PHARMACEUTICAL PROMOTION
Sudan Journal for Rational Use of Medicine (SJIRM) is a quarterly publication produced by the National Medicine Information Center and Reference Library (NMICRL); Directorate General of Pharmacy; Federal Ministry of Health; Sudan. SJIRM is funded by Global Fund and technically supported by the World Health Organization. The first issue was published in September 2012. SJIRM aims to promote Rational Use of Medicines (RUM) through disseminating principles, views, news, and educating health providers about rational use of medicines. SJIRM targets health professionals; prescribers, pharmacists, and nurses. Each issue is centered on a theme; which usually is an important subject in RUM. SJIRM highlights in each issue the current situation in Sudan relevant to the theme, presented either by evidence from local research or with reliable anecdotal evidence. SJIRM includes research studies which aim to encourage young researchers to publish their work at national and international levels. SJIRM also includes a section for educational materials relevant to RUM relying mostly on the WHO educational materials and other reliable sources. The section of news reflects some important published news that may affect RUM practice. SJIRM includes some selected case studies, reflecting current practice at different health facilities in Sudan, so as to highlight the irrational aspects in order to overcome them.

As part of NMICRL activities, medical students and the public are endowed with leaflets and fliers on selected topics of SJIRM.

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Editorial

Dear fellows and readers,

Welcome to the 13th issue of SJRUM.

On behalf of the editorial board, it gives us great pleasure to welcome you all to our issue number 13 of SJRUM on medicines pharmaceutical promotion. SJRUM is concerned with the rational use of medicines, which has become the fundamental responsibility of all healthcare providers. Holding this responsibility makes them automatically, committed to the prevention of irrational medicines prescribing and dispensing in all health care facilities.

Certain factors directly affect the doctor's process of medicine selection like knowledge about medicines, the demanding patients and the aggressive medicine promotion by the pharmaceutical companies. Medicine companies are frequently blamed for providing biased medicine information. They usually promote their pharmaceutical products by emphasizing the positive aspects of their products, while the negative aspects will be overlooked. This is the reason why doctors should not rely solely on the information provided by the medicine manufacturing companies. However, pharmaceutical promotional activities and their impact on the knowledge, attitudes and behaviors of the doctors and pharmacists, have always been a debatable issue. Even the published literature contains a wide range of evidence about their effects. Thus high quality studies that establish a concrete causal relationship between the promotion of medicines and the attitudes and behaviors of doctors and other healthcare providers are needed. An agreed upon fact, remains to be, that pharmaceutical promotional activities should be well regulated, organized and controlled under ethical guidelines by medicine regulatory bodies.

The current issue contains articles about pharmaceutical promotion in the usual format of the journal, current topic, practice issues, educational materials, focus and relevant researches.

All of the topics were written by authors and healthcare professionals, reflecting valuable experiences in their fields of knowledge and expertise.

Finally, I would like to invite our distinguished readers, to participate in writing in SJRUM journal. As we, the team of editors of the journal, welcome your feedback and comments in our website www.sjrum.com.

With my best compliments and regards

Randa AlSadig AlMahdi
Brochures of both multinational and branded generic pharmaceutical companies, for different pharmaceutical prescription products, were collected from doctors clinics in Khartoum, Sudan. Then screened to verify whether their medication informational contents, as represented by section headings, were satisfying the medication information particulars recommended in the WHO ethical criteria for medicinal drug promotion, as shown in table one.

Table 1: Brochures medication information section headings comparing with advised by the WHO ethical criteria for medicinal drug promotion.

<table>
<thead>
<tr>
<th>Section headings</th>
<th>Frequency of availability in the brochure’s text</th>
<th>Percentage of availability in the brochure’s text in a sample collected randomly selected from doctors’ clinics in (n=259) Khartoum 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand name</td>
<td>259</td>
<td>100</td>
</tr>
<tr>
<td>Generic name</td>
<td>259</td>
<td>100</td>
</tr>
<tr>
<td>Indications</td>
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</tr>
<tr>
<td>Dosage form</td>
<td>222</td>
<td>85.7</td>
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<tr>
<td>Dosage and administration</td>
<td>218</td>
<td>84.1</td>
</tr>
<tr>
<td>Side effects</td>
<td>140</td>
<td>54</td>
</tr>
<tr>
<td>Contraindication</td>
<td>130</td>
<td>50.1</td>
</tr>
<tr>
<td>Precautions</td>
<td>130</td>
<td>50.1</td>
</tr>
<tr>
<td>Drug-interactions</td>
<td>63</td>
<td>24.3</td>
</tr>
<tr>
<td>Retrievable references</td>
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<td>48</td>
</tr>
</tbody>
</table>

Current modes of pharmaceutical promotion in Sudan; trading and gifts are dominating

Kamal Addin M. Ahmad

ill the early eighties of the last century the Sudan market of pharmaceutical was almost exclusively dominated by the multinational pharmaceutical companies.

Due to the economic constraints at that time, their majority pulled out and generic manufacturers from the Middle East and South East Asia filled the gap with branded generic and frank generic product. Today they represent more than 84% of the registered medication. Actually for every one generic name at least ten (10) branded generics are on register.

By definition generic and branded generics are classical products which may differ from each other in price and source, but not in effectiveness or safety.

The central promotional slogan for generics and branded generic is: Quality products at affordable prices. These two distinguishing claims are appealing to both patients, their communities and payers due to the soaring medicine budgets in both the developed and developing countries, which limit access to the needed medicines.

It is pertaining to mention that the generics and branded generics constitute over 88% of the prescription in the USA and 40% by volume in Europe.

Currently in Sudan the generic and branded generics promotions, appeal to prescribers by samples volumes, gifts, financing of travel to conferences, donations to different medical specialties societies, and the affordable prices and availability; as these are no new

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1. Pharmacy practice and pharmaceutical promotion specialist, University of Gezira, Wad Medani, Sudan.
scientific information to offer. However, as there are huge numbers of newly graduated junior doctors who lack information and knowledge about pharmacology and therapeutics, active promotional – brochures, journal reprints and advertisements and audiovisual presentation are the main promotional means, for this sector of highly potential prescribers in all medical settings, but mainly in the public sector.

Some of the branded generic companies are adopting tactics of niche promotion, where they target specific medical specialties, specific medical settings (Primary and Secondary healthcare) and territories to differentiate themselves for the competitors' brands of the same generics name.

Public relations, cash discounts, free goods offers (bonuses), credit facilities to retailers and efficient customers services represent the most dominant promotional appeals to retailers. This is trading. These companies are also very aware of the casting role of pharmacy selling where self-care, O.T.C and the free uncontrolled but lawful rights of substitution allowed to community pharmacist.

In conclusion, the current promotional tactics depend on gifts at large to both senior and junior doctors and motivational trading to retailers. Niching in specialization and territorial targeting are also used. It is recommended that law, act or codes for ethical promotion be drawn and strictly enacted. Trading has to be controlled specially the bonus which is not favoring patients.

References:
Sales strategy and special offers may induce antibiotics over consumption

Badereldin S. Hagnour

An Unethical practices and poor regulations can encourage unnecessary medicines consumption, and in this particular case irrational use of antibiotics. This will definitely accelerate the spread of antibiotics resistance and affects the public health at large.

Highly competitive and unregulated pharmaceutical market favours non ethical trading practices. Company X is facing difficulty to penetrate the market. Seeking profit and in order to increase the sales of a low rate prescribed antibiotic X (caps 500 mg) which is about to expire, the sales department adopted the following strategy:

- Offered 70% bonus in every 1000 boxes of 16 cap unit purchased by community pharmacies and 6 months credit facilities.
- Another 10% increment every repeated order.
- Abroad conferences and tourism ticket to General Practitioner physician adjacent to pharmacy.
- Concurrent promotion campaign targeting the potential areas.
- Replenishment of remaining stock with fresh ones in case of expired quantity.

