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Ministerie van Volksgezondheid

Implementing Pharmacovigilance in Suriname: 2006 - 2009

Suriname, December 2009

Acknowledgements/Disclaimer

European Union

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Acronyms and Abbreviations

ADR	Adverse Drug Reaction
AIDS	Acquired Immune Deficiency Syndrome
BGVS	Bedrijf Geneesmiddelen Voorziening Suriname Drug Supply Company Suriname
CARICOM	Caribbean Community
HIV	Human Immunodeficiency Virus
GFATM	Global Fund to Fight Aids, Tuberculosis and Malaria
MOH	Ministry of Health
MZ	Medical Mission
NAP	National AIDS Programme
PAHO	Pan American Health Organization
RGD	Regionale Gezondheidsdienst (Regional Health Service)
UMC	Uppsala Monitoring Centre

Preface

With great pride the Ministry of Health presents the first report of the Suriname National Pharmacovigilance Centre:

Implementing Pharmacovigilance in Suriname:
2006 - 2009

One of the many tasks of the Ministry of Health is to guarantee safe, active, cost-effective medicines of good quality.

It is therefore important that we create and strengthen those structures and institutions that are tasked with Essential Regulatory Functions:

- Licensing of premises, practices and persons
- Inspection of manufacturers and distributors
- Product assessment and registration
- Monitoring quality of drugs
- Control of drug promotion and advertising
- Adverse drug reaction monitoring

Not only do we have to continuously improve our performance in carrying out these functions, it is also our obligation to develop and implement the legal framework within which actors have to operate.

It is within this context that the Pharmacovigilance Centre started its operation in 2006. The Centre works closely with the National Aids Programme in monitoring Adverse Drug Reactions in general and helps to improve on patient safety when using HAART. These efforts have to be repeated in other programmes where pharmacotherapy is an important factor in successful patient management as well as in the general delivery of pharmaceutical care.

At the same time we also have to ensure that the Pharmacovigilance Centre becomes an integral part of the institutional framework that will ensure quality of pharmaceutical care. Despite these challenges, we think it is important to present the progress achieved by the centre since its inception.

We would take this opportunity to thank all institutions and health care workers who have contributed to this report.

The Director of Health,

Dr. Marthelise Eersel, MPH

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Adriana Ivama, PhD (Advisor on Medicines and Biologicals for the Caribbean from PAHO/WHO Caribbean Programme Coordination Office), Rachel Eersel, MD, MPH (PAHO/WHO Suriname office), Miriam Naarendorp, MSc (Pharmacy Policy Coordinator, Ministry of Health Suriname) and Jose Luis Castro (PAHO/WHO Regional Advisor on Rational Use of Medicines) reviewed the document thoroughly. Primnath Ritoe MPH and Neetu Vyas, M.Com (PAHO/WHO Suriname office) facilitated the publication of this document.

Executive Summary

Suriname established a Pharmacovigilance Centre in 2006, following a training course organized by PAHO/WHO on the implementation of Pharmacovigilance in HIV/AIDS Programs for the Caribbean countries, in September of the same year. The course was one of the results of the European Union/World Health Organization Project Africa, Caribbean and Pacific "Partnership on Pharmaceutical Policies".
The main responsibilities of the Centre are collecting, analyzing and processing adverse drug reactions. The Pharmacovigilance centre processed over 260 reports between 2006 and 2009, almost half of which (60%) regard spontaneous reports of adverse drug reactions by health care workers and the other part (40%) are collected actively from the National AIDS Programme.
Most spontaneous reports from health care workers were generated as a result of the use of medicines from the following therapeutic groups: antibiotics, antihypertensive agents and analgesics. Adverse drug reactions as a consequence of the use of zidovudine accounted for almost half of the reports collected within the National AIDS Programme. Furthermore, zidovudine was also responsible for half of the reported hospitalizations as well as half of the reported referrals.
Although the number of received and collected reports at the Pharmacovigilance Centre is reasonable, underreporting is clearly present. To overcome this problem it is recommended that in addition to family practitioners, other groups of health care workers should be involved in this part of post-marketing surveillance. Secondly, connections with other public health programs should be established.
Notwithstanding the useful information in this report, health care in Suriname could benefit more from the centre if there was more time available for networking with professionals in the sector and incorporating pharmacovigilance in primary health care. This could lead to the gathering of more valuable information useful for enhancing patient safety in the country.

Introduction

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. [1] An effective pharmacovigilance system is essential if medicines are to be used safely, effectively and with confidence. Moreover, such a system benefits all parties and therefore not only individual patients and the public. [2] Pharmacovigilance forms part of the regulatory system and can also contribute to the rational use of medicines.

