Open Letter

Malaria crisis in Venezuela: a complex operating environment

National shortages of antimalarial medicines

On August 22, we honor members of the Venezuelan Society of Public Health shared analysis and ideas (privately and confidentially) with senior officers of the Venezuelan Ministry of Health (MoH) on the immediate needs of antimalarial medicines to meet the demands for the next six months.

1. Venezuela has reported 148,670 new local (autochthonous), confirmed cases (official information not disclosed by the MoH) in the epidemiological week 34 of 2016. Additionally, it is estimated that about 50% of cases (classified either as recrudescences or relapses) are not reported in the statistics to the MoH.

2. The available information collected by the MoH -including the one coming from spontaneous and non-official sources- confirms the emergency situation caused by the unavailability of medicines to prevent and treat malaria cases in Venezuela.

3. In relation to malaria, the following official data has already been reported: 1) In the Republic of Colombia (Epidemiological Week (EP)·34 of 2016) 389 imported cases were diagnosed, 81.7% of which were from Venezuelan origin; 2) In the Brazilian State of Roraima between January and July 2016, more than 2,100 cases were reported (78% of which were from Venezuelan origin); 3) In Guyana, of the 241 cases of imported malaria in 2013, 197 were from Venezuelan origin (81.7% of the total imported cases).

4. There is an urgent demand for basic health services, originated by the current malaria epidemic due to the high risk of imminent increase of the spread of malaria transmission to almost all national territories and neighboring countries.

Factors identified preventing immediate and adequate response

5. Interruption of production of one key antimalarial medicine in Venezuela -the Servicio de Elaboraciones Farmacéuticas (SEFAR) - from the MoH ceased the packing of chloroquine phosphate tablets since last year due to lack of active pharmaceutical ingredient (API).

6. The financial resources allocated to the National Malaria Control Program (NMCP) in the last 10 years have been insufficient and discontinuous to meet the basic needs of prevention and control.

7. Policy and decision-makers responsible to allocate the available financial resources have mistakenly underestimated the importance of malaria as a public health problem. They have not followed the recommendations of the national and international experts in this field regarding the allocation of financial resources with the highest cost-effective relationship.

8. In the context of the current financial insolvency of the country, inventories of API and pharmaceutical products have been gradually depleted following the high current demand. International suppliers have not received payments for already delivered products; debt with these suppliers has risen and consequently credit lines for new purchases have been closed. Currently, the delivery of new products is subjected to the previous payment of incurred debts. As a result of the above the reserve of

these essential drugs has dropped to critical levels with the impossibility to attend even the life threatening cases.

9. Confidential information obtained by us also indicates that the debt of the Government of Venezuela with the Pan-American Health Organization (PAHO)/World Health Organization (WHO) Revolving Fund has risen closely to USD 40 million (in addition to a debt to the PAHO Strategic fund, whose total amount is unknown). The Venezuelan government has offered to pay part of the debt, about USD 10 million, but to date has failed to do it. Consequently, in 2016, the planned process to procure antimalarials medicines has been delayed.

10. The extraordinary funds approved by the Venezuelan Government in 2015 via additional credits outside the regular budget -known as the Micro mission Malaria- were established for two years, but only covered the first year. The Funds corresponding to 2016 have not been assigned at this time.

11. Right now there is a need for urgent donation of antimalarial medicines to provide basic treatment to the most affected populations. Some countries, consulted on this point, would be willing to make donations to help with Venezuela´s debt and allow delivery of these medicines. Their only condition or requirement is the ability to directly assess the real needs of medicines and ensure that they effectively reach the people who need them. Apparently, the Government of Venezuela has not accepted these conditions.

12. The availability, distribution, and access to all needed types of antimalarial medicines by the most affected populations is being significantly affected. Starting with the population of the Bolivar State, where 80% of the malaria transmission occurs now. The Sifontes Municipality of the Bolívar State generates almost half of all malaria cases of the country.

13. The massive and irregular diversion of drugs to illegal distribution lines has fostered corruption and threatens the overall efficiency of the NMCP.

14. All of the above synthesize a complex operating environment situation. It can be anticipated that for more than six months the lack of antimalarial drugs will exacerbate the malaria morbidity and mortality.

15. Given the urgency in the country we are exploring alternative forms of acquisition and immediate availability of antimalarial drugs in collaboration with other partners in the country. *Exhibit 1 shows the forecasting on antimalarial medicines for 12 months.*

16. We believe that this malaria epidemic will reverse last decade's regional achievements in malaria control, prevention, and elimination and therefore, it will affect global targets moving towards malaria elimination.

17. We believe that it could be possible to obtain emergency funding from main donors including, the Global Fund to fight AIDS, Tuberculosis and Malaria (GFATM), United Nations and others to address the current malaria epidemic in Venezuela.

18. We are aware that it is essential to have the best disposition of the Government of Venezuela to accept international advice. Collaboration and willingness to provide comprehensive, adequate (updated), and reliable information to plan and implement cost effective interventions to achieve impact.

19. Short and medium-term funding -effective and sufficient to mitigate the impact of morbidity and mortality of the disease on the population increasingly at risk- is urgently needed. The lack of

transparency and official restrictions of malaria epidemiological data from the MOH, especially in the last 3 years, does not contribute to this purpose.

20. The willingness of senior MOH officials to contribute with their ideas, experience, and data sharing (confidentially) contributes to remedy the failures of undisclosed official information.