Problems:
- Promote unethical practices.
- Antibiotic over prescribing and none compliance to treatment guidelines.
- Encourage of antibiotic sale without prescriptions.
- Unnecessary medicines consumptions.
- Economic burden to public and community at large.
- Encourage self-medication.
- Emergence of antibiotic resistance and cross resistance may develop.

Solutions:
- Medicines regulatory authorities should enforce pharmaceutical laws and regulations.
- Train health professionals on how to stand against unethical situations of promotional activities.
- Generic prescribing policy should be implemented and enforced.
- Healthcare providers practice should be supervised.
- Awareness campaign to sensitize the public against irrational medicines use.
- Set policies to regulate medicines importation to avoid dumping and duplication and hence malpractices.

Misleading information change prescribing pattern

Ashwag A. Mirghani

A chief pharmacist in a maternity hospital observed that prescribing pattern for antibiotic prophylaxis for caesarean section has changed during the last 2 weeks. The prescriptions included a fourth generation cephalosporin that has been launched to the market recently. According to the hospital treatment protocol, the first line treatment is first generation cephalosporin or penicillin. When the pharmacist asked the doctors about the reason for changing the current prescribing guideline which resulted in non-availability of these medicines on the hospital formulary, it has been explained that the 4th generation antibiotics are very potent and effective antibiotic. The pharmacist found that the source of information was from a pharmaceutical representative (medical rep).

Problems:

- Massive prescribing of a medicine that is neither included on the hospital treatment protocol nor the hospital formulary.
- Health providers should not rely solely on the information from pharmaceutical companies.
- It has been found that there is a lack of evidence on the medicine efficacy as a prophylactic antibiotic for caesarean section when searching published evidence from independent sources.
- Using inefficient medicine will lead to waste of resources as the buyer of the medicine (individuals, providers or insurers) will cost its price.
- The wrong choice of a prophylactic antibiotic will expose the patients to infections. Also it may result in resistant strains of bacteria.
- The pharmacist didn’t refer to the pharmacy and therapeutic committee or committees that decide on a formulary or protocol before purchasing the new medicine.

Solutions:

- Prescribers must follow the hospital treatment protocol and formulary.
- All health providers should seek independent information from reputable sources.
- In most cases pharmaceutical promotional materials contain misleading information and highlight only the positive aspects of the product. So pharmacists need to appraise them in order to be able to persuade the prescribers who have been influenced by the biased information.
- Pharmacy and therapeutic committee should have the upper hand on the decision of introducing a new medicine to the hospital.
- The selection of the medicine must base on good quality evidence.
- Evidence could be gathered using “STEP” analysis (safety, tolerability, efficacy, and price) and then compare the findings with the current standard treatment.
- A new medicine is not always better or safer. Thus it should be selected if there is a therapeutic or safety advantages over a currently used product.
- The optimal prophylactic agent should be effective, inexpensive, and have a low side effect profile.

Shaza, a pharmacist working on the outpatient pharmacy of pediatric hospital. She became concerned when she dispensed for the fifth time this morning a prescription containing cough medication for a child less than five years. She also noticed that the cough medications were brands for a certain pharmaceutical company. Knowing that medical representatives visited the hospital, she decided to speak with the doctors who prescribed the cough syrups.

When Shaza met the doctors on the cold cases unit, she found that they were junior doctors who just started the pediatric shift and came to a conclusion that they were influenced by the medical representative talk and printed materials displayed on their desks.

Problems:

• Prescribers are influenced by the promotion of pharmaceutical products.

• The promotion’s information is not always accurate, and certainly the interest is not the patient but profit.

• Children under five years of age should not be given cough medication, based on clinical evidence and as recommended by international guidelines.

Solutions:

• Prescribers should be equipped with enough knowledge, experience and skill to be able to resist the influence of pharmaceutical promotion.

• Commitment to guidelines, and formularies is one method to prevent the negative effect of pharmaceutical promotion.

• Medical staff should have easy access to reliable, unbiased and accurate information about medicines. They also need the skill to criticize and appraise medical literature and promotion materials.

• Children less than five years should not be given cough medication as these medicines are usually combinations and generally have poor clinical value. Treatment should addressed to correct the cause and the symptoms.
Based on WHO Ethical Criteria for Medicinal Drug Promotion, the Medication Safety Division, Ministry of Health, Khartoum State developed a guideline on 2013 to be followed by pharmaceutical companies to ensure accuracy, neutralism and ethical promotion. The guideline was entitled “Prescription and Drug Promotion” to control the content of presentations and printed materials produce by pharmaceutical companies for the purpose of promotion.

The printed material must contain the following:

1. The name (s) of the active ingredient (s) using either international nonproprietary names (INN) or the approved generic name of the medicine.
2. The brand name.
3. Concentration or Content of active ingredient (s) per dosage form or regimen.
4. Name of inactive ingredients known to cause problems.
5. Pharmacological data: a brief description of effects and possibly the mechanism of action.
6. Approved therapeutic uses or indications; one or more of the therapeutic indications for the product consistent with the terms of the license.
7. Dosage form or regimen and relevant pharmacokinetic data such as average dose and range for adults and children, dosing interval, average duration of treatment and specific situations.
8. Side effects and major adverse drug reactions.
10. Major interactions.
11. Name and address of manufacturer or distributor.
12. Reference to scientific literature as appropriate.

The presentation must comply with particulars listed in the Summary of Product Characteristics (SPC) or clinical overview of the medicine that is used in registration at the National Medicines and Poisons Board.

It should contain the following:

1. Therapeutic indications listed in the SPC for that specific medicine, any other indication cannot be promoted.
2. A medicine can be promoted for use in treating or preventing conditions or illness for which it has been licensed only, i.e. not to promote unlicensed use or indication.
3. A medicine can be promoted to be used in the licensed patient groups and not any other.
4. The presentation should encourage the rational use of the product by presenting it objectively and without exaggerating its qualities.
5. The presentation must not be ambiguous or misleading for example unrealistic or inappropriate images which can give rise to unrealistic high expectations about the product or the indicated patient population should not be used.
6. Any information included in presentation or materials should be referenced.

Introduction:

Pharmaceutical companies cannot be relied on as a good source of medicine information. They are frequently accused for providing biased information in favour of their medicine products, emphasizing the positive and masking the negative information\(^1\). This is why the relationship between pharmaceutical companies and healthcare professionals has become a matter of debate and criticism. The ethical criteria for medicinal medicine promotion sets a standard to support and encourage the improvement of public health through the rational use of medicinal medicines by encouraging the appropriate use of pharmaceutical products and presenting them objectively\(^2\).

In Sudan a decree for drug promotion regulation was initiated with promulgation of advertising rules by the National Medicines and Poisons Board. However, they included no mechanisms through which the promotional campaigns by pharmaceutical companies can be monitored. However, there is enough evidence that the irrational medicine use is increasing due to unethical practices of pharmaceutical promotion\(^3\).

This survey is intending to investigate the influence of pharmaceutical marketing on the prescribing and dispensing patterns of physicians and pharmacists, respectively.

Method:

A descriptive cross-sectional survey, conducted in Khartoum State. Two sets of questionnaire forms were designed, one for the physicians in public and private sectors, and another for the community pharmacists selected on random basis during the period 15/9/2013 to 20/3/2014. The data was collected from 200 respondents, 77 physicians from different disciplines and 123 community pharmacists.

