



USAID FIRMS PROJECT

Transition to A-D Syringes Initial Assessment

February 2010

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Data Page

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Abstract

A rapid assessment was conducted to evaluate the capacity of the Pakistani syringe market and manufacturer and the ability to transition from production of disposable syringes to auto-disable syringes. To determine the benefits and most efficient course of meeting the public need for and transitioning to auto-disable (AD) syringes, the assessment team weighed the financial and logistical costs against the ability of the Government of Pakistan to enforce the use of auto-disable syringes vs. disposable syringes. The four major areas of focus in this assessment are (1) capacity of the syringe market and auto-disable syringe manufacturers; (2) the capital, start-up and production costs related to the manufacturing of auto-disable syringes; (3) safe disposal methods and practices of used injection equipment and re-use of medical waste; and (4) regulation of the syringe industry. This assessment emphasizes the importance of awareness and advocating safety and building capacity at the national level.

Acronyms

A-D	Auto-Disable Syringe
AEFI	Adverse Events Following Immunization
DDG	Deputy Director General
EPI	Expanded Program on Immunization (WHO)
GAVI	Global Alliance for Vaccines and Immunization
GMP	Good Manufacturing Practices
GOP	Government of Pakistan
HepB	Hepatitis B
HepC	Hepatitis C
HIV	Human Immunodeficiency Virus
MoH	Ministry of Health
PIMS	Pakistan Institute of Medical Sciences
QA	Quality Assurance
QC	Quality Control
SIGN	Safe Injection Global Network
SRO	Statutory Rules Order
UNICEF	United Nations Children's Fund
V&B	Department of Vaccines and Biologicals
WHO	World Health Organization

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Executive Summary

Pakistan's Ministry of Health requested USAID support in transitioning local syringe producers to the manufacture of auto-disable (A-D) syringes. USAID requested the Firms Project to conduct a rapid assessment of local industry and government oversight with respect to the production of A-D syringes and disposal of syringes. The assessment was predominantly based on review of available data, reports, interviews and observations in the interest of time.

Growing concerns over the spread of disease through unsafe injections prompted UNICEF, WHO, and UNFPA to introduce the auto-disable (A-D) syringe for immunization worldwide. The A-D syringe is designed to be automatically locked or otherwise self-disable after a single use. This significantly reduces the chance of syringe re-use and the infections associated with re-use. There are 16 syringe manufacturers in Pakistan, of which only three are licensed and registered. One manufacturer makes the A-D syringe (two versions), and has a capacity of 300 million per annum. By contrast, Pakistan's 189 million citizens demand approximately 850 million injections annually (4.5 injections/person/annum, the second highest rate in the world).

Capital and other costs related to transitioning existing manufacturers to produce only A-D syringes are enormous. The Ministry of Health estimated the costs to be about \$800,000 per factory, but figures from the sole producer suggests that costs may be closer to \$4 million. Many existing factories may have to be torn down and rebuilt, further raising costs. In addition, A-D syringes costs end users dearly - Rs 10-12 versus Rs 5-6 for currently available disposable syringes. This raises the specter of a substantial, long-term subsidy, and the development of a black market in non-A-D syringes should the government require the sole use of A-D syringes. Only two other nations, Nigeria and Uganda, have legislated the sole use of A-D syringes, and the preliminary results of these changes are not encouraging for reasons cited above.

Management of increased medical waste associated with A-D syringes is also a challenge. Few standard practices or policies exist in Pakistan for the safe disposal of used syringes. Laws exist but methods of disposal are not specified and enforcement is lax. The waste volume of A-D syringes is expected to be 200 times greater than that of syringes that can be sterilized. Improperly disposed A-D syringes could increase the already critical levels of blood-borne infections (84% Hep B, 62% Hep C, 3% HIV) and environmental pollution at the community level.

