DrugLens NEWSLETTER

DRUGLENS ISSUE 5 | JUNE 2017

MRS. DELESE MIMI DARKO, THE NEW FDA BOSS

… Women breaking through the glass ceiling

Mrs. Delese Mimi Darko, affectionately called Mimi is the new Chief Executive Officer (CEO) of the Food Drugs Authority (FDA) and the first female CEO. She is a pharmacist with over 25 years' experience in regulation. She obtained her Bachelor of Pharmacy Degree from the Kwame Nkrumah University of Science and Technology in 1991, a post-graduate certificate in Total Quality Management from the University of Leicester and a Masters in Business Administration from the University of Northampton.

After doing her National Service at the Police Hospital, her first job was in the Quality Control Laboratory of the then Pharmacy Board where she helped put in the systems to ensure that medicines available on the Ghanaian market have undergone laboratory analysis.

She played a pioneering role in establishing the Food and Drugs Board (FDB) now the FDA in 1997 and rose through the ranks to become the Head of Registration until 2010 when her career took a turn to focus on clinical trials and patient safety. She became the Head of the Safety Monitoring and Clinical Trials Department, now a Division, with primary objective of ensuring patient safety pre- and post- marketing authorization of medicines and other medicinal products.

Under her leadership, Ghana became a member of the WHO Programme for International Drug Monitoring in 2001. Also through her exemplary leadership clinical trials was initiated in Ghana, and the FDA is now considered one of the leaders in clinical trials regulation in Sub-Saharan Africa. Her most recent initiatives in Pharmacovigilance were establishment of Patient Safety Centers in Community Pharmacies nationwide and the implementation of the Pharmacovigilance Assessment Tool aimed at integrating safety monitoring of medicines into the healthcare delivery system in Ghana.

Mrs. Darko's visions as she leads the FDA are:

Staff Welfare and Development: To institute policies that will ensure that FDA's workforce is continuously trained in cutting edge regulatory science, advocate for better career aspirations for all staff and also provide excellent working conditions to guarantee each member of staff is motivated to perform his or her duty exceptionally to promote public health and safety.

Stakeholder Collaboration: Work effectively with all stakeholders, including consumers, the Industry, Healthcare Professionals, Public Health Programmes, International Organizations, Academia and media to ensure implementation of the Parts 6, 7 and 8 of the Public Health Act, Act 851.

Global Recognition: Support all departments of the Authority to perform effectively and outstandingly to position the FDA globally as a leading regulatory authority.

Mimi is married with two beautiful children, 21-year-old daughter Ayebea and a 19-year-old son Barima.

She first of all gives thanks to the Almighty God for His love, abundant grace and favour and to Pastors Biodun and Lisa Lawal . She is grateful to the President of the Republic of Ghana for giving her the opportunity to serve in the capacity as the CEO of the FDA and finally a special thank you for the love and support she has received from her dear family throughout her career.

Fourth Qualified Person for Pharmacovigilance (QPPV) Training Programme Organized

The FDA in collaboration with the World Health Organization Collaborating Centre for Advocacy and Training in Pharmacovigilance (WHO-CC) organized the fourth training course for persons to be designated as Qualified Persons for Pharmacovigilance (QPPV) from 27th February, 2017 to 17th March, 2017. This programme is the 4th in a series of trainings organized for representatives from the pharmaceutical industry to ensure implementation of the FDA's mandate in Section 125 of the Public Health Act of 2012, Act 851. The training programmes offered assistance to the pharmaceutical industry to put in place systems, structures and the personnel to monitor the safety of all marketed products to ensure public health and safety.

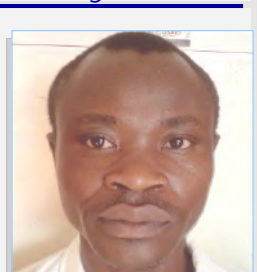
Fifty-six (56) representatives from forty-seven (47) pharmaceutical industries have been trained so far with Pilot Good Pharmacovigi-

Read more on page 4

In this issue…

Reporter of the Year

Ensuring Patient Safety in the Upper West Region



Mr. Bahaara James is a Senior Community Health Nurse at Hamile Health Centre, under the Lambussie District Health Directorate of the Upper West Region. He holds a BSc in Public Health and Allied Sciences from Catholic University College of Ghana.