Each of the questionnaire forms contained 30 questions divided into four sections, the demographics, the promotional techniques used, the given causes for brand shifting and the source of medicine information relied on.

The second, third and fourth sections were evaluated by the Likert scale. The data were analyzed using the Statistical Package for Social Science version 16 SPSS.

Results and Discussion:

Seventy seven of the participants were physicians, and one hundred and twenty were pharmacists. The physicians reported that their prescribing behaviours were mainly influenced by information about medicines safety and efficacy followed by the frequency of the medical representatives' visits and then the medicine price as shown in Figure1.

While the pharmacists have reported that their drug ordering volume have followed mainly the doctors' prescribing rate of the medicine product followed by the medicine quality and then the medicine cost.

A lot of criticism is facing the promotional activities carried by the pharmaceutical companies to increase the volume of their sales. Among the big issues is the conflict of interest that may influence the prescribing behaviours of the doctors and the dispensing practices of pharmacists, in addition with many ethical considerations.

The findings of this survey were in agreement with what was reported in the retrieved published literature where the impact of free samples and gifts had a significant influence

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on the prescribing behavior of doctors and was well documented. However, many health professionals had underestimated the effects of pharmaceutical promotion on their beliefs and professional practice and believed that they were not personally influenced by promotion (physicians 53.8%, pharmacists 49.6%). Psychologists have found that it is normal for people to believe that only other people are vulnerable to being misled by promotional techniques. This is called the illusion of unique invulnerability.

Many observational studies have found an association between prescriber reliance on medical representatives and more frequent or lower quality prescribing. Also the more a prescriber has a direct contact with medical representative, the more likely that medicine product is recommended.

**Conclusion and recommendations:**

This survey has clearly shown that pharmaceutical promotional activities have significant impact on both prescribing and dispensing practices of doctors and pharmacists, respectively. It can be safely concluded that pharmaceutical promotion should be subjected to good regulations that regulate the activities of the medical representative to prevent any negative impact that can compromise the public health. The suggested regulations are recommended to include generic prescribing and generic substitution policies and to monitor their implementations in our health facilities.

![Figure 1: Factors frequently affecting the prescribing behavior of physicians.](image)

**References:**

Pharmaceuticals companies’ promotional brochures: do they contain reliable and useful medications’ information?

Kamal Addin M. Ahmad¹, Mirghani A. Yousif ², Asim F. Mustafa ³

Introduction:

For rational use of medicines, healthcare providers should select reliable and safe medicines based on adequate, comprehensive, easily accessible, accurate and balanced medication information. They get access to such essentially needed medication information, from a diversity of sources. In developing countries, the pharmaceutical industry through various promotional tools, materials and activities represent an important source of medication information for healthcare providers. Though was known to have a negative effect on healthcare prescribing practices. However, doctors and other healthcare providers, greatly rely in their prescribing practices on medication information provided by the pharmaceutical industry.

The main objective of this study was to evaluate the content of medication information in the promotional brochures; (section headings) of pharmaceutical companies’, their possible benefits, reliability and the usefulness of the provided information.

Methods:

Three hundred and fifty-one (n=351) brochures were collected from randomly selected doctors’ clinics in Khartoum, Sudan. Ninety-two of those brochures were excluded for being either duplicates, reminder brochures, promoting medical devices or cosmetics. The remaining (259), were then screened to compare their macro informational contents (section headings) against same recommended by the world health organization ethical criteria for medicinal drug promotion.

The compared section headings were: the product’s brand name and generic name, indications, dosage and administration, dosage forms, contra-indications, precautions, side effects, drug interactions, and the supporting scientific evidence (references) for their various claims.

Only 125 cited references included in the brochures, were selected randomly, and screened to verify that they were retrievable, and then match them against the promotional claims to which they correspond. The screening was limited to the internet information sources.

Results and Discussion:

The two hundred and fifty-nine (n=259) different pharmaceutical companies’ brochures were found to belong to multinational companies (91) and (168) to branded generic companies (Group A and Group B, respectively).

The (n=259) screened promotional brochures’ macro-medication information contents (section headings), displayed unbalanced and weakly evidenced-based medication information. Those sections headings of the promoted products encourage for unrestricted use of the promoted medications, such as the brand name, generic name, indications, dosage form, dose and administration were given more attention and more frequent display, in 1213 (93.66%) average. In contrast, those section headings relating to medications’ safety issues and restrictions on products’ use, such as contra-indications, precautions, side effects and drug- interactions, were less displayed 588 (45.4%) as show in figure1.

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2. Department of Clinical Pharmacy, College of Pharmacy, Taif University, KSA.
3. (Late), Department of Pharmacy, Faculty of Pharmacy, Omdurman Islamic University, Sudan.
Figure 1: Comparison between availability of medication information section headings in promotional brochures of multinational pharmaceutical companies (Group A) and branded generic companies (Group B).

The resulted bivariate analyses based on comparison between the brochures of the multinational and the branded generic pharmaceutical companies, revealed significant differences. Other researchers had, quite often, reported similar differences between the promotional printed materials of the multinationals and branded generics, albeit those differences might not be significant. This may further confirm our hypothesis that the quality of scientific information provided in the surveyed pharmaceutical company’s brochures, of both the multinational and the branded generic pharmaceutical companies, did not provide adequately balanced and reliable information, which might be sometimes misleading. They, as well, were not exactly matching to WHO ethical criteria for medicinal drug promotion.

**Conclusion and recommendations:**

The results of the study revealed, very clearly, that the overall nature of the informational contents of the screened pharmaceutical promotional brochures, as judged from the frequencies of the informational section headings displayed, was unbalanced, biased, not educative and poorly referenced, and do not comply with, the WHO ethical criteria. Accordingly, it is recommended that healthcare providers shall be trained on how to critically appraise the quality of the medication information displayed in the promotional brochures. Those in developing countries in particular, should not solely depend on commercial information, and should seek independent sources of medication information. The official regulators of such materials shall define and strictly mandate their medication information particulars.

**Abstracted from:**

Proton pump inhibitor (PPI) use and the risk of chronic kidney disease (CKD)

JAMA Intern Med, 2016

Proton pump inhibitors (PPIs) (e.g. omeprazole, lansoprazole, pantoprazole) are among the most commonly used drugs worldwide and have been linked to acute interstitial nephritis. A population-based cohort study to quantify the association between PPI use and incident of CKD was done.

A total of 10,482 participants who reported self-medication with PPI and with an estimated glomerular filtration rate of at least 60 mL/min/1.73 m² were followed from 1996 to 2011. The findings were replicated in an administrative cohort of 248,751 patients who were discharged from different health facilities with outpatient PPI prescriptions.

Proton pump inhibitor use was found to be associated with incident CKD in both studies with higher associated risk in twice-daily PPI use (adjusted HR, 1.46; 95% CI, 1.28-1.67) than once-daily dosing (adjusted HR, 1.15; 95% CI, 1.09-1.21).

HR: Hazard Ratio
CI: Confidence Interval

Top-drug-brands-accused-huge-mark-ups and misleading claims

www.dailymail.co.uk, Dec. 2015

Manufacturers have been accused of misleading the public by selling pills that claim to tackle different ailments but have the same active ingredients. The maker of Nurofen® has been ordered by an Australian court to stop selling pills that claim to help certain ailments but are chemically identical.

The active ingredient in Nurofen Express is 200 mg of ibuprofen is selling with a mark-up of almost 1000 percent compare with standard Nurofen, which also contains 200mg of ibuprofen!

