WEEKLY EPIDEMIOLOGICAL REPORT

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Ministry of Healthcare and Nutrition

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WHO Prequalification Project for Drugs

The Prequalification project, set up in 2001, is a service provided by the World Health Organization (WHO) to facilitate access to medicines that meet unified standards of quality, safety and efficacy for HIV/AIDS, malaria and tuberculosis.

"*Good quality medicines for everyone"* is the vision for this project while its mission is "to work *In close cooperation with national regulatory agencies and partner organizations, the Prequalification Programme aims to make quality priority medicines available for the benefit of those in need".* This is achieved through its evaluation and inspection activities and by building national capacity for sustainable manufacturing and monitoring of quality medicines.

From the outset, the project was supported by UNAIDS, UNICEF, UNFPA and the World Bank as a concrete contribution to the United Nations priority goal of addressing widespread diseases in countries with limited access to quality medicines.

Prequalification was originally intended to give United Nations procurement agencies, such as UNICEF the choice of a range of quality medicines. With time, the growing list of products i.e. medicines that have been found to meet the set requirements has come to be seen as a useful tool for anyone bulk purchasing medicines, including countries themselves and other organizations. For instance, the Global Fund to Fight AIDS, Tuberculosis and Malaria disburses funds for medicines that have been prequalified by the WHO process.

Any manufacturer wishing their medicines to be included in the prequalified products list is invited to apply. Each manufacturer must present extensive information on the product submitted to allow qualified assessment teams to evaluate its quality, safety and efficacy. The manufacturer must also open its manufacturing sites to an inspection team which assesses working procedures for compliance with WHO Good Manufacturing Practices (GMP). Alternatively, the inspections carried out by stringent regulatory bodies are recognized and their work is not duplicated by WHO.

The standards against which assessment teams evaluate both quality specifications of medicines and manufacturing sites are based on the principles and practices agreed by the world's leading regulatory agencies and adopted by the WHO Expert Committee on Specification for Pharmaceutical Preparations. In other words:

- The manufacturer provides a comprehensive set of data about the quality, safety and efficacy of its product, including details about the purity of all ingredients used in manufacture, data about finished products, such as information about stability, and the results

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of clinical trials conducted in healthy volunteers

- The team of assessors evaluates all data presented and if satisfied with the evidence sends the product to professional control testing laboratories contracted by WHO in France, South Africa or Switzerland for analytical verification of quality

- If the product is found to meet the specified requirements, and the manufacturing site complies with GMP, both product linked to this manufacturing site and company are added to a list hosted by WHO on a public web site

All product and manufacturing site requirements, standards used in evaluating the product and the profile of the inspection teams are outlined on the WHO prequalification project web site. The site also includes the list of prequalified medicines and their manufacturers.

The assessment teams evaluating the products and manufacturers include experts from some of the national regulatory authorities of the European Union as well as Canada and Switzerland. These teams ensure that high quality, international standards are respected. **The teams work with regulators from the developing countries where the medicines will be used to make sure that the process and results are at all times transparent and trusted by the end-users**.

The prequalification process takes a minimum of three months if the product meets all the required standards. When products do not meet the appropriate standards the process can be longer and if the manufacturer fails to prove the quality, safety and efficacy of its medicine it will not be prequalified. Inclusion in the list does not mean that the prequalified status of a product lasts forever. All medicines already in the list are subjected to prequalification process again after three years, or earlier, if needed. WHO also carries out random quality control testing of prequalified medicines that have been supplied to countries.

Medicines which have been found to meet the required standards so far are from both brand name (42 medicines) and generic (61 medicines) manufacturers. These include 62 anti-retrovirals and 33 medicines for HIV/AIDS-related diseases; two antimalarials and six drugs for the treatment of tuberculosis.

Medicines containing one active ingredient and those combining several active ingredients in one pill, usually called fixed-dose combination drugs, have been prequalified. For tuberculosis, there is one quadruple (four-in-one pill) and one double (two-in-one) fixed dose combination drug and for malaria one double fixed dose combination drug has been approved.
In the case of AIDS medicines, two different triple (three-in-one) fixed-dose combination drugs have recently been approved; one from an originator company and the other from two different generic companies.

The principles for assessing the quality of fixed-dose combination drugs are the same as those used by the European Agency for the Evaluation of Medicinal Products (EMEA) and the USA Food and Drug Administration (FDA). In other words, the prequalification assessment team evaluates the required data, including in vivo bioequivalence tests carried out by the manufacturers. The fixed-dose combination drug is tested against separate medicines taken together in the same dosage as is present in the fixed-dose combination pill.

