Introduction

In many low-income countries, and some middle-income countries, the government’s budget for the health sector is too small to finance the national health system adequately. In Uganda, for example, the expenditure on health in 2014 was only 12 United States dollars (US$) per capita, i.e. about 35% of the value recommended by the World Health Organization (WHO), and the expenditure on pharmaceuticals was just US$2.40 per capita.1 Such poor financing means that access to pharmaceuticals, like many other health sector priorities, has to be compromised. Many health systems have no choice but to rely, at least in part, on drug donations from high-income countries and vertical supplies from development agencies.2,3 During civil emergencies and periods of severe political instability, health systems may have to rely almost entirely on drug donations.2

Unfortunately, donated pharmaceuticals often mismatch the pharmaceuticals that are needed. International guidelines require that drug donations are responsive to the health needs of the recipient country and that the drugs involved have a shelf-life of at least one year on arrival.4 However, drugs that are already past their expiry dates have often been dumped in low- or middle-income countries5–9 and many past donations have been so large or so unwanted that they could not be used entirely before their expiry dates (Table 1).

Stockpiles of expired pharmaceuticals may also build up as a result of poor forecasts of future demand. Efficient stocking may be made difficult by deficiencies in a supply chain or by poor coordination between a national supply system and the development partners or special programmes offering to supply pharmaceuticals.10 In most low- and middle-income countries, the supply of pharmaceuticals is centralized and one state agency is entrusted with the procurement, storage and distribution of pharmaceuticals to all public health facilities.11 The network of public health facilities in any given country is often so expansive and complex that it is impossible for a single agency to respond effectively to the unique demands of each client. In Uganda in 2016, one central agency – the National Medical Store – was entrusted with supplying all pharmaceuticals to the country’s two national referral hospitals, 14 regional referral hospitals, 144 district hospitals, 197 county health centres, 1289 sub-country health centres and 2941 parish health centres.12 Unfortunately, few of these health facilities have staff members with the skills needed to manage pharmaceutical inventories or forecast future pharmaceutical needs effectively. In 2010, only 31 pharmacists were employed in Uganda’s public-sector health system.11,12 Structural and technical dysfunction in the management of a pharmaceutical supply chain can promote the accumulation of large quantities of expired pharmaceuticals in central stores and health facilities. In some low- and middle-income countries, including Uganda, civic observers and government oversight agencies have raised concern over the high incidence of expiry of stocked pharmaceuticals in the public supply system.13–19 The disposal of expired pharmaceuticals may also be a very slow process. In Uganda’s national medical store and public-sector health facilities, for example, such pharmaceuticals were found to be held for a mean of six years.18

In the absence of their timely and safe disposal, expired pharmaceuticals may be simply dumped – with the risk of environmental pollution – or repackaged for the counterfeit market. Toxicity from environmental exposure to pharmaceuticals has been reported in fish20 and vultures.21 If antibiotics are dumped, exposure to subtherapeutic concentrations of the drugs may lead to the selection of drug-resistant soil bacteria, which may then infect humans22,23 and even pass on their resistance genes to bacteria that are human pathogens.24 Mechanisms to deter the entry of pharmaceuticals into the environment need to be strengthened.

Below, we review the various options available for mitigating the threats posed by expired pharmaceuticals to health systems and the environment in low- and middle-income countries.

Pharmaceutical pollution

The control of pharmaceutical pollution of the environment in low- and middle-income countries needs to be based not only on the safe disposal of expired drugs but also on the optimization of pharmaceutical use before expiry. New phar-
maceutical expiries might be curtailed by: (i) strengthening the management of pharmaceutical supply chains in the public sector; (ii) reducing the workload at central medical stores, through liberalization and reimbursement schemes; (iii) improving the regulation of drug donation; and (iv) investigating the salvage of drugs that are officially expired but still usefully active, through re-analysis and possible shelf-life extension. There should be better supervision of stockpiles of expired pharmaceuticals and the disposal of such stockpiles needs to be improved and regulated better. The enforcement of any existing national and international regulations on the safe disposal of pharmaceuticals – e.g. by incineration at so-called ultra-high temperatures – needs to be strengthened. Every country needs to have such regulations.