But many famous names use similar tactics. All big brands rely on ibuprofen or paracetamol as the basis of remedies then use marketing and packaging to present them as targeting specific conditions.

Pharmaceutical companies urge governments to take collective action on drug-resistant infections

www.pharmaceutical-technology.com, 2016

Around 85 international pharmaceutical and nine industry associations from 18 countries, generics, diagnostics and biotechnology firms have urged governments and industry to take comprehensive action on drug-resistant infections called superbugs.

The firms have launched a joint declaration at the World Economic Forum in Davos, Switzerland, calling for collective action on antimicrobial resistance. They urged governments across the globe to support companies to invest in the development of antibiotics, diagnostics, vaccines and other products to be used for the prevention and treatment of drug-resistant infections.

The declaration has recommended certain measures including reducing the development of drug resistance, increasing investment in research and development and improving access to high-quality antibiotics.
How medicine companies influence health in the developing world

Sarra I, Rashid

In many developing countries, pharmaceutical companies have been accused of exploiting the lack of independent information available to medical professionals and patients. In the absence of independent sources doctors, the public and patients have to rely to a much greater extent on companies’ marketing to tell them about the products that are available. When the information that is provided is misleading, biased and inaccurate it contributes to dangerous levels of mis-prescribing. Up to 50% of medicines in developing countries are inappropriately prescribed, dispensed or sold. The problem is compounded when medicine companies also release misleading messages and information to the public and patients. It is also estimated that 50% of patients in developing countries improperly use medicines. Such high levels of irrational use are likely to be having a disastrous impact on people’s health resulting in reduced treatment efficacy and contributing to problems like medicine resistance. The UK’s Department for International Development concludes that poor people in developing countries often receive little health benefit for their spending on medicines. In developing countries the systems and resources to effectively monitor and regulate the marketing of medicines are not necessarily in place. In 2004, the World Health Organization established that less than one-sixth of countries had a well-developed system of medicine regulation, and one-third had little to no regulatory capacity. Therefore, frameworks to enforce unethical, irresponsible or even illegal promotion to consumers are a major problem in the context of developing and emerging economy countries

Cost is a key issue for consumers of medicines in developing countries. In many developing countries medicines can account for up to 90% of household expenditure on health, making the cost of medicine a key determinant in whether or not people have access. This issue has already provoked fierce public debate about patents for medicines and the role of governments in licensing generic treatments for conditions such as HIV/Aids. What has been less explored is the role of pharmaceutical marketing in raising the prices that poor people pay for medicines. The concern is that pharmaceutical companies’ marketing has led to poor people paying for branded products that cost a lot more than the much cheaper generic but have little or no additional medical value

In Sudan a decree for medicine promotion regulation is initiated with promulgation of advertising rules by National Medicines and Poisons Board. However there are no mechanisms to monitor the medicine promotional campaign by pharmaceutical in companies in Sudan, despite the fact that there is enough evidence that the rational medicine utilization problems increasingly encountered due to unethical practices of pharmaceutical promotion

References:

1. Drugs, Doctors and Dinners (How drug companies influence health in the developing world), published by Consumers International in October 2007.

How appropriately to use creams and ointments

Sarra I. Rashid

Creams are a mixture of roughly half water and half oil. They spread easily, are well absorbed, and wash off with water. Ointments feel greasy and are "occlusive", meaning they stay on the surface of the skin and are not well absorbed. The water and oil components of creams and ointments serve primarily as a "vehicle" to carry an active ingredient.

When to use an ointment or a cream?
1. Creams are best when covering large areas of the skin or to avoid the greasiness associated with an ointment.
2. Wet or "weeping" skin lesions, such as eczema, are best treated with a cream (or gel).
3. Ointments are best when treating dry skin conditions, such as psoriasis.
4. Ointments allow greater penetration of the active ingredient in the topical medication, whether it is an antibiotic, steroid, or anti-fungal medication.
5. Ointments may be better to use on sensitive skin since many creams are manufactured with sensitizing preservatives.

Doctors should advise their patients to:
1. The first time when taking the cap off the tube may find the end of the tube sealed. It can be pierced this seal by inverting the cap of the tube and pushing it into the end of the tube.
2. Wash the affected area(s) of skin well and rinse away all traces of soap or cleanser.
3. Pat the skin dry rather than rubbing it.
4. Apply the cream or ointment thinly and evenly to the affected area(s).
5. Gently massage the cream or ointment into the skin until it has all disappeared.
6. Replace the cap on the tube.
7. Wash the hands after applying the cream or ointment, unless the hands are the affected area.
8. Follow the instructions the doctor or pharmacist gives you for how much should use.
9. If other creams, ointments or lotions is to use on the same area of skin you should try and leave about half an hour between applying each one so that they don't mix on the skin.

Other useful advice
- Creams and ointments are designed only for application to the skin. If they are accidentally taken by mouth, tell the doctor at once.
- If you get the cream or ointment in the eye, rinse it out immediately with warm water and consult the doctor if there is any on-going irritation.
- Always follow the advice on the printed label of the tube/box and/or as directed by the doctor or pharmacist.
- Do not use creams or ointments after the expiry date on the tube because it may be contaminated with germs that could cause skin infections. It may also have lost its effectiveness.
- Always keep medicines out of the reach of children.

Pierce this seal by inverting the cap of the tube and pushing it into the end of the tube.

Wash the affected area(s) of skin well.

Gently massage the cream or ointment into the skin until it has all disappeared.
Q. What is pharmaceutical promotion?

A. It is the business of advertising or promoting the sales of medicine, which is one of highly regulated market in developed countries, it also called pharmaceutical marketing.

Q. What are the different types of pharmaceutical promotion methods?

A. There are many promotion methods, which include detailer visits with prescribers; distribution of gifts and free samples; hiring of medical professionals to speak or consult on behalf of their products; and funding of organizations that provide continuing medical education, practice guidelines, and patient information.

Q. Is there any negative impact of pharmaceutical marketing upon health system?

A. There are three main concerns about the effects of pharmaceutical marketing on healthcare: higher-than-necessary expenditures, leaving less money for other healthcare needs; the use of prescription of medicines that are less effective or have more problematic side effects than alternatives; and inappropriate off-label prescribing.

Q. What about free medical samples?

A. Free medication samples is a program that was introduced as a marketing tool, but it has an important role for physicians and patients in that doctors may distribute samples to patients for several reasons for instance, to get patients started on therapy sooner, to optimize dosing or choice of medicine before committing to a particular course of treatment, and sometimes to help patients who might not be able to afford medicines on their own.

Q. What are the main ethical criteria of promotion?

A. Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product concerned. It should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly, also it must not mislead by distortion or exaggeration of certain facts, too, encourage the rational use of medicine.

White Nile State Medicines Information Center (MIC) : a success story

Abeer B. Abdalmajed

The idea of starting an Information Centre in Kosti Teaching Hospital had been promoted by National Health Insurance fund (NHIF), White Nile State. The center was established in July 2015 under the supervision of a clinical pharmacist and two others. The center was to provide service to Kosti and surrounding area.

The White Nile Ministry of Health approved the proposal which enable the center to deliver its services and as a result a Medicine Information Centre was situated inside the hospital to assure accessibility of the information to the medical team.

The center consist of one desktop computer, internet connection, projector, lab top, printer, telephone, medical references, brochures and medical posters.

The center has a link with a MIC in UK (Freeman hospital, Newcastle Upon Tyne). They kindly donated more than hundred BNF copies and suggested a list of important reference books. The BNF was distributed to the medical team in Kosti Teaching Hospital.

MIC has a library that included books of importance and relevance like Drugs in pregnancy and lactation, Renal hand book...etc.