He has a special interest in pharmacovigilance as he spearheads many public health programmes at the Sub-District level and realizes that adverse drugs reactions (ADRs) and Adverse Events Following Immunization (AEFI) are the main reasons why most inhabitants do not patronize national health campaigns though such exercises are usually free of charge and have enormous public health benefits.

James has taken it upon himself to educate members of his community on ADRs and encourage them to report at the nearest health facility for treatment in case they experience any. This has resulted in high reporting of ADRs in the Seasonal Malaria Chemoprevention (SMC) programme in the Upper West Region.

James does not miss any opportunity he gets to encourage nurses, especially public health nurses to actively participate in the monitoring of medicines used in Public Health Programmes to increase public confidence and acceptance of these programmes.

*Spontaneous Reporting for 2016 *

The National Pharmacovigilance Centre received one thousand six hundred and seven (1,607) reports in 2016. This represents the highest number of spontaneous reports received in one year in the history of pharmacovigilance in Ghana. Figure 1 shows yearly reporting for the past five years.

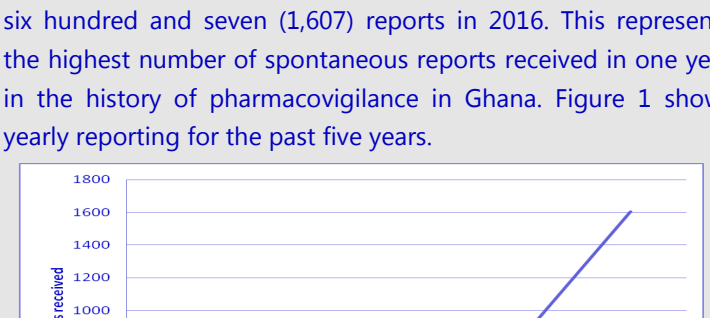


Figure 1:Number of adverse event reports received from 2012 to 2016

Although, the reports received in 2016 represents the highest number of reports in one year it still falls short of the recommended reporting rate of 200-250 reports per year per 1 million inhabitants. Ghana with an estimated population of 27 million is expected to receive at least 5,400 per year.

Of the ADR reports received 1,004 (62.5%) were from females and 560 (34.8%) from males, the gender of the remaining 43 (2.7%) is unknown. The high percentage of females reported to have experienced an ADR in 2016 is consistent with what has been reported by independent research. (1,2,3)

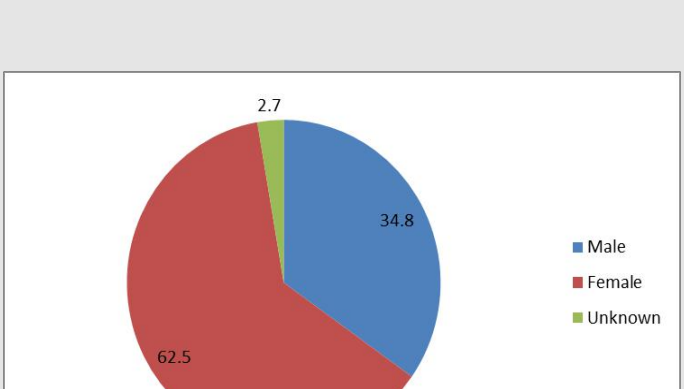


Figure 2: Gender distribution of patients

Figure 3 shows the percentage of ADR reporting by Healthcare Professionals (HCPs). The reporting rates per category of HCPs is almost the same as 2016 where the three top most reporters were Pharmacists, Nurses and Doctors.

Figure 3: Percent Reporting by Healthcare Professionals

References:

1. Zopf Y. et al. (2008) Women encounter ADRs more often than do men, Eur J Clin Pharmacol 64:999–1004 DOI 10.1007/s00228-008-0494-6 (2008),
2. Yue Y. *et al.* (2016) Systematic Analysis of Adverse Event Reports for Sex Differences in Adverse Drug Events. *Sci. Rep.* 6, 24955; doi: 10.1038/srep24955
3. Lucca JM. et al. (2017) Gender differences in the and pattern of adverse drug reactions in psychiatric patients: A prospective observational study Trop J Med Res: DOI: 10.4103/1119-0388.198134

The top 15 drugs with most commonly reported adverse drug reactions by frequency are shown in Figure 4 below:

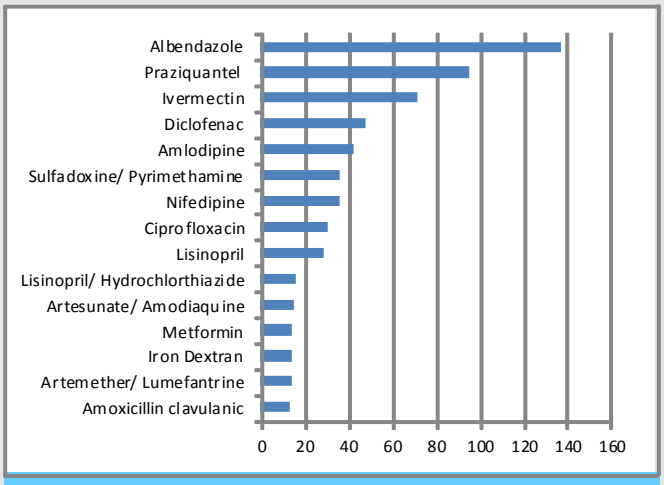


Figure 4: Drugs with most commonly reported ADRs

Figure 5 suggests that 0.8% of the outcome of cases reported was fatal, in 92.7% of the cases, the patients fully recovered while 6.5% were lost to follow up.

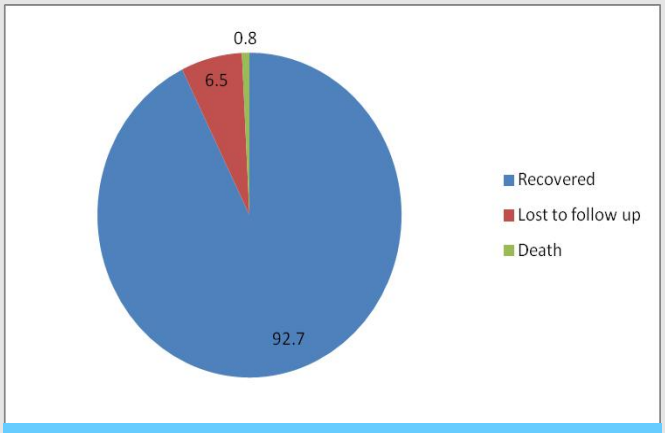


Figure 5: Outcome of the Reported ADRs

Number of reports received from the regions per 1 million inhabitants based on 2010 Population and Housing Census is shown in Figure 6.

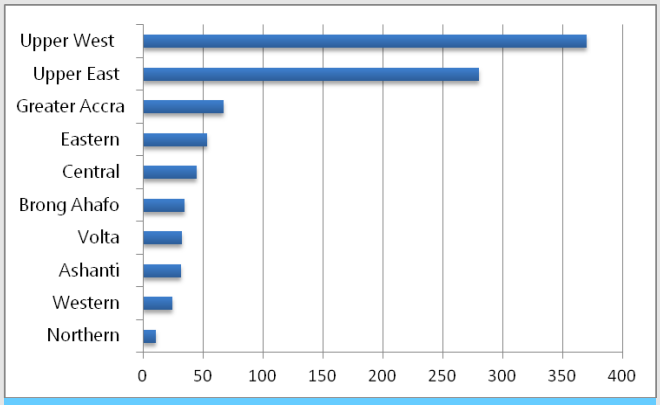


Figure 6: Reports received from the Regions per 1,000,000 inhabitants

The top thirty healthcare facilities that submitted reports to the National Pharmacovigilance Centre in 2016 is shown in Table 1

