

Source: Chapter 3, HLEG report, 2011.

revised downwards or upwards, should the allocation for medicines be revised?

Estimations based on a somewhat arbitrary proportion of a variable like the GDP has such problems. We would therefore suggest that it is better to make an estimate of the amount required for “medicines for all” in a direct way by using morbidity data or data on the number of patients accessing health-care. A related issue is that even our estimates are based on TNMSC prices, which are very low. An estimate by Narendra Gupta of Prayas Chittorgarh<sup>4</sup> is Rs 33,000 crore at Chittorgarh experiment prices, which are three to four times TNMSC prices. Medicine estimates therefore need to specify the price levels at which projections are calculated.

Nevertheless, one hopes that the increased allocation is wisely used when it comes to buying drugs such as expensive cancer medicines, antiretrovirals (ARVs), inhalers and vital medicines currently not on the National List of Essential Medicines (NLEM). There are no details in the HLEG report about what proportion of the public spending would be used for patients who access the part of the private sector that is “contracted-in” to the UHAC system. There is also no hint of what to do with more than 4,00,000 retail pharmacy shops if only a few retail chemists are contracted-in.

A sudden increase in the availability of resources, like the one envisaged, makes it essential to set up tighter financial controls, especially after the loot of NRHM money and murders or deaths in mysterious circumstances in Madhya Pradesh (MP) and Uttar Pradesh (UP). Better governance in individual states will therefore be a key element. The report does well to point out, in several places, that for replicating TNMSC-type procurement models, state governments would need to ensure transparency and accountability through enabling legislations such as the Tamil Nadu Transparency in Tenders Act (43), 1998 and the Tamil Nadu Transparency in Tenders Rules, 2000.

### **Price Regulation, Rationality of Medicines**

Recommendation 2 of the HLEG report reads, “Enforce price regulation and apply

price control on all formulations in the Essential Drug List”. This is a welcome recommendation. But again if the details are not specified, this recommendation would hardly achieve its objective. An example of apparently doing the right thing but, in effect, not doing it is the new Draft National Pharmaceuticals Pricing Policy (NPPP-2011), which was initiated at the prompting of the Supreme Court in an ongoing public interest litigation on drug pricing. We have shown elsewhere that the policy actually legitimises high prices and is, in effect, a price decontrol policy.<sup>5</sup>

The draft NPPP-2011 has a formula to discourage non-standard dosages. The same thinking needs to be applied to discourage irrational and unscientific medicines outside the NLEM as well as “me-too medicines.” Irrational combinations and attempts to circumvent the ceiling price can be discouraged by taking a cue from the Pronab Sen task force report, which proposed, “For formulations containing a combination of a drug in the NLEM and any other drug, the ceiling price applicable to the essential drug would be made applicable.” The HLEG report, as well as the draft NPPP-2011, could have taken note of this and a related recommendation from the Pronab Sen Committee – debrand, that is, remove brand names, to ensure true competition among generics. In addition, medicines of the same class such as all acid suppressants (omeprozole, rabeprazole, lansoprazole, pantaprazole, and the like) or all ACE inhibitors used to lower blood pressure (enalapril, captopril, lisinopril, ramipril, and the like) need to have the same ceiling price unless there is demonstrated superiority of some member of the class.<sup>6</sup>

Recommendation 2 of the HLEG report also needs to be buttressed by the sub-recommendations under Recommendation 5 (“Promote rational use of drugs through prescriber, patient and public education”). It discusses the prevalence of irrational combinations in the market at some length but has not taken the matter to its logical conclusion by recommending a total, immediate ban on irrational medicines. The sub-recommendation (p 134), in the subtext, says, “There is a clear need to phase out hazardous, non-essential and

irrational medicines and irrational ‘Fixed Dose Combinations’ from the market”. In general, there are many such subtexts following the recommendations in the report – most of which are well taken – but it is not clear whether they have the status or weight of a recommendation.

The presence of irrational medicines in the market, probably accounting for more than 60% of retail sales, leads to irrational prescriptions by the very act of their use and collaterally adds up unnecessary costs to patients. A ban or “phaseout” of these irrational medicines would need to be a top priority and a prerequisite for promoting rational behaviour. Mere price control of essential medicines and discouraging non-essentials through ceiling prices is not enough.