Since establishing the center has delivered lectures on a monthly basis to different medical staff and conducted a training workshop every three month e.g. therapeutics communication skills. The DIC presented a series of programs in radio and TV in JULY 2016 (Medical Advice in Ramadan).

The MIC has distributed leaflet that consist of information and advice on Irrational use of antibiotics.

The MIC has a telephone hotline (3139) to connect with the local community, and receives about ten phone calls per day from both healthcare providers and public as shown in figure 1.

Figure 1: Show the number of call per day.

Brand versus generic names

Alaa M. Hamed

What is a brand and generic medicine?

Brand medicines are innovator medicines that were originally marketed as a first version product initiated by the innovator manufacturer, while a generic medicine is defined as a pharmaceutical product manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights.

How are generic and brand medicines different?

Generic medicines and their corresponding brands should be identical in terms of active ingredients, safety, efficacy, dosage form, strength, indication for use and route of administration. They may differ only in excipients, shape, colour, mechanism of medicines release and packaging. Nevertheless, one version of a generic formulation, or brand, of a medicine may be preferable to another for some patients.

When can generic medicines substitute brand medicines?

Generic substitution is a term that means replacement of a prescribed branded medicine by another one of the same active ingredient parallel imported product that is considered bioequivalent to it. Thus, the issue of bioequivalence, is crucial in determining generic substitution of medicines. Theoretically, any generic medicine that is bioequivalent to its brand-name can be substituted to limit costs or to follow health insurance plans that requires generic medicines be prescribed. However, generic substitution should not compromise patient’s rights to select whatever brand he/she wants at all times. Pharmacists should not intervene with the patient’s choice and he may just inform patients and explain to them as needed.

Are there situations where generic substitution will not be allowed?

There should be an established policy for generic prescribing and generic substitution. There are certain medicines, that should always be exempted from substitution, like antiepileptic medicines, antipsychotic medicines and those have narrow therapeutic window. These medicines should be listed as a negative list, others that substitution is allowed for constitute the positive list. If the substituted medicine is included in the positive substitution list, pharmacists have the authority to dispense any generic medicine unless the patient demands the brand. If the medicine is included in the negative substitution list, the pharmacist HAS NO RIGHT to substitute. Similarly, if a prescriber puts an initial or sign, the dispensing pharmacist should dispense the prescribed medication as it is.

References:


The pharmaceutical industry devotes large budgets for promotion and uses many different channels of communication for promoting products. Pharmaceutical representatives are an important promotional tool for pharmaceutical companies.

Pharmaceutical representatives (rep.) mostly present selected positive information about their products and are sometimes inclined to give inaccurate (biased) information to make sales. This type of information might be misleading, increase non-evidence-based use of medicines, promote irrational prescribing, and so increase prescribing costs.

Pharmacists and physicians are important members of the health care providers’ team; they are often subjected to promotional pressures by representatives. Therefore they should be fully aware of the content of promotional materials in order to put forward a rational argument for the appropriate use of medicines.

The following WHO guidelines may be used to obtain the most out of a visit by a “medical rep”:

- See the “rep” only if you are not busy.
- Take charge of the interview. Do not hear out a rehearsed sales routine but ask specific questions, especially about the adverse events and the therapeutic value of the product.
- Request independent published evidence from reputable peer-reviewed journals.
- Promotion brochures often contain unpublished material, misleading graphs and selected quotations. The pharmacist needs to appraise them so as to be able to deal with prescribers who have been influenced by the graphics and claims.
- Request evidence by using the “STEP” analysis:
  - Safety— the likelihood of long-term or serious side-effects caused by the product;
  - Tolerability— is best measured by comparing the pooled withdrawal rates between the product and its most significant competitor;
  - Efficacy— the most relevant dimension is how the product compares with your current favorite products;
  - Price— direct plus indirect costs should be taken into account.
- Ignore anecdotal “evidence” such as the fact that a known senior medical specialist or major institution is prescribing or using the product.
- Ask for copies of papers of any clinical trials used to support the company’s argument. Evaluate the evidence stringently, paying particular attention to the power (sample size) and methodological quality of clinical trials and the use of surrogate end points.
- Do not accept theoretical arguments in the product’s favor without direct evidence that they translate into clinical benefit. Bear in mind that negative papers are unlikely to be quoted or referenced in the promotional literature or mentioned by the rep. Do an independent search of the literature, if you can.
- Do not accept the newness of a product as an argument for changing to it. There are good scientific arguments for doing the opposite. A new medicine is not always better or safer.
- Record in writing the content of the interview and return to these notes if the “rep.” request another audience.
- Ask about the price and evaluate it on the
cost of daily dose and not the cost of pack.

- As regards visit to discuss "old" product, concentrate and ask about possible:
  - New indication
  - Drug interaction
  - Precautions
  - Contra indications
  - Serious side effect
  - Price
- As for generic or branded generics ask for bioequivalence studies if not available stick to the brand you are prescribing.
- If the medical representative fails to answer your question or provide the needed information, tell him openly not to waste your time.
- Do not be carried away by gift and sample asks for concrete, unbiased scientific information.

References:
The World Health Organization (WHO) defines pharmaceutical promotion as, “all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal medicines”. These activities include advertisements, one-to-one sales visits, free samples, sponsorship of educational and scientific events that could affect treatment decisions, and a range of other activities.

Pharmaceutical promotion as a source of information
WHO developed in 1988 an Ethical Criteria for Medicinal Drug Promotion, key criteria include the following:

- All promotion-making claims concerning medicinal medicines should be reliable, accurate, truthful informative, balanced, and up-to-date.
- Promotion should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable medicine use or to give rise to undue risks.
- The word “safe” should only be used if properly qualified.
- Promotional material should not be designed so as to disguise its real nature.
- Promotion in the form of financial or material benefits should not be offered to health care practitioners to influence prescription of medicines.
- Scientific and educational activities should not be deliberately used for promotional purposes¹.

Impact of pharmaceutical promotion on prescribing and medicine use
It is increasingly important to understand the effects that medicine promotion has on prescribing and the use of medication given the growing amounts of many companies are devoting to this activity.

A valuable research was conducted in Khartoum state to study the impact of medicine promotion practices on health professional prescribing in teaching hospitals, Khartoum state.

The results indicate that 91.6% of the interviewed doctors believed that information provided by medical representatives are valuable. 99.5% of them stated that they use this information particularly for newly registered medicines. 57.5% used this information for low risk medicines. 79.1% of doctors stated that they are influenced by discussion with medical representatives, 98.6% of these stated that they are positively influenced. 82% of doctors stated that the most unethical method of promotion is giving financial incentives to doctors. Only 6.5% of doctors have good knowledge about the ethical criteria of medical promotion. 95% of analyzed prescriptions of the top three items in ABC analysis were in trade name; all were imported by the same local agent².

Why doctors should prescribe generically?
Prescribing a medicine generically is an indicator of WHO good prescribing practice. The ultimate objective of the Sudan National Medicines Policy (NMP) 2014-2019 is to achieve generic prescribing and dispensing in public sectors.

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¹ Clinical pharmacist and senior specialist of pharmaceutical services management at Haj Elsafi Teaching Hospital.

² Impact of pharmaceutical promotion on prescribing and medicine use. It is increasingly important to understand the effects that medicine promotion has on prescribing and the use of medication given the growing amounts of many companies are devoting to this activity. A valuable research was conducted in Khartoum state to study the impact of medicine promotion practices on health professional prescribing in teaching hospitals, Khartoum state.

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Why doctors should prescribe generically?
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How is pharmaceutical promotion regulated in public hospitals?