In soliciting applications from companies, WHO does not question whether the products presented are patented or generic, since patent laws vary according to different national legal systems. It suffices that a company is duly authorized for pharmaceutical manufacture in its own country and that the final product meets stringent standards of quality, efficacy and safety.

The availability of quality, safety and efficacy of medicines is a major concern of WHO. To ensure that quality pharmaceuticals are available, WHO sets norms and standards, develops guidelines and advises Member States on issues related to quality assurance of medicines in national and international markets. WHO assists countries in building national regulatory capacity through networking, training and information sharing. These activities have been endorsed and supported by Member States through numerous World Health Assembly resolutions.

The Prequalification project is part of these activities and mandate. It does not intend to replace national regulatory authorities or national authorization systems for importation of medicines. Prequalification draws from the expertise of some of the best national regulatory authorities to provide a list of prequalified products that comply with unified international standards.

With the obvious success and the importance of this project, WHO was able to extend similar types of service to two other important fields of healthcare services i.e. vaccine and the laboratory technology. This enables the developing world to purchase vaccines and the laboratory technology with guaranteed quality and safety through UN agencies or on their own. Today, many of the countries in the world have benefited through this successful project.

Source : World Health Organization.

Table 1: Vaccine-preventable Diseases & AFP

31st July - 06th August 2010(31st Week)

Disease	No. of Cases by Province									Number of cases during current week in 2010	Number of cases during same week in 2009	Total number of cases to date in 2010	Total number of cases to date in 2009	Difference between the number of cases to date in 2010 & 2009
	W	C	S	N	E	NW	NC	U	Sab					
Acute Flaccid Paralysis	0	01	00	00	01	00	00	01	00	02	02	58	49	+ 18.3 %
Diphtheria	00	00	00	00	00	00	00	00	00	00	00	00	00	-
Measles	03	00	00	00	00	00	00	00	00	03	01	61	87	- 29.9 %
Tetanus	00	00	00	00	01	00	00	00	00	01	00	16	18	- 11.1 %
Whooping Cough	00	00	01	00	00	00	00	00	01	02	00	20	33	- 39.4 %
Tuberculosis	121	03	03	17	23	00	00	00	07	174	264	5484	5929	- 07.5 %

Table 2: Newly Introduced Notifiable Disease

31st July - 06th August 2010(31st Week)

Disease	No. of Cases by Province									Number of cases during current week in 2010	Number of cases during same week in 2009	Total number of cases to date in 2010	Total number of cases to date in 2009	Difference between the number of cases to date in 2010 & 2009
	W	C	S	N	E	NW	NC	U	Sab					
Chickenpox	16	04	03	01	04	05	08	01	03	39	145	2123	11263	- 81.1 %
Meningitis	05 GM=1 KL=4	00	03 GL=3	01 VU=1	03 BT=2 TR=1	01 KN=1	05 PL=5	01 BD=1	01 KG=1	20	11	1101	624	+ 76.4 %
Mumps	01	01	04	02	00	04	01	00	09	22	31	645	1165	- 44.6 %
Leishmaniasis	00	00	00	00	03 TR=3	01 KN=1	03 AP=3	00	00	07	13	181	486	- 62.8 %

Key to Table 1 & 2

Provinces: **W**: Western, **C**: Central, **S**: Southern, **N**: North, **E**: East, **NC**: North Central, **NW**: North Western, **U**: Uva, **Sab**: Sabaragamuwa.

DPDHS Divisions: **CB**: Colombo, **GM**: Gampaha, **KL**: Kalutara, **KD**: Kandy, **ML**: Matale, **NE**: Nuwara Eliya, **GL**: Galle, **HB**: Hambantota, **MT**: Matara, **JF**: Jaffna, **KN**: Killinochchi, **MN**: Mannar, **VA**: Vavuniya, **MU**: Mullaitivu, **BT**: Batticaloa, **AM**: Ampara, **TR**: Trincomalee, **KM**: Kalmunai, **KR**: Kurunegala, **PU**: Puttalam, **AP**: Anuradhapura, **PO**: Polonnaruwa, **BD**: Badulla, **MO**: Moneragala, **RP**: Ratnapura, **KG**: Kegalle.

Data Sources:

Weekly Return of Communicable Diseases: Diphtheria, Measles, Tetanus, Whooping Cough, Chickenpox, Meningitis, Mumps.

Special Surveillance: Acute Flaccid Paralysis.

Leishmaniasis is notifiable only after the General Circular No: 02/102/2008 issued on 23 September 2008.