There is also a substantial need for strengthening and clarifying the law on the power of the government to ban medicines, especially Section 26 A of the Drugs and Cosmetics Act, so that legal challenges by vested interests among drug manufacturers – who are not too worried about rationality at the best of times – do not succeed. We make this comment in the light of recent attempts to weed out some harmful medicines such as nimesulide (use in children below 12 years of age), cisapride, phenylpropranolamine (PPA), human placenta extracts, silbutramine and R-silbutramine. The ban order was stayed and successfully challenged in the Chennai and Delhi high courts, the latter even substantially modifying the ban order on placental products. This experience needs separate analysis and, if anything, indicates that faulty bans or phaseouts inflict greater damage on public health in the long run.

A closely allied matter is that the NLEM 2011 covers only 348 medicines. In reality, there may be some more medicines in use that are rational and essential. The UHC process needs to be flexible to accommodate the specific, genuine medicine needs of special groups.

Transparency and accountability is listed on the third page of the HLEG report as one of the 10 principles that guided the formulation of the recommendations. Drug regulation in India is notoriously non-transparent. Separate recommendations on this would have been desirable –

transparency in the process of approval of new drug formulations for manufacture and marketing, easy public access to research data used in the approval of new medicines and data related to all clinical trials. Accountability would need to be ensured, among other things, by declarations of conflict of interest in all medicine-related policymaking bodies, followed by withdrawal from decision-making bodies of those who have declared such conflict of interest. For instance, those who have been legal counsel for big pharmaceutical companies anytime in the last 20 years in the Supreme Court should ideally not be involved in pharmaceutical policy formulation. But as of today they are.

The report suggests (under Recommendation 6) that an agency independent of the office of the Drug Controller General of India (DCGI), like the National Institute for Health and Clinical Excellence (NICE) in the UK, be set up in India to create a scientific basis for the decisions of the Central Drugs Standard Control Organisation (CDSCO) and DCGI on vaccines and medicines. We suggest such an organisation be mandated to also extend the logic of evidence-based introduction or approval of medicines to new medical devices, diagnostic technologies and procedures, and health policies and interventions in general.

If such an institution had been in existence, many of the doubtful decisions on the introduction of new vaccines to the country probably would not have been taken. We point out a related matter here. In a chapter of the report titled "Access to Medicine, Vaccines and *Technology*" (emphasis ours), there is some brief comment on regulating and promoting technologies, medical and pharmaceutical; however, there are no related recommendations, especially in the light of vaccine and drug security advocated in Recommendation 3.<sup>7</sup>

### Challenges Ahead

Much of the workability of the recommendations is predicated on the assumption that the boom period of Indian pharmaceuticals – which elicits sobriquets like "the pharmacy of the developing world" – will continue. However, there are

some areas of concern. Many have been pointed out by the report and it rightly suggests full use of the flexibilities afforded by the trade-related aspects of intellectual property rights (TRIPS) and compulsory licence (CL) provisions in India's Patents Act; and that the government not yield to international pressure (primarily from western governments) on diluting Section 3d or introducing patent linkage and data exclusivity.

Many of the so-called TRIPS-Plus measures are primed for entry through bilateral free trade agreements (FTAs). Of special concern are two sets of provisions in agreements such as the Anti-Counterfeiting Trade Agreement (ACTA) and the India-European Union FTA on which talks are currently on. The first are "border measures" that legitimise seize and destroy of suspected "counterfeit" goods (that is, goods inter alia violating IP provisions) without a hearing – something that has happened to India's medicine exports transiting Amsterdam with Africa and South America marked as destinations. The second set of measures are "investment proposals" that seek to legitimise individual private investors (read foreign pharmaceutical companies or even investment groups) suing sovereign governments (read the Government of India) if they feel that any measures taken by nation states are likely to affect their investments adversely. The resulting dispute resolutions will be beyond the pale of national laws and have to be settled through secret private arbitral tribunals, usually in places such as London or Singapore. Many governments have paid millions and even billions to private parties as a result of such arbitral decisions. And such arbitral decisions are not known for pro-public health concerns.<sup>8</sup>