Adverse drug reactions (ADRs) significantly lead to diminishing of the quality of life, increase of hospitalization, prolongation of hospital stay and increase of mortality. *Furthermore*, the financial cost of ADRs to health care systems is significant. There are several recent trends in the use of medicines that are likely to expose more people to ADRs: for example, the Pan-American Organization/World Health Organization (PAHO/WHO) has been promoting access, safety, quality and rational use of medicines. WHO considers equitable access to safe and affordable medicines to be vital to the attainment of the highest possible standard of health by all[1]. With regard to HIV/AIDS, WHO has been promoting public health approach to antiretroviral therapy (ART) to improve access in resource-poor settings. In 2005, 1.3 million people were receiving ART compared with 400,000 in 2003. [3]

PAHO/WHO organized a training course on the implementation of pharmacovigilance in HIV/AIDS programmes for the Caribbean countries in September 2006, as part of the European Union/WHO Asia, Pacific and Caribbean Project "Partnership on Pharmaceutical Policies. After participating in the course, the pharmacy unit at the Ministry of Health of Suriname endorsed the initiative to set up a pharmacovigilance centre in Suriname (December 2006). With the establishment of the centre, an ADR reporting system is now in place, covering all medical products. Suriname is a member of the WHO Drug Monitoring Programme since January 2007 and mechanisms are in place to take action based on ADR-related information. [4]

In this report we shall briefly describe the achievements and the lessons learned from establishing a pharmacovigilance centre in Suriname.

[1] http://www.who.int/mediacentre/news/statements/2009/access-medicines-20090313/en/index.html

Suriname

Suriname is a former Dutch colony on the northeast coast of South America, bordered by French Guyana to the east, Guyana to the west, and Brazil to the south. Eighty-nine % of the population lives along the coastal strip (59.4% urban, 29.6% rural), which makes up 10% of the land surface (163,820 km of territory). The remaining 11% of the population lives in the interior which is characterized by rainforest vegetation. Most of the population lives along a 30 km wide coastal band. Fifty percent of the population resides in the capital city, Paramaribo. The climate in Suriname is hot and humid. The official language is Dutch, but many other languages are spoken, due to its multi-cultural nature. The country's Gross National Product was USD 1.6 Billion in 2006, equaling USD 3,173/capita, making it a high-middle income country[5]. The Surinamese Dollar (SRD) has a rate of 2.75-2.80 SRD per US dollar (USD). The economy is mainly based on the mining, agriculture, and manufacturing sectors.[2]

The Ministry of Health central office, Inspectorate, and the Bureau of Public Health are responsible for policies, standard setting, inspection and monitoring, and program development. Primary health care is provided on behalf of government by the Regional Health Services (state foundation) and the Medical Mission Primary Health Care Suriname (Medische Zending, MZ) (NGO). Private sector primary health care is mainly provided by private medical practitioners and some large employer firms. Four public (including 1 psychiatric center) and 2 private hospitals provide secondary and specialist care. In addition, the military hospital caters for the military and their dependants. The Regional Health Services operates clinics in the coastal area and the Medical Mission for Primary Health Care Foundation provides health care to the population living in the interior. Financing of health care is separate from the provision of healthcare. Approximately 31% of the population - 'the under-privileged' - are covered through the Ministry of Social Affairs and Housing; 26% through the State Health Insurance Fund (government employees + dependants); 8% by the Medical Mission (communities in the interior; Ministry of Health subsidized); and 34% is covered by private health insurance, company plans, or pay out-of-pocket.[3]

The main cause of death is cerebrovascular disease, followed by conditions related to the peri-natal period, ischemic heart disease, HIV/AIDS, and diabetes.[4]

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[2] Adapted from Lee et al: Suriname Study on Public Sector Drug Procurement (MSH 2003) and Schurman et al: Regional Assessment of Drug Registration and Regulatory Systems in Caricom Member States and the Dominican Republic. Final report Volume II (HERA 2009)

[3] ibid

[4] ibid

Suriname has 22 pharmacies, of which five are hospital pharmacies; there are 14 private pharmacies (including one operated by the State Health Insurance foundation), which only provides services to polyclinic patients. The total number of facilities that dispense medicines for the public sector is 63 (including the RGD and medical mission clinics). The population per functional public facility that dispenses medicines is 7,006. However, the total number of facilities that dispense medicines, including the private pharmacies is 77, resulting in a coverage of 5,771 inhabitants per facility. The number of pharmacists is 31, of which 8 are currently not engaged in pharmacy practice. There are 332 registered physicians, 42 dentists, and 127 medical specialists that are authorized to prescribe medicines.[5]