Table 1: The Top 30 Reporting Healthcare Facilities

FACILITY	REGION	NO. OF REPORTS
War Memorial Hospital	Upper East Region	128
St. Martin's Hospital	Ashanti Region	44
Sacred Heart Hospital	Volta Region	39
Komfo Anokye Teaching Hospital	Ashanti Region	35
Cape Coast Teaching Hospital	Central Region	31
Holy Family Hospital	Brong Ahafo Region	27
Madina Polyclinic	Greater Accra Region	25
Bolgatanga Regional Hospital	Upper East Region	24
Koforidua Regional Hospital	Eastern Region	24
Korle Bu Teaching Hospital	Greater Accra Region	21
Hamile Health Centre	Upper West Region	19
Sene District Hospital	Brong Ahafo Region	19
Achimota Hospital	Greater Accra Region	18
Ejisu Government Hospital	Ashanti Region	17
Nadowli District Hospital	Upper West Region	16
VRA Hospital, Akosombo	Eastern Region	15
Nsuta Health Centre	Ashanti Region	14
Piina Health Centre	Upper West Region	13
Hohoe Municipal Health Directorate	Volta Region	12
Kwahu Government Hospital	Eastern Region	12
St. John of God Hospital	Western Region	12
Mamprobi Polyclinic	Greater Accra Region	11
Nagel Memorial SDA Hospital	Western Region	11
St. Joseph's Hospital	Eastern Region	11
Ga South Municipal Hospital	Greater Accra Region	10
St. Dominic Hospital	Eastern Region	10
Ashaiman Polyclinic	Greater Accra Region	9
Fian Health Centre	Upper West Region	9
Gengenkpe Health Centre	Upper West Region	9
Ketuo Health Centre	Upper West Region	9
Ponyentanga Health Centre	Upper West Region	9

The Upper West and Upper East regions submitted the highest number of reports per 1,000,000 inhabitants in 2016; this is largely due to the Seasonal Malaria Chemoprevention (SMC) programme in these two regions.

FDA Reconstitutes Technical Advisory Committees

The FDA inaugurated the underlisted Technical Advisory Committees on March 2, 2016.

1. Technical Advisory Committee on Clinical Trials (TAC- CT)
2. Technical Advisory Committee on Safety of Medicines (TAC-SM)
3. Technical Advisory Committee on Safety of Vaccines and Biological Products (TAC- VBP)

With the exception of the Technical Advisory Committee on Safety of Vaccines and Biological Products (TAC-VBP) which was newly established, the other two Committees have been in existence for more than 8 years. The TAC –VBP was constituted due to the increasing number of new vaccines to be soon introduced for use in Sub-Saharan Africa for the first time and in line with international best practice. The TAC-VBP will also be involved in the assessment of safety issues relating to blood and blood products.

Mr. Hudu Mogtari, the then Chief Executive Officer of the Food and Drugs Authority (FDA) inaugurated the Committees and expressed his appreciation to the members for their willingness to serve and also reminded them to perform their functions with distinction to promote public health and safety.

Fourth QPPV Training Programme Organized

continued from page 1

lance Practice (GVP) inspections conducted for sixteen (16) to further help in the establishment of robust pharmacovigilance systems to ensure safety of marketed products.

Mrs. Delese Darko, CEO of FDA and Prof. Alex Dodoo, Director of WHO-CC (middle) with Participants of the 4th QPPV training course

The Chief Executive Officer, Mrs Delese Darko in an opening remark mentioned her passion for patient safety and stated that the overarching objective of the training programme is to ensure safety of marketed products. She informed participants that the fourth training programme has been updated with current information and recommendations from those who participated in the previous programmes.

She also stated the FDA will from June, 2017 commence implementation of the safety monitoring requirements in accordance with section 125 of the Public Health Act 2012, Act 851.

Training for Lecturers and Tutors from the Nursing and Midwifery Training Schools and Colleges

The Food and Drugs Authority (FDA) in collaboration with the Nursing and Midwifery Council of Ghana (NMCGH) has completed a comprehensive training in Pharmacovigilance and Vaccinovigilance for lecturers and tutors from nursing and midwifery training schools and colleges in Ghana. This initiative was funded by the UK Department for International Development (DFID) as part of their support to the FDA to improve patient safety.

The programme was held for two days each in the Northern, Middle and Southern sectors for lecturers and tutors from all the schools and colleges for a total 158 participants from October 25, 2016 to November 1, 2016. The programmes were opened by the then Chief Executive of the FDA, Mr. Hudu Mogtari and the Registrar of the NMCGH, Mr. Felix Nyante. The two men reiterated their support for the programme and looked forward to the graduating nurses and midwives playing pivotal roles in ensuing patient safety in Ghana. The objectives of the training workshops were presented by Mrs Delese Darko, the then Acting Deputy Chief Executive, Safety Monitoring and Clinical Trials Division of the FDA as below:

- Share knowledge on pharmacovigilance and vaccine safety with lectures from the Nursing and Midwifery training institutions
- Lecturers are to acquire the appropriate knowledge so they can teach the students Pharmacovigilance and vaccine safety

Participants at the training in Kumasi with staff of FDA

The training workshop follows the successful incorporation of the Pharmacovigilance and Vaccinovigilance into the newly revised curriculum in 2015. It is expected that after graduation midwives and all cadre of nurses who will be thought this course will be knowledgeable about pharmacovigilance and vaccine safety issues and therefore play an active role in promoting patient safety

during practice. This course will be taught and examinable for the underlisted cadre of nurses and midwives.