The prospect of 15 existing syringe producers converting to A-D only manufacturing at a total cost near or exceeding \$60 million, combined with expected long-term subsidies, a possible black market in non-A-D syringes, and Pakistan's poor record on waste disposal enforcement suggests that there might be more cost effective and life-preserving alternative uses of such funds in the following activities that would facilitate the conversion:

- Conduct a comprehensive injection safety assessment to ascertain all the facts surrounding the spread of disease through syringe re-use
- Develop and advocate widespread awareness in the healthcare industry, healthcare providers, practitioners, the government and the general population of the risks associated with re-use and improper disposal of syringes
- Support international best practice policies, regulations, and standards for the proper use and disposal of syringes of all types
- Encourage rigorous enforcement of such policies, regulations, standards
- Conduct pre-feasibility study to include determination of the full cost, financial, health, social, and environmental of a legislated transition to the sole use of A-D syringes

1. Findings

In December 2008, WHO conducted a Rapid Interim Evaluation of the National Hepatitis Program, launched in 2005 and recommended, “The use of Auto-Disable (A-D) syringes and the progressive phasing out of standard single use syringes to allow Pakistani syringe manufacturers to start producing locally these devices. The use of A-D syringes should become mandatory in 2-3 years.”

The A-D syringe has a built-in mechanism designed to give a single dose injection. Once used it is permanently locked or disabled and cannot be re-used, eliminating re-packaging and re-sale, hence eliminating the risk of transmission of blood-borne viruses and infections (such as Hepatitis B, Hepatitis C or HIV). The A-D syringe was introduced in Pakistan in February 2001, for use in the EPI immunization campaigns.

Pakistan uses 4.5 injections per capita per year, the second highest in the world. The HIV epidemic is driven by injecting drug use (IDU) due to sharing of contaminated syringes and needles. There are approximately 125,000 injection drug users (IDUs), with a capacity for 136 million syringes per annum. All new cases of Hep B, Hep C and HIV are attributed to unsafe injecting practices, according to World Health Organization. There is also wide spread use of non-sterilized injecting equipment in medical settings and a lack of proper and safe disposal methods of waste.

Pakistan’s market capacity for syringes is approximately 1.2 billion per annum. The existing manufacturers have a capacity to produce approximately 600 million per annum. There are 16 disposable syringe manufacturers (Annex 1: Table), only 3 are Registered and Licensed (Amson Pharma, Becton Dickinson and Silver Surgical). The remaining 13 manufacturers are not in compliance with the Good Manufacturing Practices (GMP) requirements. The number of “free” UN distributed syringes to the Government of Pakistan (GOP) is approximately more than 1 million per annum, supplied through the Global Alliance for Vaccines and Immunization (GAVI) initiative.

Amson Pharma is the only manufacturer of the A-D syringe, with a capacity to produce 300 million per annum (1 million per day). Amson manufactures two WHO prequalified A-D syringe devices (models), i.e. the Apple K1 (Star Syringes, UK) available in 0.05 ml, 0.2 ml and 0.5 ml and the Destroject (Germany) available in 0.5 ml. Destroject is the first infant immunization syringe manufactured locally, it is the most popular syringe device worldwide and is supplied in all UNICEF programs. The locally manufactured A-D syringes are only available for EPI immunization campaigns, and in private and government hospitals.

The K1, is an auto-disable syringe mechanism approved by UNICEF, WHO and ISO that prevents re-use. A small ring etched on the inside of the barrel allows the specially adapted plunger to move in one direction and not the other. After one complete

injection, the plunger automatically locks in place and will break if forced, rendering the syringe useless.

The DestroJect Syringe is a so-called autodestruct syringe. It is designed to provide maximum safety for children receiving immunization shots, while maintaining the ease of use for the health care workers. Whereas a normal syringe consists of a plunger and a cylinder, the DestroJect syringe has a small plastic ratchet that prevents the syringe from being filled more than once. The plunger breaks if an attempt is made to withdraw the plunger a second time by force. The three major benefits of the DestroJect syringe are as follows:

- Highest level of auto destruction (very difficult to tamper with)
- Ease of use – no special instructions necessary
- Environmental friendly – no toxic fumes by incineration, and no metal parts that cannot be incinerated - only the needle remains

Amson pulled its syringes off the market after it discovered that the syringes were being damaged due to improper handling and use by healthcare workers and practitioners, causing excessive waste. Even though the syringes are user friendly, Amson found that the end-user needed training in the proper handling and techniques of using the device. The syringes will be available through Amson’s Distributors once the client has received the necessary training.