The American Society of Health System Pharmacist (ASHP) states that the multiplicity of medicines available and complexities surrounding their safe and effective use make it necessary for hospitals to have an organized program for maximizing rational use of medicine; the PTC is the organizational keystone for this program.

Sudan NMP 2014-2019 recommended the establishment of PTCs in hospitals emphasizing on the RUM according to Standard Treatment Guidelines (STGs) and essential medicines list.

Pharmacy and therapeutics committee (PTC) is defined by ASHP as “a committee that evaluates the clinical use of medicines, develops policies for managing medicine use, and manages the formulary system”3.

The WHO published a manual in 2003 on how to establish and maintain a PTC at hospitals.

Functions of PTC

- Advisory committee to medical staff, administration, and pharmacy;
- Development of medicine policies;
- Evaluating and selecting medicines for the formulary list;
- Developing STGs;
- Assessing medicine use to identify problems;
- Conducting effective interventions to improve medicine use;
- Managing ADRs;
- Managing medication errors;
- Information dissemination and transparency.

All hospitals should have specific policies concerning medicine representatives and promotional literature.

Ethical concerns of the PTC

The success of a PTC will depend upon its being active, working regularly in a consistent direction and making sound decisions in a transparent way. This is especially important in medicine selection and procurement policies. The people involved should not be influenced by inappropriate medicine advertisements, promotional activities or personal financial interests.

All committee members should be required to sign a ‘declaration of interest’ to bind members to the working principles and ethics of the PTC4.

Role of General directorate of pharmacy- Khartoum state to control pharmaceutical promotion in public hospitals

In 2011 a research was conducted to study the performance of PTCs in Khartoum State public hospitals stated that only two hospitals had developed a policy for controlling the access of medicine representatives and promotional literature. They were Omdurman Emergency Pediatric hospital and Albolok specialized hospital for children5.

In 2013 the general directorate of pharmacy- Khartoum state had developed its instructions for medical representative to be adopted in developing and presenting promotional materials in its related public hospitals. In 2014 it had developed its instructions for delivery and distribution of free sample in its related public hospitals.

References:
Teach the mother how to give oral medicines at home

Ali M. Arabi

This document teaches mothers how to give oral medications properly to their children, which improves the outcomes of the prescribed oral medications (tablets, capsules, syrups or suspensions). For every oral medicine, the following instructions must be followed:

• Check the prescribed medication, its dose and exact instruction for use.
• Inform the mother about the reason for prescribing the medication and what was the medication prescribed for?
• Show the mother how to measure the prescribed dose by demonstration.
• When tablets need to be divided to make the prescribed dose, show the mother how dividing can be done correctly. If the tablets need to be crushed adding few drops of water makes crushing easier.
• If the medication is in a liquid form (syrup or suspension), show the mother how to measure the prescribed dose accurately using a household measure or disposable syringe. Inform the mother that, suspensions need to be shaken before taking a dose.
• Make the mother demonstrate to you how tablets can be divided or crushed and how oral liquid doses are measured by household measures.
• If you are giving the mother vitamin A capsules: Show the mother the amount to give per dose. If a child needs a half vitamin A capsule (or cannot swallow a whole capsule), show the mother how to open the capsule and squirt a half or all of the liquid into the child’s mouth.
• For children who have vomiting, tell the mother to watch her child for 30 minutes after taking her oral medication, if vomiting occurs during this time, the dose must be replaced.
• If the vomiting child is dehydrated wait until the child is rehydrated before replacing the dose (or refer to hospital for injectable alternative).
• Explain carefully how to give the medication, then label and pack the medicine.
• Tell the mother how many times per day to give the dose. Tell her when to give it (such as early morning, lunch, dinner, before going to bed) and for how many days.
• Write the information on the medicine label. As shown below

<table>
<thead>
<tr>
<th>NAME</th>
<th>DATE</th>
<th>DRUG</th>
<th>QUANTITY</th>
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</tbody>
</table>

1. Director General Dr. Gafar Ibnouf Paediatric Tertiary Hospital Khartoum, Sudan.
An illustration of using the medicine label to show the amount and adequate time for taking the dose makes the instructions easier for illiterate mothers

➤ **To write information on a medicine label:**
   a. Write the full name of the medicine and the total amount of tablets, capsules or syrup to complete the course of treatment.
   b. Write the correct dose for the patient to take (number of tablets, capsules, squirts or spoonfuls that is, ½, 1, and 1½...). Write when to give the dose (early morning, lunch, and dinner before going to bed).
   c. Write the daily dose and schedule, such as **½ tablet twice daily for 5 days**
   ➤ Use only the labeled container to dispense the prescribed medication
   ➤ Ask the mother checking questions to make sure the mother understands fully how to give her child his/ her medication.
   ➤ If more than one medicine will be given, collect, count and pack each medicine separately.
   ➤ Each medicine should be prepared at one time, and then move to the other to avoid mistakes.
   ➤ Explain to the mother that her child is getting more than one medicine. Show the mother the different medications. Explain how to give each medicine. If necessary, draw a summary of the medicines and times to give each medicine during the day.
   ➤ Explain to the mother that it’s important to finish the prescribed treatment course, even if she feels that her child gets better, especially when the medicine is an antibiotic or antimalarial.
   ➤ Tell the mother when and how to discard the medications after use
   ➤ Ask the mother always to check expiry dates of medications before use. Expired products should not be used.
   ➤ Inform the mother to keep medicines in a dry cool place away from direct light and out of the reach of children.
   ➤ Finally, ask the mother a number of checking questions to see does she understand all the instructions well. Example

   **Ask the mother checking questions, such as:**
   "How much quantity of medicine will you give each time?"
   • When will you give it?" "For how many days?"
   • How will you prepare this tablet?"
   • Which medicine will you give 3 times per day?"
   ➤ If you feel that the mother still does not fully understands what you have told her, use a different approach to make her understand.

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Using an oral syringe can be helpful when administering medication to children. An oral syringe is a measuring device used to accurately measure small doses of liquid medicine, which are then given to children by mouth. Here are the instructions on how to use an oral syringe:

1. **Wash both hands properly.**
2. **Shake the medicine bottle thoroughly upside down.**
3. **Open lid and withdraw correct amount.** (Pharmacist should label the syringe at the correct level).
4. **Slowly and gently push the plunger down to gently squirt a small amount of medicine, at a time, into the inside of child’s cheek. Allow them to swallow it. DO NOT forcefully push down the plunger, or squirt the medicine to the back of the child's mouth or throat, as your child may choke. DO NOT close their nose to force swallowing they might choke and/or cough and may vomit the medicine.**
5. **Rinse the bung and syringe in warm water and leave to dry.**

Visit [www.safemedication.com](http://www.safemedication.com) for more information on how to use an oral syringe effectively.
How can medical and pharmacy students interact with the pharmaceutical industry?

Kamal Addin M. Ahmad

In developing countries Pharmaceutical industry, represents the major source, if not the only one, of medication information for Healthcare Providers (HCPs). Besides having a strong hold on the peer reviewed medical and pharmaceutical journals, it has an appreciable share in continuing educational activities and training of physicians and pharmacists. The quality of the medication information it provides to HCPs has proved to be deficient, imbalanced, may be blatantly misleading and, sometimes, even illegal. In addition to its standard promotional tactics and tools, the pharmaceutical industry uses enticements (gifts, honoraria, hospitality and even bribes) to persuade health care professionals to prescribe their products in order to increase sales and maximize profit.

They expend at least 20-30% of revenue on the promotional activities of their products, for instance, in 2012, more than $ 27million was spent on promotion.