Table 1. General data from Suriname, (Ministry of Health, NHIS, 2009)

Suriname	
Population	509,970
Regions	10
Hospitals	5
Registered Physicians	332
Medical specialists	127
Pharmacists	31

There are 26 licensed pharmaceutical importers, the largest being the government owned Drug Supply Company Suriname (BGVS). There are only 3 pharmaceutical manufacturers including BGVS.[6]

In Suriname medicines regulation responsibilities are currently divided between two entities, the Pharmaceutical Inspectorate and the Registration Committee. The Registration Committee is the body that issues marketing approval for medicines. The Registration Committee reports to the Director of Health but is otherwise independent. The Registration Bureau under the Ministry of Health provides the administrative infrastructure for the Registration Committee. The Pharmaceutical Inspectorate is a division of the Ministry of Health Inspection Department. It is tasked with the supervision and enforcement of compliance with medicine related legislation and regulation. In practice the Pharmaceutical Inspectorate is responsible for issuing import permits and recommendations regarding pharmaceutical licenses, and for inspection of distribution channels. The head of the Pharmaceutical Inspectorate reports to the Director of Health.[7]

[5] ibid
[6] ibid
[7] ibid

The project ‘Strengthening of Pharmaceutical Quality Assurance & Legislation for the Ministry of Health in Suriname’ project is currently being implemented as part of the execution of the National Medicines Policy. The expected outcomes include a quality assurance policy, proposals for a new comprehensive pharmaceutical legislation, and recommendations for adequate structures for the medicines regulatory system, including the incorporation of pharmacovigilance as one of the regulatory pillars.

The Government of Suriname has committed itself to the free provision of ART, selected medicines for opportunistic infections (on top of access to medicines on the Essential Medicines List) and nutritional products, to decrease mortality and morbidity related to HIV and AIDS. Part of these funds are made available through the Global Fund to Fight Aids, Tuberculosis and Malaria (GFATM; GF), as well as from the national budget. ART is procured and made available through the Drug Supply Company Suriname (BGVS) and managed by the National Aids Programme. Patients on HAART get their medication through pharmacies that have been contracted to deliver this service. At the time of writing this report, there are approximately 900 patients on HAART.

Suriname has followed initiatives undertaken world wide and has ensured access to quality pharmaceuticals by improving its procurement systems, procuring WHO pre-qualified pharmaceuticals and by collaboration through mechanisms such as the Revolving Fund for Strategic Public health Supplies (Strategic Fund).

Pharmacovigilance Centre Suriname

The establishment of the Pharmacovigilance Centre followed the procedures described in the booklet published by the Uppsala Monitoring Centre (UMC, WHO Collaborating Centre for International Drug Monitoring) which deals with setting up and running a Pharmacovigilance centre. [6]

The main responsibilities of pharmacovigilance centres are to collect ADRs, assess reported cases, and help health care providers to put pharmacovigilance into practice, give professionals advice on individual cases, stimulate ADR reporting, organize post graduate training and planning and conduct studies in pharmacovigilance.

Main activities of the Pharmacovigilance Centre Suriname

Pharmaceutical expertise is scarce in Suriname. This is one of the reasons that the activities of the national centre are primarily focused on collecting, analyzing and processing ADRs and dissemination of information gathered. To promote the generation of spontaneous reports, the Centre provides short presentations on Pharmacovigilance at continuing education sessions of physicians and pharmacists. The Centre also conducted a 3 day workshop on risk management in 2007. During each activity reporting forms are widely handed out. The Pharmacovigilance Centre is currently in the process now of preparing a booklet which will give physicians advise in handling adverse drug reactions. The launching of the booklet will coincide with a poster campaign which aims to raise awareness among patients on the occurrence of adverse drug reactions.

The ADR reports are received by e-mail, fax and hard copy (delivered by the health care worker in the centre). The centre makes use of the database developed by the UMC VigiFlow, a case management system for adverse drug reactions.

The ADR reports are received by email, fax and by hard copy. The Centre uses the database developed by the UMC, VigiFlow™, a case-based management system for adverse drug reactions.

Methodology

For the purpose of this report we used de adverse drug reactions, spontaneously reported by health care workers and received by the national Pharmacovigilance Centre between 2006 and 2009. These reports are sent by e-mail, fax and hard copy.