There are more than 85 World Health Organization prequalified, A-D syringe devices manufactured worldwide. Amson chose the Apple K1 and Destroject devices for several reasons. The moulds required to manufacture the two devices are simpler and less expensive. Most importantly, Apple K1 and Destroject were the only manufacturers that sold their Patent and Branding rights for manufacturing of their devices in Pakistan. In order to receive the Patents and Branding rights, Amson had to build their manufacturing plant with strict compliance and requirements of the GMP to produce the A-D syringe.

Estimated capital, start-up and production costs (US\$) related to “converting” a disposable syringe manufacturing plant to an A-D syringe manufacturing plant with the capacity to produce 300 million syringes per annum are as follows:

Table 1: Estimated capital, start-up and production costs (US\$) related to “converting” a disposable syringe manufacturing plant to an A-D syringe manufacturing plant with the capacity to produce 300 million syringes per annum			
Moulds ¹		\$450,000	
Screen Printing Machine		\$30,000	
Assembly Machine		\$200,000	
	<i>Total</i>	<i>\$680,000</i>	<i>\$2,040,000</i>

¹ A set of moulds including plunger, barrel and gasket are required. A separate mould for 1cc, 3cc and 5cc.

Table 1: Estimated capital, start-up and production costs (US\$) related to “converting” a disposable syringe manufacturing plant to an A-D syringe manufacturing plant with the capacity to produce 300 million syringes per annum			
Loading Robotic Machine	\$50,000		
Blister Machine		\$150,000	
Double Door Sterilizer		\$159,000	
	<i>Total³</i>	<i>\$359,000</i>	<i>\$1,077,000</i>
QC and QA Lab, Microbiology Lab		\$100,000	
HVAC System ⁴		\$100,000	
Injecting Molding Machine		\$45,000	
	<i>Total</i>	<i>\$245,000</i>	<i>\$245,000</i>
Generator (1,300 kva)	<i>Total</i>	<i>\$234,000</i>	<i>\$234,000</i>
	Total		\$3,596,000

The above estimates do not include the costs related to the staffing requirements (130 staff needed to operate the plant), technical training and the technical expertise (HVAC system/design/layout) required to construct, operate and maintain the plant. The approximate fuel consumption for running the generators is 120 liters/hour.

It is not possible or feasible to “convert” the existing manufacturing plants for several reasons. The technical training requirements for the staff, technical/engineering skills needed for construction of an A-D syringe plant and manufacturing equipment are not available locally.

According to Amson Pharma, syringe manufacturers in Pakistan would have to tear down their existing plants and re-construct to comply with Patent and Branding laws and to obtain the Registration and Licenses for the production of A-D syringes and in order to meet the GMP area requirements of an A-D syringe manufacturing plant (e.g. assembly area, molding area, sterilization area, washing drying and sealing area, lab and testing area, and storage area). The existing machines, moulds, technology, etc. for manufacturing disposable syringes cannot be “converted” to produce A-D syringes. The moulds alone, used to manufacture the disposable syringe, cannot be used to manufacture the A-D syringe due to the built-in auto disable mechanism.

² At least 3-5 sets required for one manufacturer.

³ At least 3 sets required for one manufacture

⁴ HVAC system includes 1. Chiller, 2. Air handling units, 3. Air ducting and piping, 4. HEPA box with filters

The cost of “converting” a plant is not the only issue. Proper disposal of syringes is even a bigger issue, in Pakistan. According to the World Health Organization, to prevent risk of infection, safe disposal of used needles and syringes is a critical component of any vaccination program. The most commonly used methods of syringe disposal in Pakistan are Cutter method and incineration. The burning and burial/encapsulation method, for disposal of syringes, is used only in the immunization campaigns (MoH, EPI program). Once A-D syringes are introduced for use in all injections in Pakistan, it is predictable that infections and environmental pollution will increase, even at the community level, due to the improper disposal of the huge numbers of used A-D syringes, which can be 200 times as many as sterilizable ones (Battersby et al, 1999).

The EPI program uses approximately 42 million A-D syringes per annum. Majority of the syringes used in the EPI program are imported, with Becton Dickinson being the main supplier. The used syringes are collected in sharp containers from outreach centers and fixed sites. The disposal method used is pit burning/encapsulation and incinerators in major cities.