Influenza Surveillances at Sentinel Hospital

Month	Human Surveillance							Animal Surveillance		
	Number of Expected	No Received	Influenza A	Influenza B	Pan H1N1	H3N2	Other	Pooled Sample	Serum Samples	Positives
June	600	97	00	00	00	01	00	115	724	00
July	600	120	00	00	00	01	00	145	809	00

Table 4: Selected notifiable diseases reported by Medical Officers of Health

31st July - 06th August 2010(31st Week)

DPDHS Division	Dengue Fever / DHF*		Dysentery		Encephalitis		Enteric Fever		Food Poisoning		Leptospirosis		Typhus Fever		Viral Hepatitis		Human Rabies		Returns Received
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	%
Colombo	223	4262	6	204	0	14	38	86	0	29	6	379	0	7	3	41	0	1	**92**
Gampaha	90	3015	2	109	0	18	3	34	0	17	4	251	1	9	0	65	0	4	**67**
Kalutara	35	1386	5	165	1	13	0	15	1	74	3	220	0	2	2	25	0	1	**75**
Kandy	69	1219	8	231	0	3	0	20	0	4	1	67	1	101	3	43	0	1	**78**
Matale	8	491	3	232	0	3	0	24	1	69	1	68	0	4	0	32	0	0	**75**
Nuwara	13	145	3	263	0	0	0	88	0	84	0	21	0	49	0	27	0	0	**85**
Galle	50	803	9	184	1	5	0	5	0	12	3	60	0	15	1	9	0	3	**95**
Hambant	27	597	0	54	0	4	0	1	0	10	1	67	1	61	0	7	0	0	**82**
Matara	45	428	7	134	0	6	0	5	1	47	1	196	0	97	0	16	0	0	**100**
Jaffna	28	2570	3	186	0	3	16	436	0	8	0	1	0	108	2	48	0	2	**83**
Kilinoch-	2	10	1	10	0	0	0	6	0	1	0	0	0	0	0	0	0	0	**100**
Mannar	79	315	0	34	0	1	1	36	0	10	0	0	0	0	0	15	0	0	**60**
Vavuniya	4	538	0	31	0	2	0	38	0	8	0	2	0	1	0	10	0	1	**50**
Mullaitivu	0	3	0	1	0	0	0	1	0	0	0	0	0	0	0	0	0	0	**0**
Batticaloa	9	1135	1	109	0	3	1	18	0	30	0	10	1	3	0	4	0	2	**86**
Ampara	6	116	0	62	0	1	0	6	0	6	0	30	0	0	0	10	0	0	**43**
Trincomal	7	875	0	111	0	12	0	4	0	11	1	19	0	12	0	13	0	1	**80**
Kurunega	91	1113	4	209	0	15	0	27	0	9	3	228	3	38	6	86	0	3	**100**
Puttalam	28	836	6	93	0	6	0	42	0	124	1	60	0	0	0	20	0	1	**78**
Anuradha	29	894	2	49	0	5	1	10	0	37	2	63	0	22	1	35	0	3	**79**
Polonnar	21	347	2	61	0	1	1	6	0	8	1	51	0	1	2	35	0	0	**100**
Badulla	70	833	4	134	0	1	1	67	0	16	3	51	1	63	0	79	0	0	**73**
Monaraga	95	754	3	125	0	1	0	30	0	4	0	27	1	50	1	62	0	2	**82**
Ratnapur	121	1994	2	345	0	4	0	10	0	26	6	278	1	44	2	70	0	2	**56**
Kegalle	30	708	2	100	0	11	1	42	0	19	8	178	1	13	6	68	0	0	**82**
Kalmunai	2	493	4	169	0	2	1	6	0	3	0	0	0	0	0	11	0	1	**85**
SRI LANKA	**1182**	**25880**	**77**	**3405**	**02**	**134**	**64**	**1063**	**03**	**666**	**45**	**2327**	**11**	**700**	**29**	**831**	**00**	**28**	**80**

Source: Weekly Returns of Communicable Diseases WRCD).
***Dengue Fever / DHF** refers to Dengue Fever / Dengue Haemorrhagic Fever.
****Timely** refers to returns received on or before 06th August , 2010 Total number of reporting units =311. Number of reporting units data provided for the current week: 255
A = Cases reported during the current week. **B** = Cumulative cases for the year.

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Comments and contributions for publication in the WER Sri Lanka are welcome. However, the editor reserves the right to accept or reject items for publication. All correspondence should be mailed to The Editor, WER Sri Lanka, Epidemiological Unit, P.O. Box 1567, Colombo or sent by E-mail to **chepid@sltnet.lk.**

ON STATE SERVICE

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