In addition, we used reports of adverse drug reactions collected by the National AIDS Programme (NAP) and sent to the Pharmacovigilance Centre. The NAP provides the Pharmacovigilance Centre with copies of the reported adverse drug reactions in the programme which makes use of a paper-based patient monitoring system. To complete the data of the NAP, adverse drug reactions to 2002 were retrieved retrospectively.

Table 2. Pharmacovigilance Centre Suriname

Overview of Pharmacovigilance Centre Suriname	
Personnel	2 part timers 1 intern
Number of ADR reports collected (since December 06)	> 260
Number of reports sent to WHO database	> 220
Full membership WHO International Drug Monitoring Programme	January 2007

Results

The Pharmacovigilance Centre in Suriname received over 260 reports between November 2006 and September 2009 and forwarded over 200 reports of ADRs to the WHO database, managed by the Uppsala Monitoring Centre.

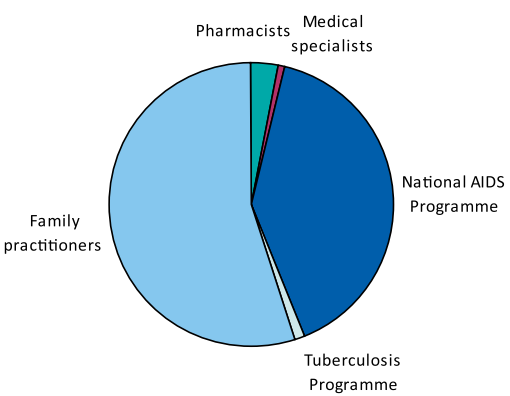

Figure 1. Reports by health care professionals 2006 -2009

Over 50% of the reports are received from family practitioners. About 40% of the reports are received from the National AIDS Programme where pharmacovigilance is sustainable implemented and 10% are received from medical specialists, pharmacists and the National TB Programme together.

Reports received from pharmacists, family practitioners and medical specialists

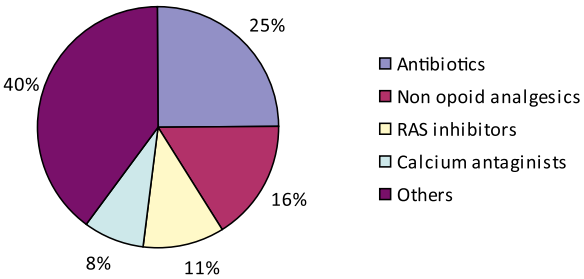

Figure 2. Therapeutic Drug Groups of most spontaneously reported ADRs from 2006 to 2009

Family practitioners report most of the ADRs (50%). Adverse drug reactions as a consequence of antibiotic therapy, accounts for 25% (n=34) of all spontaneous reports. The rather large group of “others” includes 1-2 reports of adverse drug reactions as a consequence of among others corticosteroids, anaesthetics, antipsychotics, ophthalmologics.

Figure 3. Spontaneous reports received in the first months after establishment of the centre

In December and November short presentations on the establishment of the Pharmacovigilance Centre were held for health care professionals at continuing education sessions. At the launch of activities, the Pharmacovigilance Centre received reports dating back as far as 15 years. After this initial high number of reported ADRs after the start of the centre in 2007, the number of monthly

reports decreased to an average level with a slight increase after presentations at continuing education sessions (March 2007).

Reports received from the National AIDS Programme

We started to collect adverse drug reactions from the National AIDS Programme in September 2006. To complete the data we collected the ADRs reported in the Programme retrospectively to 2002. The primary therapy is Zidovudine (AZT) – Lamivudine (3TC) – Nevirapine (NVP). Most of the patients treated receive this combination.

Between 2002 and 2008, more than a thousand patients received ARVs. The reported ADRs are almost equally distributed between men (64) and women (68). 132 ADRs as a consequence of ARVs, are reported between 2002 and 2008 to the National AIDS Programme are collected. 110 of these 132 ADRs resulted in drug substitution, 17 led to other actions (reduction of doses, additional medication for relieve of the adverse drug reaction) and 5 times the ADR resulted in discontinuation of the medicines.