There are other issues of concern – the easy takeover of India's pharmaceutical companies by big pharma and the related easing of foreign direct investment (FDI) norms is one.<sup>9</sup> And, above all, the dependence of India's formulation manufacturers on China for active pharmaceutical ingredients (APIs) – currently at least 40% of India's APIs (or bulk drugs) come from China. Dependence on a neighbour, who blows hot and cold, on a vital sector like

pharmaceuticals is not prudent in terms of a health security strategy. Incidentally, there are no recommendations in the report on nurturing indigenous, self-reliant research and development (R&D) in pharmaceuticals although there is a bit of discussion.

The last recommendation of the HLEG report that pharmaceuticals-related decision-making be transferred from the Department of Pharmaceuticals (under the Ministry of Chemicals and Fertilisers) to the Ministry of Health is a welcome one; it has been a long-standing demand of many concerned public health persons. It will of course be resisted by the pharmaceutical industry.

### Will the Report Work?

When a government-appointed committee's recommendations are right, one is not all that optimistic of them being accepted in toto. In this case, except for the increase in the health sector investment, the other recommendations may be resisted tooth and nail, or worse bypassed, by the powers that be. The deputy chairman of the Planning Commission and some state governments espousing public-funded health insurance programmes as a means of universal coverage, despite recommendation to the contrary by the HLEG, is a case in point.

We nevertheless live in the hope that good sense will prevail. These recommendations, with our comments, deserve to be implemented in full in the interests of public health and for a reduction of impoverishment due to ill health.

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## NOTES

- 1 This article specifically refers to Chapter 3, "Access to Medicines, Vaccines and Technology", pp 119-40, of the High Level Expert Group report on Universal Health Coverage for India (2011), Planning Commission, New Delhi, hereafter, the HLEG report.
- 2 Rs 5,735 crore (or say Rs 6,000 crore) at TNMSC prices for 52% of all patients attending public health facilities; and Rs 15,881 crore (or say Rs 16,000 crore) at three times TNMSC prices for the 48% attending private-sector facilities. The latter is taken at three times TNMSC prices to allow for distribution costs along the private retail chain. For more details, see S Srinivasan and Anant Phadke (2011): "Scheme for 'Free Medicines for All' during the 12th Five-Year Plan", note submitted to the Ministry of Health Working Group on Drug Regulation for 12th FYP, available at <http://www.mfcindia.org/main/bgpapers/bgpapers2012/am/bgpap2012f.pdf>
- 3 The GDP of India is taken as Rs 89.8 lakh crore (or trillion). Source: *Economic Outlook*, 2011-12, Economic Advisory Council to the Prime Minister, viewed on 13 January 2012, available at <http://pib.nic.in/archieve/others/2011/aug/d2011080101.pdf>
- 4 See Narendra Gupta (2010-11), "What It Costs to Provide Medicines to All Sick Persons in India", *MFC Bulletin*, August-January, Issues 342-44.
- 5 For more on the problems with the draft pricing policy, see the author's "Pharma Industry Gets Away Lightly", *Business Line*, 8 November 2011.
- 6 At present there is a wide variation in their retail prices and the usage of a particular member of a drug class is supplier driven while the price of the latest entrant in the class is usually higher. The generic version of enalapril 5 mg costs Rs 5 per strip of 10 tablets; its branded version costs around Rs 25. In contrast, the branded versions of lisinopril, ramipril and perindopril for the same dose are priced at Rs 38, Rs 67 and Rs 79 respectively per strip (price data, *MIMS India*, December 2011, courtesy Anant Phadke).
- 7 The National Health Systems Resource Centre (NHSRC) and National Institute of Science Technology and Development Studies (NISTADS) have been coordinating recently in putting together a report on such issues.
- 8 For more details, see the author's "A European Pill Best Avoided", *Business Line*, 3 January 2011.
- 9 For more, see the author's "Dangers of FDI in Pharma", *Business Line*, 13 October 2011.