Management systems

Robust management systems for the supply of pharmaceuticals, in which reorder quantities are informed by reliable consumption data and demand forecasts, are essential in minimizing the amounts of pharmaceuticals that remain unused when they reach their expiry dates. In many low-income countries, it may be wise to invest in both robust information systems for logistics management, to track consumption, and the development of skilled human resources capable of optimizing forecasts of future demand. The use of computerized inventory management can greatly enhance data retrieval and analysis.25 In Uganda12 and wherever else that the unregulated pushing of pharmaceuticals to peripheral health facilities is often the norm, there needs to be a change to a demand-responsive system of supply. Oversupply, e.g. as a consequence of parallel procurements by several vertical health programmes,27 should be avoided by synchronizing the supply of all health commodities to public health facilities. Lastly, as unusual volatility in demand can reduce the turnover of inventory, channels for the redistribution of excess inventory to other public or even private health facilities28 should be strengthened.

Central stores

To enhance the performance of publicly funded pharmaceutical supply, many low- and middle-income countries need to transfer some of the duties of the often overworked and stressed staff at central pharmaceutical stores to the staff at community pharmacies. Such a transfer might be supported by price-regulated, state-run reimbursement schemes or health insurance, as found in most high-income countries.27 At peripheral health facilities, where the capacity to track consumption and forecast demand is often inadequate, the delegation of prescription services to community pharmacies – wherever available – could again help to reduce the amounts of pharmaceuticals that remain unused when they reach their expiry dates.

Drug donations

To suppress the unregulated export – from high-income countries to lower-income countries – of pharmaceuticals coming towards the end of their shelf-lives and other nonconforming medications, countries need to strengthen the enforcement of national policies and WHO guidelines on drug donations. According to WHO, any low- or middle-income country considering the receipt of a proposed drug donation should ensure that: (i) only solicited donations are allowed entry; (ii) any donated drug is approved for use in the recipient country and congruent with the relevant national policies and regulations; (iii) donations are in accordance with a plan mutually agreed upon by both the recipient and the donor; (iv) the donation is on the essential medicines list of the recipient country; and (v) the donation meets the quality standards of the donor and the recipient country.20 Ideally, the presentation of any donated medicine should match that already used in the recipient country, the labelling should be in a language that is widely understood in the recipient country and any donations of recycled medicines should be denied entry.26

Many low- and middle-income countries have designed their own policies, on the receipt of drug donations, that conform with WHO guidelines. For example, Uganda developed a national policy on drug donations in 1997. This policy not only adopted WHO recommendations but also added that any labelling and prescribers’ information should be in English and that details of the distribution and use of any donated drug must be sent, by the facility in which the drug was used, to the national medicines regulatory agency.23 In countries where there are no existing relevant laws and regulations, the national governments need to legislate on drug donations.

Table 1. Examples of drug donations to low- and middle-income countries that did not appear useful, 1992–1999

| Country                        | Problematic drug donation                                                                 | Reference          |
|--------------------------------|------------------------------------------------------------------------------------------|--------------------|
| Albania                        | Only 20% of donated drugs in 1999 were found useful                                       | Bonn               |
| Bosnia and Herzegovina         | Between 1992 and 1996, up to 60% of the 27 800–34 800 tonnes of medical supplies donated to what is now Bosnia and Herzegovina were not needed, resulting in 17 000 tonnes of pharmaceutical waste | McGregor and WHO et al. |
| Djibouti                       | In 1994, only 12 co-trimoxazole tablets were found useful out of a large consignment of medicines donated to Médecins Sans Frontières, by a French nongovernmental organization | van der Heide and Schouten |
| Georgia                        | In 1994, 20 tonnes of silver sulfadiazine ointment that was one year past its expiry date were given to an aid organization without notice and a large consignment of donated short-acting insulin arrived just 3 days before its expiry and, in 1995, there were 12 tonnes of unneeded drug donations – including 9 tonnes of expired drugs | Schouten |
| Honduras                       | In 1998, many of the drug donations received were expired or close to expiry               | Bonn               |
| Sudan                          | In 1990, large amounts of inappropriate drugs were received as donations                  | Bonn               |
| The former Yugoslav Republic of Macedonia | In 1999, more than 40% of drug donations were unneeded and about 30% arrived when expired or about to expire | Bonn               |

WHO: World Health Organization.
Pharmaceutical salvage

Manufacturers generally assign pharmaceutical shelf-lives of one to five years. Some pharmaceuticals are held in reserve for use in an emergency situation, such as an outbreak of an infectious disease, and many of these expire before any relevant emergency occurs. This can result in large stockpiles of expired pharmaceuticals, inventory losses and financial losses associated with stock disposal and replacement.

