

Uganda pharmaceutical sector review 2018

Component	Indicators	Update	Implications
Legislation, regulation and quality assurance	<p>Proportion of sampled pharmaceutical products failing NMRA quality tests</p> <p>Percentage of pharmaceutical products sampled from post marketing surveillance failing quality tests</p>	<p>8.67% (AHSPR 2016/17)</p> <p>13% (AHSPR 2016/17)</p>	<p>8.67% includes pharmaceutical products sampled from both the ports of entry and post marketing surveillance, while 13% is includes only products sampled in post marketing surveillance. These figures show that more pharmaceutical products are failing quality tests post marketing. Nevertheless, both these figures are on the higher end as the country targets <1% pharmaceutical products failing quality tests (http://shrinx.it/9u4).</p> <p>This indicates that either poor quality pharmaceutical products are finding their way on to the market, or that quality of the products deteriorates while they are already on the market. Therefore;</p> <ul style="list-style-type: none"> • The National Drug Authority (NDA) needs to be more stringent in enforcing regulations pertaining to manufacturing and distribution of medicines and other medical products to reduce the percentage of low quality products in the country. • Manufacturers should endeavor to monitor the quality of their products post marketing in order to determine the factors that commonly lead to deterioration of the product and propose necessary cautions to guard against them. • Distributors of pharmaceuticals should have in place appropriate transport, storage and monitoring systems to ensure that the products remain of good quality while under their custody. • Service delivery points hospitals and pharmacies should also maintain appropriate facilities for storage and have guidelines in place for proper handling and storage of pharmaceutical products in order to maintain quality.
Medicines Use	Percentage of prescriptions	Malaria: 77%	All prescriptions need to be written in accordance with the recommended Clinical Guidelines e.g. the Uganda Clinical Guidelines (UCG). These scores however indicate that for

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	for different conditions complying with approved clinical guideline.	Diarrhea: 75% Non Pneumonia URTI: 59% (SPARS)	<p>the three selected conditions, not all prescriptions are fully compliant with the recommended guidelines. This indicates that there is still inappropriate prescription of medicines despite the fact that the clinical guidelines have been availed to most health facilities all over the country. This inappropriate prescription often times takes the form of; unnecessary drug, wrong medicine prescribed for a condition or wrong duration of treatment regimen. This can lead to poor treatment outcome for patients, wastage of resources, and emergence of resistance to anti-microbial agents which can have hazardous implications.</p> <p>The Ministry of Health (MoH) has done a good job distributing the UCG to almost all health facilities in Uganda therefore the health service delivery points need to ensure that the prescribers have easy access to the guidelines for reference as they go about their daily work. The prescribers should also make effort to get familiar with the available guidelines and make use of other relevant electronic references to improve appropriateness of prescriptions.</p>
Traditional and Complementary medicines	Number of TCM products on the medicines register	132 (NDA drug register, September 17, 2018)	<p>Only a few of TCM products (132) have been notified to the National Drug Authority drug register (https://bit.ly/2N7SOOZ)</p> <p>However, there are presumably more than 132 TCM products available on the market. The non-notified TCM products may be of substandard quality or may be adulterated with modern medicines which can pose health risks to unsuspecting consumers. E.g. recently the NDA released a list of herbal sex boosters for men that were found containing dangerous substances that could lead to serious cardiovascular events and sudden death (https://bit.ly/2RbWouC).</p> <p>The NDA requires that all herbal medicines be notified with them before they can be commercialized through distribution, promotion or advertisement. In fact, pharmacies and drug shops aren't authorized to stock herbal medicines that aren't notified by the NDA (https://bit.ly/2DSelLY). Therefore, manufactures of TCM products should endeavor to cooperate with the NDA for notification of their products. This will not only guard consumers against substandard products but will also improve marketability of the TCM products.</p>

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Medicines Financing	Per capita expenditure on medicines (based on GoU budget)	1.9 (APSPR 2015/16)	It is estimated that between \$13 and \$25 per capita is needed to finance a basic package of 201 essential medicines (Wirtz, et al., 2016). A \$1.9 per capita expenditure in Uganda implies that the balance (\$11.1 and \$23.1) is covered by the consumers. This direct out of pocket expenditure on medicines by many households brings about inequitable access to medicines as not all households can afford to spend out of pocket. There is need to reduce the cost of medicines in the country through local manufacturing and the government should increase budget allocation to Essential Medicines and Health Supplies.
Medicines pricing	Percentage of international indicator price paid by warehouses for tracer EMHS	NMS- 42% (APSPR 2015/2016)	JMS is paying more for a basket of medicines than NMS by 27%. This shows that public sector procurement (NMS) is obtaining better value for money as compared to the private sector procurement (JMS). This is good for the country as it optimizes use of the already limited financial resources, and also helps to mitigate the low per capita allocation by the government.
		JMS- 69% (APSPR 2015/2016)	JMS can create more value for money by improving competitiveness of procurement of EMHS for the non-public sector.
Human Resource Development	Number of pharmacists and pharmacy technicians per 100,000 population	2.3 pharmacists and 1.7 pharmacy technicians for a population of 100,000 persons (APSPR 2015/16)	The WHO recommends a ratio of 1 pharmacist per population of 2,000 persons in order to provide optimal health care (https://bit.ly/2lseHYt). This is equivalent to 50 pharmacists per population of 100,000 people. At 2.3 pharmacists and 1.7 pharmacists per population of 100,000, Uganda has an insufficient number of pharmaceutical personnel to be able to deliver optimal pharmaceutical care. There is need to train and retain more pharmacists and pharmacy technicians for the country.
Research and development	Number of new products / formulations developed in the country	None	There is an opportunity to invest in research and development of new products/ formulations targeting the essential medicines that are not readily available.
Health commodity supply chain	Availability of a basket of EMHS at	At central level;	These figures indicate that stock outs of Essential Medicines and Health Supplies continue to occur at both central and