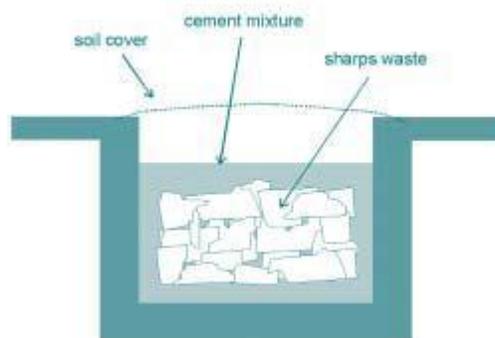


Figure 1: Cement encapsulation (WHO/V&B/02.26. 2002)

The cement encapsulation method involves: (1) digging a trench large enough to hold the accumulated waste; (2) adding a cement mixture to line the bottom of the trench and allowing it to set; (3) carefully placing the waste inside the trench; (4) encasing the waste completely with the cement mixture; (5) after the cement has hardened, it should be covered with approximately 15 cm of soil.

Although the latest World Health Organization guideline provides several options for disposal of A-D syringes (WHO, 2002), they are unrealistic for developing countries, especially in rural areas. For example, uncollected safety boxes, filled with blood stained used A-D syringes, will pile up at district hospitals and health centers, because it is difficult to collect the boxes as instructed by the WHO (2002).

Challenges of using incinerators as a means of disposal, in Pakistan, are the costs related to running and maintaining them. There are approximately 48 incinerators in the Pakistan, manufactured in Karachi, by Strongman. The incinerators were provided by the MoH, for the Hepatitis Control Program, only 25 are functioning due to the shortage of gas and electricity. Newly made incinerators, at provincial level, may be broken within a few years because of the increased volume of syringes and other items incorrectly put into the incinerators.

According to the Deputy Director General, QA (Drugs), MoH and Amson Pharma, there are no standard practices or policies in place for the safe disposal of waste. Disposal laws exist, but the method is not specified. There is no monitoring or supervision of hazardous waste handling and management.

The MoH initially included syringes in the category of “Drugs” in 1994 through implementing Statutory Rules Order (SRO) 324(I)/94, dated 19-04-94 directing all manufacturers and importers to have their products registered with the MoH by 15-07-94. This directive was extended several times due to successful lobbying by several of the manufacturers who obtained a Restraining Order from the Lahore High Court against the Ordinance. According to Amson Pharma, the manufacturers were successful due to their association/influence on officials in the MoH and extended the deadline for registration twice for their own vested interest and patronage to the unregulated syringe industry. The Restraining Order was vacated in November 2006 and the decision of the MoH regarding regulation was upheld. Subsequently, a new deadline of 31 December 2007 was given and once again extended. Finally, SRO 866(I)/2009, dated 7 October 2009, was imposed banning all import, export, manufacture, distribution, storage and sale of unregistered disposable syringes. Only 3 syringe manufactures have complied with the Order. The remaining unregistered manufactures continue to manufacture and sell their products.

The parameters used for issuance of Registration and License for the manufacturers are simple. For registration, the manufacturer must submit an application for registration based on compliance with GMP. The application is evaluated by the Registration Board, once a unanimous decision is reached by all members, approval for registration is granted. The Registration Fee is Rs. 8,000 (approximately U.S. \$93), per product. For issuance of a license, a panel of experts conducts a site visit. An inspection of the layout plan, area requirements, equipment and building with GMP compliance are conducted. The case is then submitted to the Central Licensing Board. Once all criteria are approved and met, a final approval is granted for issuance of the License. The e-License Fee is Rs. 35,000 (approximately U.S. \$407).

The oversight and ability of the GOP to take concrete steps to encourage and enforce the manufacturing and use of A-D syringes is not apparent. Furthermore, there is no mechanism in place to monitor proper usage of syringes or the disposal of waste. This could be managed through mapping of districts, conducting trials/pilot programs for A-D syringes, conducting spot checks to determine how many needles are sold/used and

how many are properly disposed of. In addition, the MoH must regulate and inspect private and government hospitals.

There are several indicators that could be regularly monitored and periodically assessed to combat the safe use and disposal of syringes* (WHO/V&B/02.26. 2002).