To minimize the burden posed by the disposal and replacement of expired pharmaceuticals, the United States of America’s Food and Drug Administration has for more than three decades employed periodic testing and shelf-life review of pharmaceuticals that have good stability profiles. As a result of this initiative, which is known as the shelf-life extension programme, the shelf-lives of at least 88% of the tested products have been increased by at least one year.10–12

In low- and middle-income countries, it should be possible to extend the useful lives of medications that pass tests for efficacy and safety – and help save both money and the environment – in a similar manner. However, such shelf-life extension or drug salvage is only feasible where there is sufficient capacity for pharmaceutical analysis. In most low-income countries, any consideration of this intervention will have to be accompanied by discussion of investments in analytical infrastructure.

Disposal

If unsafe disposal and leaching of pharmaceuticals into soil and water bodies are to be avoided, many low- and middle-income countries will have to strengthen the enforcement of national policies and WHO guidelines on pharmaceutical disposal. Within the WHO guidelines, it is recommended that: (i) the user unit should obtain approval for drug disposal from the appropriate authority, such as the national medicines regulatory agency; (ii) personnel at the disposal site should wear protective gear; (iii) expired pharmaceuticals are sorted into their different categories to ensure the appropriate disposal method is used for each category; and (iv) appropriate security is ensured during the disposal of controlled pharmaceuticals.9

Many low- and middle-income countries have adapted the WHO guidelines to their own situations. In Uganda, for example, the national medicines regulatory agency is the approving authority for medicines disposal. This agency has prescribed the steps to be taken and acceptable methods for the safe disposal of expired pharmaceuticals.33 Where none currently exists, national regulations on safe drug disposal ought to be formulated.

Although ultra-high-temperature incineration may be the most effective technique for the safe disposal of unwanted pharmaceuticals, it is not a cheap option4 and even the United States has found it hard to implement.34–36 Despite the perpetual burden posed by huge stockpiles of expired pharmaceuticals in the country, Uganda has only recently built its second ultra-high-temperature incinerator approved by the national medicines regulatory agency (D Naha-Mya, National Drug Authority, personal communication, 2017). In 2016, the costs of using these incinerators were high: an hourly supervisory fee, charged by the national medicines regulatory agency, of about US$30 plus a service fee, charged by the service provider, of US$0.75 per kg of pharmaceutical waste.37 The shortage of suitable incinerators and the high cost of using those that do exist promote the accumulation of pharmaceutical stockpiles. Given the threat to the environment posed by the unsafe disposal of pharmaceuticals, many low- and middle-income countries need to prioritize investments in ultra-high-temperature incineration and/or evaluate the safety of using cheaper methods of drug disposal – e.g. engineered landfill or waste immobilization by encapsulation or inertization.9

Accountability

A potentially effective but rarely mentioned tool to prevent the misuse and improper disposal of expired pharmaceuticals is the enforcement of routine accountability for pharmaceuticals. For optimal effectiveness, low- and middle-income countries should make user accountability for expired pharmaceuticals part of the routine accountability regimes for their health sectors.

Conclusion

As expired pharmaceuticals pose threats to both health systems and environments, low- and middle-income countries need to suppress the accumulation of such pharmaceuticals and their slippage into the environment or counterfeit drug markets. Critically, such countries need to strengthen the management of their pharmaceutical supply chains and the associated accountability and regulatory mechanisms.

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Résumé
Menaces représentées par les stocks de produits pharmaceutiques périmés dans les pays à revenu faible et intermédiaire: exemple de l’Ouganda