- Registered General Nursing
- Registered Community Nursing
- Registered Midwifery
- Post NAC/NAP Midwifery
- Registered Nurse Assistant (Preventive)
- Registered Mental Nursing
- Registered Nurse Assistant (Clinical)

Training for Healthcare Professionals on ADR Reporting Using Online Software, the SafetyWatch System®

The Safety Monitoring Department has completed the first phase training for one hundred and eighty-five (185) healthcare professionals from the Western, Central, Volta and Grater Accra Regions on reporting adverse events using online reporting software, **the SafetyWatch System® (SWS)** in March 2017.

The SWS in an online ICH E2B compliant data management system for ADR reporting received from clinical trials including phase IV studies and spontaneous reports from healthcare professionals, patients and the pharmaceutical industry.

Section of participants from the Central Region during a hands-on session

The key benefit of the SWS is that adverse event reports are received by the FDA in real time particularly serious events, therapeutic failures and suspected counterfeit for early decision to better enhance patient safety.

The SWS can be assessed online through the URL http://adr.fdaghana.gov.gh/

The training was sponsored by the Access and Delivery Partnership with TDR (the Special Programme for Research and Training in Tropical Diseases at the World Health Organisation) and PATH.

Participants appreciated the training workshop and believe the training will further promote patient safety by timely reporting of all safety issues.

Performance of Initiatives to Improve Patient Safety

1. Patient Engagement in Medicine Safety Programme

The Food and Drugs Authority (FDA) launched "Patient Engagement in Medicine Safety" on June 6, 2016, to encourage patients to report adverse drug reactions and other safety issues with their medicines and vaccines.

As part of this programme the FDA developed patient reporting form, **The Blue Form®**, which is available in community pharmacies and hospitals. Other ways of reporting by patients are through online at http://adr.fdaghana.gov.gh/patient.php and by SMS message to short code **4015**.

Seventy Seven (77) adverse drug reactions reports have been received from six regions except the Western, Upper West and Volta regions. Joegani Pharmacy in the Brong Ahafo region contributed 11(14.3%) out of the 77 reports. Pharmacies who contributed reports are awarded every three months with certificates graded as bronze, silver and gold with the ultimate being a plaque.

For more information on how to participate in this programme contact the Safety Monitoring Department of the FDA on Mobile: **0244 310 297** or Email: **drug.safety@fdaghana.gov.gh**

A representative from Joegani Pharmacy receiving an award from the then CEO of the FDA

2. Pharmacovigilance Assessment Tool

The Pharmacovigilance Assessment Tool (PAT) is adapted from the Indicator-Based Pharmacovigilance Assessment Tool (IPAT) developed by Management Sciences for Health (MSH) Strengthening Pharmaceutical Systems (SPS). The IPAT was adapted by the FDA and Ghana Health Service (GHS) as one of the indica-

tors of the peer-review. The objective of the Pharmacovigilance Assessment Tool is to integrate pharmacovigilance into the healthcare delivery system.

The five pharmacovigilance indicators which are measured are listed below with examples.

No	Indicator	Example
1	Staff and Infrastructure	Institutional Contact Person (ICP) available and trained
2	Tools for Pharmacovigilance	Availability of Adverse Reaction and Adverse Event Following Immunization forms
3	Systems and Structures	Drug and Therapeutics Committees exists and has the mandate to carry out pharmacovigilance activities
4	Training and skills	Pharmacovigilance training for healthcare professionals within the past 12 months
5	Safety issues	Knowledge of safety issues to report

FDA Organized Continuous Professional Development Training Course for Pharmacists

The FDA on 10th April, 2017 organized a one-day Continuous Professional Development (CPD) training workshop for ninety-nine Pharmacists on Drug Regulation and Life Cycle of Pharmaceutical Products at the FDA Offices in Accra. The programme was accredited by the Pharmacy Council as a compulsory CPD for all Pharmacists.