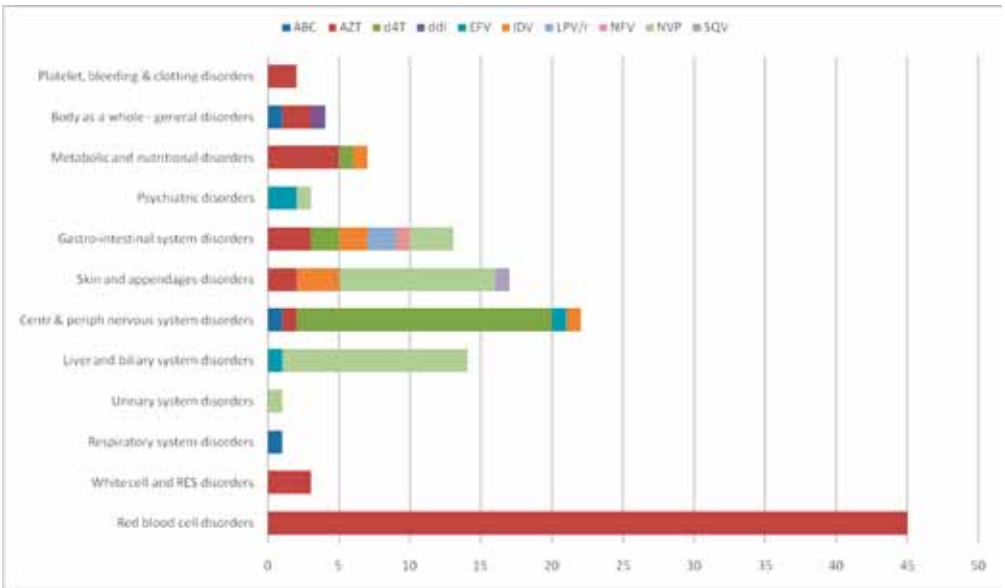

Figure 4. Organ-systems affected by adverse drug reactions

Table 3. Reported adverse drug reactions by ARV from 2002 to 2009

Anti retroviral	Number of toxicities	%
Abacavir	3	2.3
Zidovudine	63	47.7
Stavudine	21	15.9
Didanosine	1	0.7
Efavirenz	4	3.0
Indinavir	7	5.3
Lopinavir/r	2	1.5
Nelfinavir	1	0.8
Nevirapine	29	22.0
Saquinavir	1	0.8
Total	132	100

In the years between 2002 and 2008, adverse drug reactions led to at least 79 referrals to medical specialists and to 45 hospitalizations.

For 19 of 45 hospitalizations, Ziduvudine was the immediate cause, among which 15 for anaemia and 2 for anaemia in combination with leucopenia.