Influence of the promotional activities on both doctors and pharmacists medication prescribing and dispensing, is well documented in the literature.

Ethical standards of pharmaceutical industry are very different from those of medicine and pharmacy professions; providing gifts to vendors is a usual and normal practice for such a business industry. Accordingly, the profitability of the pharmaceutical industry’s products comes ahead of the other healthcare priorities like rational use of medicines, essential lists of medicines, standard treatment guidelines, availability and affordability of medicines (generics). In fact, the pharmaceutical industry claims that, these mentioned healthcare priorities may compromise free prescribing and deprive healthcare providers from innovative prescribing!

The pharmaceutical industry does not only target the practicing doctors and pharmacists in practice, but as well, interferes at their undergraduate educational level by attempting to influence medical & pharmacy students knowledge and attitudes in favor of its products.

Sponsoring the various educational and social activities of junior professionals, like providing “free” samples, gifts, offering meals and before all influencing the attitude and perception of their seniors are some recognized promotional practices which are part of the strategic plans of pharmaceutical industry. When the students were questioned about these practices, they showed acceptances of gifts from the industry, citing financial difficulties as a main reasons behind limiting educational opportunities and thought that these practices were helpful to them. They also endorsed that medication information provided by the pharmaceutical industry were useful and valuable for their education.

Our current medicine and pharmacy educational curricula are not abreast with the paradigm shift in the modern clinical practices. Deficiencies in therapeutics and pharmacology courses curricula may specifically, be the reason for motivating the pharmaceutical industry to fill this gap and consequently, sensitize students against

1. Pharmacy practice and pharmaceutical promotion specialist, University of Gezira, Wad Medani, Sudan.
resistance to these ethically controversial practices.

Considering all the above, it becomes a top priority to train the future medical and pharmacy students on how to properly and safely interact with the pharmaceutical industry\textsuperscript{6,7}. Students should be trained on how to critically appraise, the contents of the various industry promotional messages, both the verbal and written materials (brochures, package inserts, reprints etc).

**Students should be trained on how to acquire sufficient skills and knowledge so they become aware that; the quality of information provided by the industry is deficient, imbalanced, poorly supported and could even be misleading.**

The claimed “New” products are not necessarily more than the classical standard and time-tested treatments Generics which are bioequivalent to branded products, are the best choices for their availability and affordability. Much of the published clinical studies supporting industry’s claims are under its control. It is important that students know how to read, understand and evaluate the different research studies, as much of the published clinical studies are written by industry’s ghostwriters. Moreover, the various head-to-head comparisons of industry’s products are mainly against placebo. Those claimed “New” products do not respect patients’ genetic variations. The way the industry portrays the results of its clinical studies in their brochures, uses graphics and relatives risk reduction, which may be difficult for untrained staff to apprehend and interpret. Accepting gifts entails reciprocation as a normal human moral obligation and constitutes a frank conflict of interest. Those Key Opinion Leaders’ academics (KOLs), who quite frequently lecture both graduates and students, are paid to confuse their own colleagues. They are part of the pharmaceutical industry promotion staff. Students should be aware that the pharmaceutical industry has the financial and political stamina to force its interests. Moreover, the pharmaceutical industry sales representatives are highly trained to gain doctors’ prescribing behavior through finely titrated “friendship” and other well tested psychological approaches.

References:
6. Lieb K, Koch C. Medical Students’ Attitude to and contact with the pharmaceutical industry, a survey at eight German University Hospitals. DtschArztebl Int. 2013.110 (35-36):584-590.
Antimicrobial policy
part two

Kamal M. Elhag

Purpose of the Policy

The purpose of the antimicrobial policy is to control antimicrobial use as shown in evidence of antimicrobial resistance in Sudan. Rational prescribing shall ultimately lead to more effective treatment of infections and contribute to minimizing patients’ morbidity and mortality and should significantly reduce expenditure on health. Since control of antibiotic prescribing is a crucial part of the strategy to limit the development of resistance, the Minister of Health for Khartoum State appointed a committee in order to formulate a policy to control the use of antimicrobials and to promote antimicrobial stewardship in the Khartoum State. However, the Committee was faced with several challenges; habitual overuse of antimicrobials by prescribers and the public, an unpresented antimicrobial resistance rate, deficient antimicrobials, scarcity of reliable microbiology service and finally unawareness of most prescribers of the true situation.

The Antimicrobial Policy

Principles of antimicrobial stewardship were first laid down. Targets for antimicrobial stewardship include decision to start antimicrobial therapy, selection of the antimicrobial, dose, route of administration and duration of therapy. Antimicrobial therapy must be started only when there is clear clinical justification. Critically ill patients with sepsis should have the first dose of a potent antimicrobial therapy administered within one hour of diagnosis. Microbiology culture should be collected prior to initiation of antimicrobial therapy. Knowing the susceptibility of an infecting organism reduces the use of broad spectrum therapy, changing therapy to effectively treat resistant pathogens and modifying antibiotics according to susceptibility. The clinical diagnosis and the need for continuing antibiotics are reviewed by 48 h. For surgical prophylaxis, a single dose of antibiotic is administered within 60 min prior to surgical incision to ensure peak blood levels at the start of the surgical procedure. A repeat dose of antibiotic prophylaxis is required when the operation is longer than the half-life of the antibiotic. Further antibiotic treatment should be given to patients having surgery on a dirty or infected wound.

Infection prevention and control, was combined with antimicrobial stewardship to limit the emergence and transmission of multi-drug-resistant pathogens. The policy was tailored for inpatients. Antimicrobials were thus divided into four categories based on route of administration, spectrum of activity, antimicrobial efficacy, cost and development of resistance. The right to prescribe an antibiotic from any of the four categories depends on the position and the experience of the prescriber, culture report or microbiology advice. Limited amounts of antibiotics are issued only through the pharmacy as per the policy. Details pertinent to antimicrobial therapy shall be recorded in the patient’s notes, which will be approved by the head of unit. Similarly, prescribing should be undertaken in a treatment sheet. The therapeutic committee must see that the policy is implemented and should regularly audit consumption of antimicrobial agents and development of resistance in the hospital.

In order to implement the antimicrobial policy, the committee members held several meetings with prescribers in major Khartoum hospitals, explaining the policy and highlighting the challenges. The meetings were fruitful and participants made useful comments and suggestions. Accordingly, plans have been set to upgrade efforts to implement Essential Medicine List (EML) and to start an educational programme on antimicrobial stewardship.
among physicians and pharmacists. To support this policy, microbiology technologists from different hospitals are currently, being trained on antimicrobial susceptibility testing.

**Conclusion**

The members of the Antimicrobial Policy Committee have made an appreciable effort to produce this valuable document. Although the committee is slowly moving towards implementation, it is faced with hurdles that may delay progress, principally the lack of standard antimicrobials. Education programmes on antimicrobial stewardship need time and patience. However, with the determination of the committee, the support of the medical professionals and understanding of all stakeholders we shall achieve our objectives.

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**References:**


Generic medicines policy

Randa A. Almahdi

Access to medicines is one of the biggest challenges confronting the global political agenda. In developing countries, un-affordability was found to be the most frequently cited cause of inadequate access to medicines. There is a wide gap between types and volumes of required drugs and those that can be affordable by the poor segment of the population.

The World Health Organization (WHO) has recommended individual countries to develop their own locally appropriate national medicines policy, focusing on improved access to quality and rational use of medicines.

The world’s experience has shown that the strategy of using generic medicines seemed promising, when certain prerequisites are secured; like ensuring a functioning medicines regulation authority, creating a powerful market and aligning incentives for physicians, pharmacists and patients as consumers.