Mrs. Delese Darko, the Chief Executive Officer of the FDA in her opening remarks welcomed participants and stated that the programme is part of FDA's efforts to actively involve stakeholders in its activities to enhance collaboration which will in the long term promote patient safety. She further indicated that the programme will be organized again in Accra for pharmacists who were unable to take part in the first session and also in the other regions later in the year. Mr. Seth Seaneke, the Acting Deputy Chief Executive (DCE), Drug Registration and Inspectorate Division gave the expected outcomes of the workshop as to improve Pharmacists' knowledge on the regulatory requirements for the conduct of clinical trials and marketing authorization of products to enhance compliance to the regulatory requirements and reduce the timelines for product approvals and encourage pharmacists to contribute to post-approval safety monitoring and pharmacovigilance system in Ghana.

Mr. Seth Seaneke, Ag. DCE, Drug Registration and Inspectorate Division (front row) with section of participants

Mrs. Delese Darko, the Chief Executive Officer of the FDA welcomes participants to the Training Workshop

Hyoscine butylbromide (Buscopan) injection and risk of serious adverse effects in patients with underlying cardiac disease

The UK medicines regulation agency, Medicines and Healthcare products Regulatory Agency (MHRA) in their Drug Safety Update newsletter, volume 10 issue 7, published in February 2017, provided updates to guide the prescribing and administration on Hyoscine butylbromide injection.

Read more on page 7

Drugs of Current Interest

Questionable Dosing with Anti-Snake Venom Identified through Spontaneous Reporting

Two Anti-Snake Venoms have been registered by the Food and Drugs Authority (FDA) for the treatment of patients with clinical signs of snake envenomation .

The National Pharmacovigilance Centre received eleven adverse event reports in 2016 which were presented to the Technical Advisory Committee on Safety of Vaccines and Biological Products for review.

The review of the cases revealed that the dosage of the Anti-Snake Venom given by the healthcare professionals was inconsistent with the product information and the available literature.

To prevent this in the future, the Committee recommended that Marketing Authorization Holders (MAHs) of Anti Snake Venom should educate health workers on the correct dosing of the product.

Notice of Market Authorization Withdrawal

The registration of the underlisted drugs have been withdrawn by the respective Marketing Authorization Holders (MAH). The decision to discontinue the registration and marketing of the products is based on commercial reasons and not due to efficacy or safety.

MAHs	Brand Name	Active Ingredient(s)	Indication
MSD	Peg-Intron Injection 50mcg, 80mcg, 100mcg, 120mcg, 150mcg and 250mcg	Peginterferon alfa-2b	Chronic Hepatitis C (CHC) in patients with compensated liver disease
	Quadriderm Cream	Bethamethasone + Tolnaftate g + Clioquinol + Gentamycin	Relief of the inflammatory manifestations of corticosteroid responsive dermatoses complicated by secondary infection caused by organisms sensitive to the components. E.g. inguinal dermatosis, eczematoid
	Sustanon 250 Injection	Testosterone propionate + Testosterone phenylpropionate + Testosterone isocarproate + Testosterone decanoate.	Testosterone replacement for men
Sanofi Aventis	Quinimax 125mg Tablets 18's	Quinine hydrochloride + Quinidine hydrochloride + Cinchonidine hydrochloride + Cinchonodine Hydrochloride	Plasmodium Falciparum Malaria
	Quinimax 500mg Tablets 9's	Quinine hydrochloride + Quinidine hydrochloride + Cinchonidine hydrochloride + Cinchonodine Hydrochloride	Plasmodium Falciparum Malaria
	Flagyl 500mg Pessaries	Metronidazole	Topical treatment of Trichomonas vaginitis and nonspecific vaginitis
	Nospa Forte Tablets (80mg)	Drotavarine	Smooth Muscle Spasms Connected with Diseases of Biliary Origin e.g. cholecystolithiasis Smooth Muscle Spasms of the Urinary Tract e.g. nephrolithiasis As an adjunct in treatment of: Smooth Muscle Spasms of Gastrointestinal Origin e.g. gastric and duodenal ulcer Headaches of Vascular Origin Gynecological Diseases e.g Dysmenorrhoea,
	Insuman Basal 100IU/ml suspension for injection in a vial 5ml	Human insulin	Diabetes mellitus where treatment with insulin is required
	Insuman Rapid 100 IU/ml suspension for injection in vial 5ml	Human Insulin	
F Hoffman La Roche Limited	Pegasys Vial 180 mcg/1ml	Peginterferon alfa-2a	Chronic Hepatitis B and C with compensated liver disease
Glaxo-SmithKline	Augmentin Infant Drops	Amoxicillin+Clavulanic Acid 62.5mg/1ml	Short-term treatment of susceptible bacteria infections

Continued from page 6

Hyoscine butylbromide (Buscopan) is indicated for acute muscular spasm including renal or biliary colic, in radiology for differential diagnosis of obstruction and to reduce spasm and pain in pyelography, and in other diagnostic procedures where spasm may be a problem. Hyoscine butylbromide injection can cause adverse effects including tachycardia, hypotension, and anaphylaxis.

