

But is the intrinsic bias of the commissioning process in favour of for-profit bidders enough to make a real difference? The evidence that it will be is still limited but is starting to emerge. The National Council for Voluntary Organisations (NCVO) and the King's Fund have identified problems with existing contracts—for example, the costs of service delivery are reimbursed in arrears—that means charities effectively act as providers of short-term finance to government,<sup>6</sup> which causes them cash flow difficulties. Furthermore, for-profit bidders can raise funds to invest in entering new markets and can cross-subsidise losses with income from profitable activities, so they can undercut other providers even if doing so makes a short-term loss, and can afford to market their services aggressively in order to increase market share at the expense of weaker competitors.<sup>6</sup> Thus, the NCVO and the King's Fund conclude “the new system will be anything but a level playing field”.<sup>6</sup>

Emerging evidence from social care points to the possible manipulation of UK charities that are participating in joint private–voluntary sector bids.<sup>8</sup> Voluntary sector links with communities enhance the credibility of such bids. Once the bid is won, however, the dominant private sector partner could prevent the voluntary sector partner from receiving enough income to cover the costs of providing services.<sup>8</sup> Preparation, agreement, and enforcement of the watertight contracts needed to protect the voluntary body from exploitative behaviour by their bid partners are unlikely to be achieved in practice.

If the UK Government is serious about the “Big Society”, then a solution that would be consistent with European law would be to restrict substantial areas of provision to non-profit organisations.<sup>9</sup> Without such provision, it would appear that charities are being put at risk in order to obscure the handing over of health-care delivery in England to private corporations.<sup>10</sup> Since

they will almost always out-bid would-be non-profit providers in the more lucrative services that they choose to compete for, the market dominance and profits of private corporations will grow as they suck resources away from the provision of care.<sup>11</sup> David Cameron’s “Big Society” vision will then turn out to amount to no more than a smokescreen for the funnelling of public sector budgets into the pockets of corporate giants, to the detriment of charities and communities.

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## Pakistan's deadly cocktail of substandard drugs

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On Feb 3, 2012, WHO issued a drug safety alert about pyrimethamine-contaminated isosorbide 5 mononitrate in Pakistan.<sup>1</sup> 125 people have died as a result of fatal bone-marrow suppression after taking the contaminated drug, which was given free of cost to the poor from a public cardiology pharmacy in Lahore, in the province of Punjab (Haroon Jehangir Khan, Director Health Services

[Management Information System Cell] Directorate General of Health Services, Government of Punjab, personal communication). These events are linked to the country's decision to abolish its Ministry of Health last year, which has led to a massive decentralisation in favour of provincial autonomy.<sup>2</sup> Despite good intentions, the reforms have decentralised functions that need to be

federally (nationally) mandated in a globalised environment.<sup>3</sup> The “drug regulation turf” became complicated by an existing political rivalry between the federal and provincial government. The resulting 7-month struggle—since the Ministry of Health’s abolition—delayed the process of establishing an independent Federal Drug Regulation Authority.

Cabinet approval for the establishment of a Federal Drug Regulation Authority was given in 2005, but the Ministry of Health moved slowly because it was reluctant to relinquish its prerogative. After devolution, steps to create a Federal Drug Regulation Authority were complicated when the provinces objected to the proposed structure on the grounds that it was too federal. Early provincial calls for devolving drug regulation seemed misinformed and deviated from the international norm of national regulatory authorities. There is now a clear imperative for Pakistan to retain drug regulatory arrangements for licensing, registration, and pricing under a unified federal statutory autonomous structure. But an innovative approach will have to be adopted for the governance of a Federal Drug Regulation Authority. Past experience with so-called independent regulatory agencies in Pakistan, for which unqualified members are often handpicked, has seen control remaining with the government. Therefore, the priority should be to address existing weaknesses in regulation, including capacity and resource constraints, by taking advantage of experiences from other established regulatory agencies.

The issue of substandard drugs has been long standing: Pakistan’s progressive Superior Court demanded independent action on the issue in 2006.<sup>4</sup> In 2004, WHO estimated that 40–50% of drugs consumed in Pakistan were counterfeit or substandard.<sup>5</sup> The reasons for this situation are complex. Pakistan’s Drug Act of 1976 has exploitable covenants and enforcement of the law is additionally weak. Traditional medicines are prescribed by about 130 000 practitioners and remain outside the law’s purview.<sup>6</sup> A draft bill on traditional medicines has been in the parliamentary review pipeline for the past 10 years, without action. Drug regulation is also weak. There are 15 federal drug inspectors to oversee more than 500 licensed pharmaceutical manufacturing units (Farnaz Malik, Chief/Joint Executive Director Drug Control and Traditional Medicine Division, National Institute of Health, Islamabad, personal communication). There is just one laboratory for testing drug quality in each

province but most are either closed or lack infrastructure. Sale and resale of second-hand manufacturing machinery is unregulated and pharmaceutical raw materials are traded in the open market. Hospitality-based intensive marketing by many pharmaceutical entities or companies is rife and corruption in procurement is common.<sup>7</sup>

The government needs to document the magnitude of substandard and counterfeit medicines in Pakistan, which has become a major public health concern just as it has in many other countries.<sup>8,9</sup> A systemic approach to this problem is needed. The first two steps—the creation of a Federal Drug Regulation Authority and a revamp of the Drug Act—are crucial, but transparency and capacity-building initiatives are also needed. More broadly beyond drug regulation, challenges arising as a result of the abolition of the Ministry of Health require attention at a time when the outlook for health care in Pakistan seems uncertain.<sup>2</sup> Effective regulation is an absolute responsibility of the state to the population. While the deaths from contaminated isosorbide 5 mononitrate have focused attention on a major regulatory failure, it is also important to establish how many other patients have been unknown victims of a regulatory failure to enforce quality standards of locally manufactured medicines in Pakistan. It is conceivable that a similar disaster might occur in other provinces or other countries.

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