21. It is not clear what would be the mechanism of cooperation if the Government of Venezuela does not officially accept an aid of this nature. We know that international donors and malaria partners apply special procedures of humanitarian aid, even in circumstances or calamities in which the Member States do not accept the aid, which seek to satisfy the fundamental health rights and life of affected populations.

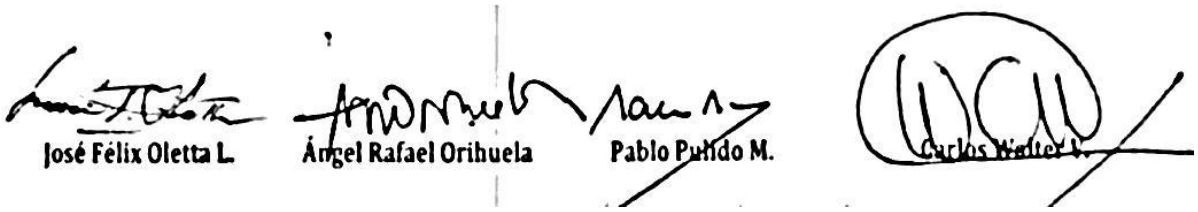
22. We believe that the participation and cooperation of Non-Government Organizations (*Caritas Internationalis*, *Caritas Venezuela*, the *Salesian Congregation*) and other NGOs such as *Médecins Sans Frontières* and *International Red Cross* could be of great value as allies. They have experience supporting the NMCP in Venezuela in distribution and verification of supervised drug use.

23. We believe it is very important to unify the efforts of various institutions interested in supporting this emergency. This could be coordinated by specialized organizations such as the GFATM and malaria stakeholders including PAHO/WHO, NGOs, affected populations, and NMCPs from Venezuela, Guyana, Brazil and Colombia.

24. We hope the ideas expressed can help develop a successful public health proposal, timely, promptly and effective in the fight against malaria in the Americas, especially in Venezuela and neighboring countries. It is a serious reemerging public health threat that requires extraordinary responses and sustainable political commitment.

From now on, you can count on our full support and commitment to advance an initiative of this nature.

Sincerely,



Former Ministers of Health of Venezuela

Exhibit 1. Forecasting of antimalarial medicines for 12 months, Venezuela.

Name of medicine	Treatment P. vivax/Mixed	Treatment P. falciparum/Mixed	Presentation	Units per treatment	Total Units	5% lost	WHO (+25%)	Collagenosis	Total treatment 12 months
Chloroquine phosphate 150 mg	333039		Tab/Blister	11	3663424	183171	915856	594000	5356451
Chloroquine suspension 50 mg/5 ml	3704		Tab/Blister	1	3704	185	926		4815
Primaquine phosphate 15 mg	308343	64903	Tab/Blister	16	5128201	256410	1282050		6666661
Primaquine phosphate 7.5 mg	34584	7280	Tab/Blister	16	651809	32590	162952		847352
Primaquine phosphate 5 mg	21114	4444	Tab/Blister	16	351164	17558	87791		456513
Artesunate/Mefloquine 100/220 mg		67032	Tab/Blister	9	603291	30165	150823		784278
Artesunate/Mefloquine 50/50 mg		5716	Tab/Blister	9	51443	2572	12861		66876
Artemether/Lumefantrine 20/120 mg		22988	Tab/Blister	24	551716	27586	137929		717231
Quinine sulphate 300 mg		1166	Tab/Blister	42	48991	2450	12248		63688
Quinine chlorhidrate inj 600 mg		416	Vial	10	4157	208	1039		5404
Artesunate inj 60 mg		485	Vial	6	2910	146	728		3783
Artemether inj 80 mg/ml		520	Vial	11	5716	286	1429		7431
Clindamycin inj 600 mg		208	Vial	15	3118	156	780		4053
Clindamycin 300 mg		208	Tab/Blister	21	4365	218	1091		5675

Notes:

(*) Those antimalarial drugs must be accompanied with rapid diagnostic tests and long-lasting treated nets to meet the minimum package of prevention and diagnosis in emergency situations like ours. In total, 65,112 mosquito nets and 160,000 rapid tests are needed.
(**) Includes treatment for patients with connective tissue disease

(***) Basic assumptions:

Basic considerations for calculating drugs

CASOS VZLA	
P. vivax	245566.8
P. falciparum	68213
Mixtos	27285.2
TOTAL	341065

72.0
20.0
8.0

CASOS VZLA + RECAIDAS+RECRUD.	
P. vivax	333971
P. falciparum	76398
Mixtos	27285.2
TOTAL	437654

CASOS + RECA/RECRUD+ IMPORTADOS	
P. vivax	336743
P. falciparum	76627
Mixtos	27299
TOTAL	440669

TRATAMIENTOS (CORRECCIÓN X MIXTOS)	
P. vivax	336743
P. falcip + Mixto	103926
TOTAL	440669

% IMPORTADOS:	% Total	1.2
P. v	P. f	Mixto
0.83	0.3	0.05

% RECAIDAS	36.0
TOTAL RECAIDAS	88404
%RECRUDESC.	12
TOTAL RECRUD.	8185

% de EMBARAZADAS en total casos	0.45
EMBARAZADAS ESPERADAS	2333

GENERAL	
Sin intervencion Impactante	
CASOS ESPERADO AÑO 2016	
Maximo	Minimo
518419	484312

% < 5años
% 5 a 14 años
% 15 años o +
TOTAL

Promedio Ponderado Venezuela			
P. v	P.f	Mixto	% Pond
5.5	1.1	0.3	6.9
9.0	2.1	0.5	11.5
57.1	20.7	4.7	81.6
71.6	24.0	5.5	0.0