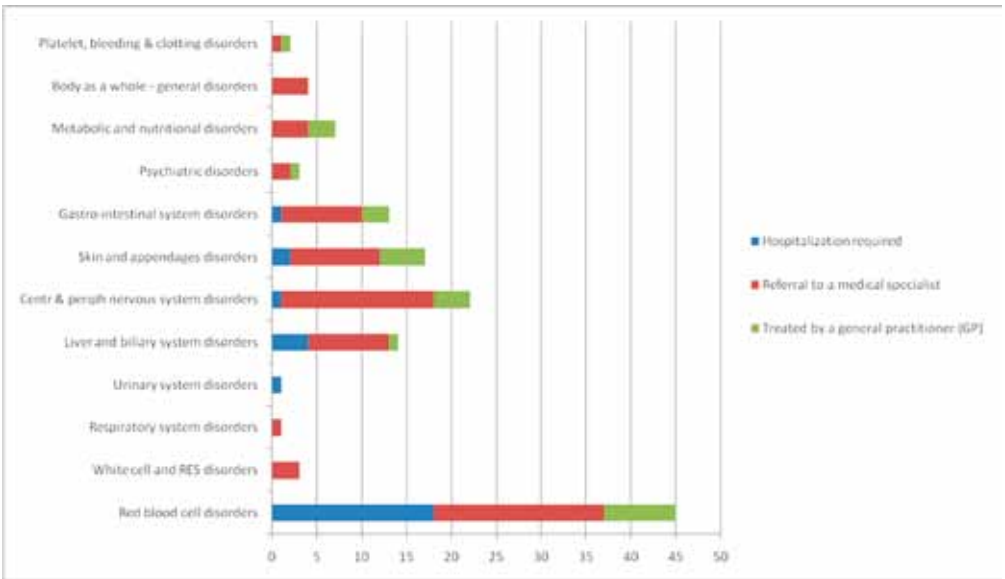

Figure 5. Management of adverse drug reactions

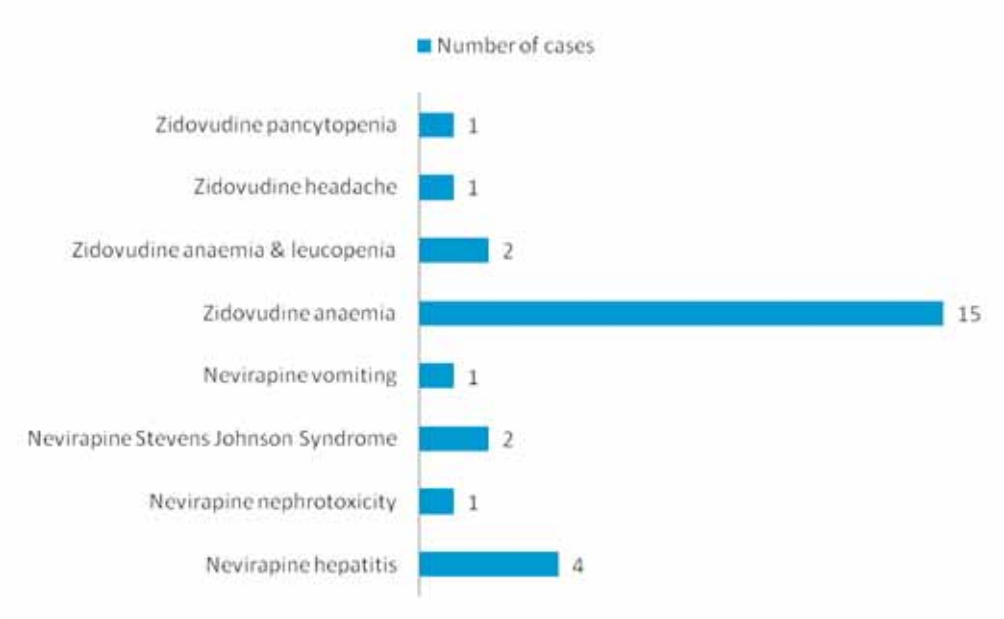

Figure 6. ADRs resulting in hospitalization

Discussion

Although the number of reported adverse drug reactions compared to the estimated population is around 200 per million inhabitants, we recognize clear signs of underreporting. For example: there is a small group of family practitioners who send reports on a frequent basis, and there is a rather large group of physician from whom we never receive reports.
Even with regard to the active collection of ADRs from the National AIDS Programme we recognize underreporting; with more than a thousand patients who ever started ARV treatment we would expect more reports of ADRs.

Also, in many reports all fields were not completed but most physicians were willing to give us the remaining information during the follow up. The handling of the reports sometimes led to the discovery of medication errors, e.g. inappropriate medication prescribed for children, prescriptions not written out according to the guidelines etc. These incidents contributed to discussions on patient safety issues in Suriname.

Lessons learned

For a successful pharmacovigilance programme a good working relation with the reporters is a detrimental. We still conduct pharmacovigilance presentations at continuing education sessions to keep pharmacovigilance on the agenda and in 2009 we started with sending feedback letters. It is therefore suggested that the short presentations during the continuing education sessions prove their value, and we expect the same from the feed back letters.

Although reporting and processing of adverse drug reactions is taking place, we need more than 2 part timers to expand the programme, especially if we want to continue with the transformation of becoming a Centre for Patient Safety. If this centre is established, the centre will receive reports on medication errors, incidents and near misses next to the reports on ADRs.

Fortunately, we had a very good experience with trainees from pharmacy and medical schools, and we will therefore continue to provide places for internships.

Use of available data is another aspect of the Pharmacovigilance Centre. For the purpose of sharing our experience we aim at publishing at least annual reports.

What was effective?

- Promotion of the possibility to report ADRs during every continuing education session.
- Wide distribution of reporting forms.
- Sustainable implementation of pharmacovigilance in the National AIDS Programme.

What needs more attention?

Reporters often complain about the lack of feedback. With the introduction of feedback letters and the dissemination of more information on the data collected during the short presentation in continuing education sessions, we try to overcome this obstacle.

In addition to collecting and processing adverse drug reactions, the pharmacovigilance centre tries to emerge into a centre for patient safety.

Within this scope, we organized a workshop on risk management, introduced the bow tie methodology and introduced reporting forms for incidents, near-misses and medical errors. In doing so, the centre promotes corrections with regard to the use of medicine, improvement of knowledge on the risks of medicine and contributing to patient safety.

Final considerations and recommendations

Family practitioners are the largest of group of health workers and the main contributors of spontaneous reports of adverse drug reactions. Their involvement is essential for the spontaneous reporting system.

Other groups of health workers are equally important (medical specialists working in hospitals) but with regard to the collection of data they are much less involved. The first recommendation is therefore to enhance the participation of other health care workers.