Generic medicines are defined as pharmaceutical products usually intended to be interchangeable with an innovator products, it represents a key strategy used by governments and third-party payers to contain the cost of healthcare and improve access to existing medicines. Generic medicines are manufactured without a license from the innovator company and marketed after the expiry dates of the patent or other exclusive rights.

The practice of generic medicines prescribing and substitution is strongly supported by health authorities in many countries. It proved to have a direct effect on cost reduction for essential medicines, regulation of medicines promotion, and increase adherence to Essential Medicines List (EML) and Standard Treatment Guidelines (STG) by healthcare providers i.e. improving equity, affordability and access to medicines.

This cost reduction was evidenced in Sudan by a survey conducted in 2012 on medicines prices, availability, affordability, and price components, which has revealed that originators branded medicines were generally sold at 3.47 times their international reference prices compared to 2.22 times for the lowest price generic medicines in public sector.

This significant price difference negatively affects medicines affordability and accessibility. Another national survey conducted by the Directorate General of Pharmacy (DGoP) to assess medicines affordability and pricing in Sudan, has recommended that affordability, availability and prices of medicines should be improved to ensure better access to medicines.

The reduced accessibility to essential medicines in Sudan is even frequently threatened by other factors like; fake and counterfeit medicines, weak distribution system in addition to unregulated aggressive promotional activities. The results of these surveys have necessitated interventions through setting a policy that shall promote for prescribing and substituting generic medicines among healthcare providers in the public sector.

One of the threats to national generic prescribing...
policy, was the unregulated promotional activities which have a great impact on the priorities of health professionals considering their prescribing and dispensing patterns, which hinders free market competition. This may become complicated by the knowledge gap of health professionals when considering bioavailability and bioequivalence.

Currently, a national policy has been developed in Sudan, pending for approval and launching for generic prescribing and generic substitutes. However, other national polices that regulate uses of medicines in Sudan and advocate generic medicines policy are equally needed, among which is the regulation of pharmaceutical promotion activities by manufacturers and distributors to ensure reliability, accuracy, trueness, neutrality, and currency of their information. The medicines’ advertisement should include the generic name of the drug among other important information such as approved therapeutic uses, adverse effects and major interactions.

The policy calls for generic prescribing and all medicines should be prescribed by their generic names or International Nonproprietary Name (INN). Prescribers should refer to the negative substitution list when prescribing in brand/brand generic names. However, prescribers may write their prescriptions in brand names - even if the medicines were out of the negative list - if they have evidence-based information regarding the efficacy of particular medicines. In certain cases - and when absolutely necessary - when a particular brand name is required; the prescriber should put an initial or sign indicating so (e.g. do not substitute).

References:
4. Sudan Medicines Price Survey 2012 official report
5. Wedaa AM, Abuturky H &Atabani MI. 2013. Medicines prices, availability, affordability and price components in Sudan, FMOH in collaboration with DoMOH with WHO.
The pharmaceutical industry has prime responsibility for the safety of medicines and the construction of databases, registries and published studies must be provided to support post-approval surveillance activities which can largely be attributed to the needs of the pharmaceutical industry, which has made many technological advances in medicine developments and have improved the safety of new medicines. Pharmaceutical industry is an important partner of pharmacovigilance.

The pharmaceutical industry and other medicine importing companies should be strongly involved in pharmacovigilance program as Marketing Authorization Holders (MAH) by having their own pharmacovigilance centers that become responsible for reporting Individual Case Safety Reports (ICSR) regularly to the National Medicines and Poison Board (NMPB) on their medicine products. MAH have obligations to set up a pharmacovigilance system to collate, collect and evaluate the information on the suspected adverse medicine reactions and share this information with the national pharmacovigilance center. They must jointly anticipate, understand and respond to the continually increasing demands and expectations of the public health needs. This communication and exchange of information between the industry and regulatory authorities has improved as a result of the regional and international harmonization arrangements that have emerged in recent years. Continuing professional education, patient education, and sponsorship by industry of medicine information activities have also contributed to safer use of medicines.

References:
1. The pharmacovigilance definition by WHO.
3. The National plan of the national pharmacovigilance center, NMPB- Sudan, 2013
Guide for authors

Scope of the journal:
Rational use of medicines (RUM) issues directed to health care providers and medical students.

Suitability of publication:
All topics related to the different aspects of RUM will be evaluated by the editorial board. Prospective authors with a subject(s) or questions about the suitability of their papers or materials are invited to request an opinion from the Editorial Board. (sjrum@khmic.org).

Avoid plagiarism

How to submit materials:
Manuscripts can be handed over directly to the Directorate General of Pharmacy as soft copy or by e-mail (sjrum@khmic.org).

Types of manuscripts:
1. Research papers.
2. Case reports.
3. Thematic topics.
4. Success stories.

Preparation of manuscripts
All manuscripts must be typed in Arial font size 12, with 1.5 line spacing. Manuscripts must be in Word. Page margins on all sides must be at least 2.5 cm wide. You can use either English or American spelling but not both on the same manuscript.

1. Research papers
Original research will have the priority of publications. Author(s) name and affiliations should be clearly written. Contact person, telephone number and e-mail address should be included.
Total words count should not exceed 800 words including references, tables, table captions, figure legends, and footnotes. Maximum of three tables and figures are accepted.
The manuscript should be divided into sections. Each section should have a separate heading. Subheadings take the form of paragraph lead-ins (should be bold case), indented and run in with the text, separated by a period.
Introduction: This section should provide the reader with sufficient background information to evaluate the results of the research. An extensive review of the literature is not needed in this section. It should also give the rationale for and objectives of the study that is being reported.
Methods: Sufficient information must be provided so that the reader will understand the methodology and be able to repeat the experiment.
Results: The results section should be written in such a manner to provide information by means of text, tables and figures. Results and discussion may be combined or there may be a separate discussion section. If a discussion section is included, place extensive interpretations of results in this section. Do not repeat the results. Give numbers to figures and tables in the order in which they are mentioned in the text. All figures and tables must be cited in the text.
Conclusions and recommendations: Acknowledge personal, financial and institutional assistance at the end of this section.
References: Use the Vancouver reference system. Cite 6 references maximum.
Ethical clearance is a requirement for all researches from 2012 onward.

2. Case reports
Any case that is related to RUM will be considered. The manuscript should include the following setting: complete description of the case, consequences and outcome and finally follow up if applicable. Suggestions for solutions should be included.
Words count should not exceed 400 words.

3. Thematic topics
Any topic related to rational medicine use is considered. The manuscript should not exceed 400 words.

4. Success stories
Any story that reflects rational use of medicine and positive changes towards rational medicines use is welcomed. The manuscript should not exceed 400 words.

NOTE: Accepted manuscripts may be subjected to minor/appropriate changes prior to publishing.
Please check the website for previous issues and updates www.sjrum.sd
White Nile State Medicine Information Centre was established in 2015. It is located in Kosti Teaching Hospital. It provides evidence-based information on medicines to healthcare providers as well as the public using updated, reliable, and evidence-based information resources. The centre is financed by the National Health Insurance Fund in White Nile State. The centre offers a wide spectrum of activities including:

- Answering medicine-related inquiries such as:
  - Indications, contraindications, and dosage for specific medicines.
  - Drug interactions and adverse effects.
  - Medicine use in pregnancy, breastfeeding, liver, and renal impairment.
  - Identification of medicines.
- Educational activities to medical staff, e.g., lectures, seminars, workshops, and training courses.
- Publishing and reprinting of the most recent medicine information and clinical guidelines.
- Promoting rational use of medicines through public mass media.

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