Dans certains pays à revenu faible et intermédiaire, les pharmacies nationales et les centres publics de santé détiennent dénormes stocks de produits pharmaceutiques périmés. Dans les pays à revenu faible comme l’Ouganda, nombre de ces stocks proviennent de dons. Or, s’ils ne sont pas correctement contrôlés et réglementés, les produits pharmaceutiques périmés peuvent être reconditionnés et revendus en tant que contrefaçons ou bien jetés sans considération du danger pour l’environnement. Dans la chaîne d’approvisionnement, le pourcentage des produits pharmaceutiques périmés doit diminuer, et les produits périmés doivent être éliminés au bon moment et de façon sûre. De nombreux pays à revenu faible et intermédiaire doivent: (i) renforcer le système public de gestion des médicaments, afin d’améliorer le contrôle des stocks et la fiabilité des prévisions d’approvisionnement; (ii) réduire la pression à laquelle les pharmacies centrales sont soumises, grâce à des programmes de libéralisation et de remboursement; (iii) renforcer la régulation des dons de médicaments; (iv) étudier les options envisageables pour réemployer les produits pharmaceutiques officiellement périmés mais dont la durée de conservation pourrait éventuellement être prolongée après la réalisation de nouveaux tests; (v) renforcer l’application des réglementations pour une élimination sans risques des médicaments; (vi) investir dans des infrastructures d’élimination sans risques des médicaments, éventuellement au moyen d’incinérateurs à ultra-haute température; et (vii) responsabiliser les utilisateurs, en intégrant dans les programmes d’encadrement du secteur de la santé publique une obligation de rendre compte pour les produits périmés.

Resumen
Amenazas que suponen las reservas de medicamentos caducados en países con ingresos bajos y medios: una perspectiva de Uganda

En algunos países con ingresos bajos y medios, los almacenes nacionales y las instalaciones del sector sanitario público contienen grandes cantidades de existencias de medicamentos que han superado su fecha de caducidad. En países con ingresos bajos como Uganda, muchas de estas existencias son el resultado de donaciones. Si no se controlan o se depositan sin tener conciencia del potencial daño medioambiental, estos medicamentos caducados pueden ser recondicionados y vendidos como falsificaciones o bien depositados en instalaciones públicas sin considerar el peligro para el medio ambiente. En estos países, la eliminación de los productos caducados debe ser realizada en un momento adecuado y de manera segura. Para algunos países con ingresos bajos y medios, es necesario: (i) fortalecer los sistemas públicos de gestión de medicamentos para mejorar el control de los stocks y la fiabilidad de las previsiones de aprovisionamiento; (ii) reducir la presión a la que se enfrentan las farmacias centrales, mediante programas de liberalización y reembolso; (iii) fortalecer la regulación de los donativos de medicamentos; (iv) estudiar las opciones para el reempleo de los medicamentos oficialmente caducados con la posibilidad de prolongar su vida útil después de nuevas pruebas; (v) fortalecer el cumplimiento de las regulaciones para una eliminación segura de los medicamentos; (vi) invertir en infraestructuras y sistemas de eliminación segura de los medicamentos, incluso mediante el uso de incineradores a altas temperaturas; y (vii) responsabilizar a los usuarios, incorporando en los programas de supervisión del sector de la salud pública una obligación de informar si se usan los medicamentos caducados.

A Ugandan perspective on expired pharmaceuticals

Policy & practice

A Ugandan perspective on expired pharmaceuticals

Regulatory control of medicinal products; to what extent do they exist in the national pharmaceuticals stores? Menaces représentées par les stocks de produits pharmaceutiques périmés dans les pays à revenu faible et intermédiaire: exemple de l’Ouganda

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Resumen
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En algunos países con ingresos bajos y medios, los almacenes nacionales y las instalaciones del sector sanitario público contienen grandes cantidades de existencias de medicamentos que han superado su fecha de caducidad. En países con ingresos bajos como Uganda, muchas de estas existencias son el resultado de donaciones. Si no se controlan o
a tiempo y de forma segura. Muchos países con ingresos bajos y medios necesitan: (i) fortalecer los sistemas públicos para la gestión de medicamentos para mejorar el control del inventario y la fiabilidad de la adquisición de provisiones; (ii) reducir el estrés en los almacenes médicos centrales a través de sistemas de reembolso y liberación; (iii) aumentar la regulación de las donaciones de medicamentos; (iv) investigar la recuperación de medicamentos oficialmente caducados a través de análisis y una posible extensión de la vida útil; (v) fortalecer la aplicación de regulaciones sobre la eliminación segura de medicamentos; (vi) invertir en una infraestructura para dicha eliminación, tal vez basada en incineradores de alta temperatura; e (vii) incluir la responsabilidad por parte de los usuarios en relación con los medicamentos caducados en los regímenes de responsabilidad rutinaria seguidos por el sector sanitario público.

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