These effects are potentially more serious in patients with underlying cardiac disease and caution should be exercised during use. Hyoscine butylbromide injection is contraindicated in patients with tachycardia.

The MHRA recommended that patients with underlying cardiac conditions who are administered Hyoscine butylbromide injection should be monitored. It should also be ensured that resuscitation equipment and personnel who are trained on how to use this equipment are readily available.

In Ghana, the National Pharmacovigilance Centre has received seven cases of ADRs to Hyoscine Butylebromide injection since 2005, five of which were anecdotal. Cardiac symptoms reported include restlessness, sudden collapse with hypovolemic shock and sweating with cold peripheries.

Reference: Article citation: Drug Safety Update volume 10 issue 7, February 2017: 1.Mueller UR. Cardiovascular disease and anaphylaxis. Curr Opin Allergy Clin Immunol 2007; 7: 337–41. Triggiani M, et al. Allergy and the cardiovascular system. Clin Exp Immunol 2008; 153: 7–11.

What to Report?

You don't need to be certain, just be suspicious!

The FDA encourages the reporting of all suspected adverse reactions to medicines, including vaccines, over-the-counter medicines and herbal, traditional or alternative remedies. We particularly request reports of:

- All suspected ADRs whether known or not which causes concern in the caregiver/the patient.
- Lack of efficacy/therapeutic failure
- Suspected pharmaceutical defect
- Counterfeit Pharmaceuticals
- Blood and Blood Products

Reports may be submitted using the FDA **"blue form"** available at all hospitals and some pharmacies and also available at the FDA website at http://www.fdaghana.gov.gh.

Contact the National Pharmacovigilance Centre: Tel: 024 431 0297
Email: drug.safety@fdaghana.gov.gh

FDA Regional Offices:

Kumasi
P.O. Box ST 402, Kumasi
Tel: 03220 36070
Fax: 03220 36027
Location : Regional Coordinating Council (RCC)
Danyame, Kumasi

Sunyani
Private Mail Bag,
Tel: 03520 28791
Fax: 03520 28790
Location: Sam Bennet Building
Central Market Area

Bolgatanga
P.O. Box 612, Bolgatanga
Tel/Fax: 03820 23727
Location: Regional Administration Building, Bolgatanga

Cape Coast
P.O. Box CC1373
Cape– Coast
Tel: 03221 32300/0322 090110
Location: Within the premises of the Regional Administration, Cape Coast

Koforidua
P.O Box KF 2431, Koforidua
Tel: 03420 20580/1
Fax: 03420 205802
Location: Hospital Road, Opposite Assemblies of God Church

Tamale
P.O Box TL1763, Tamale
Tel/Fax: 03720 24889
Location: Regional Administration Building, Tamale

Ho
Private Mail Bag, Ho
Tel: 0362026659
Fax: 03620 28411
Location: GNA Building, Ho

Takoradi
P.O. Box MC2129, Takoradi
Tel/Fax: 03120 27558
Location: SSNIT Building Room 309, Near Central Police Station

Wa
P.O Box 291,
Upper West Region
Tel: 0392020111
Telefax: 0392020001
Location: Controller Block, Ministries

In our attempt to improve on our information sharing on safety issues relating to medicines through our newsletter, the *DrugLens*, we wish to collect your views on any edition of the newsletter you receive.

Name (optional): .....

Organization (optional): .....

E-mail (optional): .....

1. Has the Newsletter been beneficial to you*:*

.....

2. Do you plan to share the newsletter with others? Colleagues, friends? Yes No

3. Any other comments: .....

.....

.....

Design : Iverta Addo

Editorial Team: Chief Editor: Delese M. Darko Editor: G. Sabblah Contributors: Staff, Safety Monitoring Department