The sustainable implementation of Pharmacovigilance in public health programmes leads to close monitoring and very useful data which can be used among others for revising and adjusting treatment protocols. Currently, the Pharmacovigilance Centre is only linked to the National AIDS Programme and consequently misses out useful data collected in other programmes. The second recommendation would therefore be more involvement with public health programmes, preferably in a sustainable relationship.

Although the centre may maintain the basic functions such as assessment of the reported cases and stimulation of ADR reporting, more personnel would mean that other responsibilities can also be carried out. One of these could be more dissemination of the results and to give professional advice on individual cases. The third recommendation is to consider the human resources available to the centre. Despite limited resources, it was possible to implement the pharmacovigilance centre in Suriname. The centre represents a place where health care professionals can share their concerns of medical products on the market with the Ministry of Health and serves as a post marketing surveillance tool for the country.

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Vertrouwelijk

Meldformulier Bijwerkingen Geneesmiddelen

Ministerie van Volksgezondheid

Pharmacovigilance Centre Suriname

A. Vermoedelijke bijwerking

Omschrijving:

Begindatum bijwerking dag | maand | jaar

Indien gebruik korter dan 1 dag uur | minuut

Ernstigheid indien van toepassing

- ○ **Overlijden**
- ○ **Levensbedreigend**
- ○ **Ziekenhuisopname**
- ○ **Aangeboren afwijkingen**
- ○ **Blijvend arbeidsongeschikt of invalide**
- ○ **Overige ernstige afwijkingen**

Verloop en aanvullende opmerkingen

Zo nodig kunt u op de achterzijde / 2e pagina verder invullen

Melddatum dag | maand | jaar

Een kopie van de volgende bijlagen is toegevoegd

- ○ **Correspondentie**
- ○ **Lab gegevens**
- ○ **Overig**

Is er over deze melding eerder contact geweest? ○ **Ja** ○ **Nee**

B. Gebruikte medicatie

Medicatie met bijwerkingen

(Handels)naam	Dosering	Wijze van toediening	Indicatie	Startdatum	Stopdatum
				dag maand jaar	dag maand Jaar
				dag maand jaar	dag maand Jaar

Co-medicatie gegevens				Startdatum	Stopdatum
				dag maand jaar	dag maand Jaar
				dag maand jaar	dag maand Jaar
				dag maand jaar	dag maand Jaar
				dag maand jaar	dag maand Jaar

C. Gegevens van de patiënt

Geboortedatum dag | maand | jaar ○ Vrouw ○ Man Gewicht kg Lengte cm

Medische voorgeschiedenis Etniciteit

Zo nodig kunt u op de achterzijde / tweede pagina verder invullen

D. Gegevens van de melder

Naam Naam instelling

Adres

District Plaats

Telefoonnr. Faxnummer E-mail adres:

Beroep / specialisme ○ Apotheker ○ Specialist, nl:

○ Arts ○ Overige, nl:

*Dit formulier per e-mail opsturen naar: **pvsuriname@gmail.com** of per fax naar: (597) 470448*
U kunt contact met ons opnemen via bovenstaand e-mailadres of bellen naar (597) 470416 of 470418
Mevr drs P. Tjin A Kwie of Mevr drs. N.T. Jessurun (Pharmacovigilantie Coördinator Suriname)