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	central and peripheral level	NMS- 60% JMS- 67% At peripheral level; 89% (APSPR 2015/16)	peripheral levels, and this undermines provision of pharmaceutical care in the country. This calls for more accurate quantification and forecasting processes at both central and peripheral levels to reduce stock outs that may be caused by understocking. There is also need to allocate more financial resources to procurement of EMHS at both the central and peripheral levels.
Domestic manufacturing	Number of locally manufactured EMHS with import restrictions or differential fees or full / partial waiver of import restrictions at bilateral or regional level	37 (NDA)	Manufacturers should focus on producing medicines on that list so as to benefit from this incentive. The medicines are listed below; <ol style="list-style-type: none"> 1) Albendazole 400mg Tablets / Suspension 100mg /5ml 2) Amoxicillin trihydrate equivalent to amoxicillin 125mg/5ml 3) Amoxicillin trihydrate equivalent to Amoxicillin 250mg 4) Ampicillin 125mg + Cloxacillin 125mg/5ml 5) Ampicillin 250mg + Cloxacillin 250mg capsules 6) Artemether / Lumefantrine 20/120mg 7) Artemether / Lumefantrine 15/ 90 Dry suspension 8) Ascorbic acid (Vitamin C) 100mg 9) Cetrizine Hydrochloride 10mg Tablets / Syrup 1mg /ml 10) Chloramphenicol Palmitate 125mg/5ml 11) Ciprofloxacin 500mg 12) Ciprofloxacin 0.2% 13) Cloxacillin 125mg/5ml 14) Cloxacillin sodium equivalent to cloxacillin 250mg 15) Dextrose 5% 16) Dextrose 50% (D50) 17) Diclofenac Sodium 50mg 18) Doxycycline 100mg 19) Erythromycin 125mg/5ml (as Estolate and Ethynyl Succinate) 20) Erythromycin 250mg 21) Hartmann's Ringer Lactate 22) Ibuprofen 200mgTablet / Suspension 100mg/5ml 23) Loperamide 2mg 24) Magnesium Trisilicate 250mg + Dried Aluminium Hydroxide 120mg/gel 25) Mannitol 20% 26) Metronidazole 0.5% 27) Metronidazole 200mg Tablets / Suspension 100mg /5ml

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			28) Sodium Chloride 0.9% 29) Omeprazole 20mg 30) ORS: Glucose anhydrous 13.5gm + Trisodium citrate Dihydrate 2.9gm + Sodium Chloride 2.6gm + potassium Chloride 1.5gm ORS + Zinc sulphate Monohydrate 20mg Tablets (2sachets ORS + 10 Zinc Tablets 31) Paracetamol 500mg Tablets /Suspension 120mg/5ml 32) Quinine sulphate 300mg Tablet / Syrup 100mg/5ml 33) Sulfamethoxazole 200mg/ Trimethoprim 40mg/5ml 34) Surgical Spirit 35) Trimethoprim 80g + Sulfamethoxazole 400mg 36) Zinc Sulphate monohydrate BP (54.9) equivalent to 20mg elemental zinc/solution supplement 10mg/5m
	Proportion of manufacturing plants with external certification for plant or product	1 (6.7%) i.e. 1/15 pharmaceutical manufacturing plants in Uganda	Currently only CIPLA Quality Chemicals Industry has external certification from the WHO for GMP in Uganda. Only it can experience the benefits that come along with being WHO certified e.g. being able to sell their products on international market e.g. the public health programs such as HIV/AIDS, TB and Malaria programs which specify that medicines used in the programs are procured from only WHO GMP certified pharmaceutical manufacturers. Other local manufacturers therefore can't tap into such markets even when they have the capacity to do so. This grossly reduces their market base and potential revenue from their products may not be reached because of this limitation. Local manufacturers should work towards getting WHO GMP certification.