Vervolg

Toelichting op het meldformulier	
Vermoedelijke bijwerking *Omschrijving*: De symptomen of diagnose die voor u de aanleiding waren om aan bijwerkingen van het geneesmiddel te denken.	**Gebruikte medicatie** Het gaat hierbij alleen om geneesmiddelen die voorafgaand aan de bijwerking gebruikt werden. Gebruik bij voorkeur de ***handelsnaam*** van de geneesmiddelen.
De ***begindatum*** bepaalt hoeveel tijd na de eerste inname de bijwerking(en) optrad(en). Als deze tijd ***korter dan 1 dag*** is, vermeld dan het aantal uren en minuten.	De wijze van toediening en indicatie van de medicatie met bijwerkingen zijn van belang voor de analyse van uw melding. Vraag eventueel bij de apotheek (indien mogelijk) een geanonimiseerde ***medicatiehistorie*** op en sluit deze bij. U hoeft dan de co-medicatie niet in te vullen.
Kruis in voorkomende gevallen één criterium aan voor een ***ernstige bijwerking***. Als u de bijwerking ernstig vindt zonder aanwezigheid van de andere criteria, kruis dan overige ernstige afwijkingen aan.	**Gegevens Patiënt** ***Gewicht*** en ***lengte*** zijn optioneel. Invulling van het patiëntnummer is alleen bedoeld voor uw eigen administratie. Zo kunt u de geanonimiseerde correspondentie van PVS herleiden tot uw patiënt
Als de bijwerking een ***aangeboren afwijking*** betreft, vermeld dan de gegevens van de moeder.	**Gegevens melder** Uw persoonlijke gegevens worden aan geen enkele instantie doorgegeven, tenzij we uw toestemming hebben verkregen.
PVS wil graag weten in hoeverre, en eventueel met welke behandeling, de bijwerking is hersteld. U kunt dit vermelden bij ***verloop en aanvullende opmerkingen***. Hier kunt u ook de gegevens vermelden waarvan u denkt dat ze van belang zijn voor de melding. Als deze gegevens in een bijlage staan aangegeven kunt u volstaan met een verwijzing hiernaar.	Uw melding wordt, zonder persoonlijke gegevens doorgegeven aan het registratiebureau, de Wereldgezondheidsorganisatie en eventueel aan de fabrikant van het vermoedelijk geneesmiddel.
Het bijvoegen van geanonimiseerde kopieën van correspondentie, laboratoriumgegevens of overige documentatie (PA-verslag, obductieverslag) wordt zeer op prijs gesteld.	Indien u tevens namens een andere behandelaar meldt, verzoeken we u zijn/haar gegegens op de achterzijde aan te geven. Deze behandelaar ontvangt dan ook bericht over deze melding.
	Tot slot Indien u op- of aanmerkingen heeft op het in te vullen formulier en de wijze waarop uw melding is behandeld, horen we dit graag van u.

Vervolgformulier	○ Vervolg zonder wijziging	○ Vervolg met wijziging (in therapie)

A Gegevens patiënt

Cliënt-code:		Datum bezoek patiënt:	Dag	Maand	jaar

Gewicht	kg	lengte	cm	Begeleider:	○ nee	○ ja t.w.	

Betalinswijze:	SOZA	SZF	MZ	PZS	AZPAS	ER	FHIP	Bedrijf:

Indien wijziging therapie reden:	○ Toxiciteit / bijwerking op	
	○ Therapiefalen	○ Anders

B Laboratorium resultaten — Datum: Dag / Maand / Jaar

HB	mmol/L	**SGOT**	U/L	**Bili**	umol/L	**Cholesterol**	mmol/L	**VL**	cp/ml
Leucocyten	10/L	**SGPT**	U/L	**MCV**		**Triglyceriden**	mmol/L	**CD4**	10 of /mm
Trombocyten	10/L	**LDH**	U/L	**Urine-sediment**		**Glucose**	mmol/L	**Urine eiwit**	– / + / ++ / +++
Abs Aant Lymfo's	10/L	**AF**	U/L	**Serum-amylase**	U/L	**HBsAg**	Pos / neg	**Urine Glucose**	– / + / ++ / +++
Lymfo % in diff		**CPK**	U/L	**Urinezuur**	mmol/L	**HCV**	Pos / neg	**VDRL**	Pos / neg

C Huidige symptomen

Huidige symptomen:	Datum:	HIV-gerelateerd:	Medicatie gerelateerd:
			(Indien bijwerking startdatum bijwerking en behandeling zo nauwkeurig mogelijk aangeven)

D Gebruikte medicatie

Medicatie (dosering invullen)			**Medicatie voor wijziging**						**Medicatie na wijziging**				**Compliance**
Medicatie aanvinken ☑			Startdatum			Stopdatum			Startdatum				
Lamivudine	dd	€											Is de patiënt poli-trouw?
Zidovudine	dd	€											
Nevirapine	dd	€											
Stavudine	dd	€											Is de patiënt lab-trouw?
Efavirenz	dd	€											
Nelfinavir	dd	€											
Didanosine	dd	€											Aantal gemiste doses afgelopen maand?
Abacavir	dd	€											
Indinavir	dd	€											
Lopinavir / ritonavir	dd	€											
Ritonavir	dd	€											Therapietrouw?
		€											○ Ja (indien > 95%)
		€											○ nee

Co-medicatie (naast ART)	Startdatum	Stopdatum

Co-morbiditeit

D Gegevens behandelaar

Naam:												
Instelling	RGD		RKZ		MZ		SZN		MH			
	DH		AZP		LH		Part.					
Telefoon no			Email adres									

Dit formulier per e-mail opsturen naar:
Per fax naar:
Voor informatie kunt u terecht bij::