- Safe Injection Practices at a proportion of health facilities in which, during the supervisory visit, immunizations are observed to be administered in a safe and correct manner.
- Adequacy of syringe and needle supplies at health facility level where a proportion of facilities (Districts) are supplied with an adequate (i.e. equal or more) number of A-D syringes for all injections during the year (on a quarterly or other specified period).
- Disposal of used injection equipment at a proportion of health facilities with adequate stock of safety boxes; availability of appropriate waste disposal options; absence of used syringes and needles at the facility, in rubbish areas close to the health center or present in municipal waste dumps where public access is not controlled.

In conclusion, converting existing syringe manufacturing plants to A-D syringe manufacturing plants is only a quick fix and not the solution to combating the spread of blood-borne diseases in Pakistan. The biggest gap and first steps that must be taken to manage the epidemic is an investment in promoting the safe use of injections. This requires a behavior change strategy, which must involve consumers as well as public, private and traditional health workers. Awareness campaigns and advocacy strategies for injection safety must be developed to target not only managers of immunization services, but also government decision-makers and managers, health workers, and the general population.

2. Recommendations

Actions required to achieve the successful transition of A-D syringes and ensure injection safety include:

- Conduct a comprehensive injection safety assessment
- Develop injection safety policies, strategies and annual work plans
- Establish a reliable estimate of equipment requirements, minimum stock levels and effective supply and distribution systems for injection equipment
- Plan the safe disposal of used injection equipment through the progressive introduction of appropriate waste management options
- Provide training for health workers, practitioners and general public on safe injection practices
- Create and implement disposal procedures
- Institute monitoring and supervision procedures to ensure correct practices by health workers
- Provide adequate supplies and disposal facilities at all levels
- Secure required financial resources for all the components of the injection safety plan, including safe disposal of used equipment
- Subsidize the cost of A-D syringes so it is more affordable to the end user
- Provide incentives/subsidies to the manufacturers

3. Annexes

3.1 List of Manufacturers of Syringes (Pakistan) – Provided by MoH

No.	Name and Address	Registered/Licensed
1	Armoz Pvt. Limited 74/6, Tariq Road, Lahore Cantt	No
2	Amson Vaccines & Pharma (Pvt.) Ltd. 113, Industrial Triangle, Kahutta Road, Islamabad	Yes
3	Becton Dickinson Pakistan Ltd. 19-D/1, Gulberg III, Lahore	Yes
4	Crespak Medical Industries S-60, R-57A, Muntaqi Mansion Beside Jalal Center, Mozang, Lahore	No
5	Frontier Pharmaceutical W-10, Industrial Estate, Jamrud Road, Peshawar	No
6	Injection Systems Pvt. Ltd. 271, Industrial Estate, Gadoon Amazai	No
7	Japanz International 6-Kim Gujranwala- Sheikhupura Road, Sheikhupura	No
8	Lahore Medical Instruments 65, Sayed Maratab Ali Road F.G. College, Gulberg IV, Lahore	No
9	Medicare Industries 45, Rasool Park Shamin Road, Lahore	No
10	Ravi Medical Industries 59-T, Gulberg SI, Lahore	No
11	SAB Polymer Industries Pvt. Ltd.	No

No.	Name and Address	Registered/Licensed
	2-Main Gulberg, Lahore	
12	Silver Surgical Complex Plot 40 I, Industrial Estate Super Highway, Karachi	Yes
13	Surgitax Industries	No
14	Surgi Plast Industries Plot 78-I, Industrial Estate Super Highway, Karachi	No
15	TAJ Syringes Pvt. Ltd. Plot 303-A, Industrial Estate, Gadoon Amazai	No
16	Zafar International Korangai Industrial Estate, Karachi	No

3.2 RO 866(I)/2009

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PART II

Statutory Notifications (S. R. O.)

GOVERNMENT OF PAKISTAN

MINISTRY OF HEALTH

NOTIFICATION

Islamabad, the 7th October, 2009

S. R. O. 866(I)/2009.—In exercise of the powers conferred by sub-section (6) of the section 7 of the Drugs Act, 1976 (XXXI of 1976), the Federal Government is pleased to fix the 10th October 2009, to be the date after which the import, export, manufacture, distribution, storage and sale of unregistered disposable syringes shall not be allowed.

[No.F-6-6/2009-(QC-11).]

RAUF KHALID,
Drugs Controller (QA)

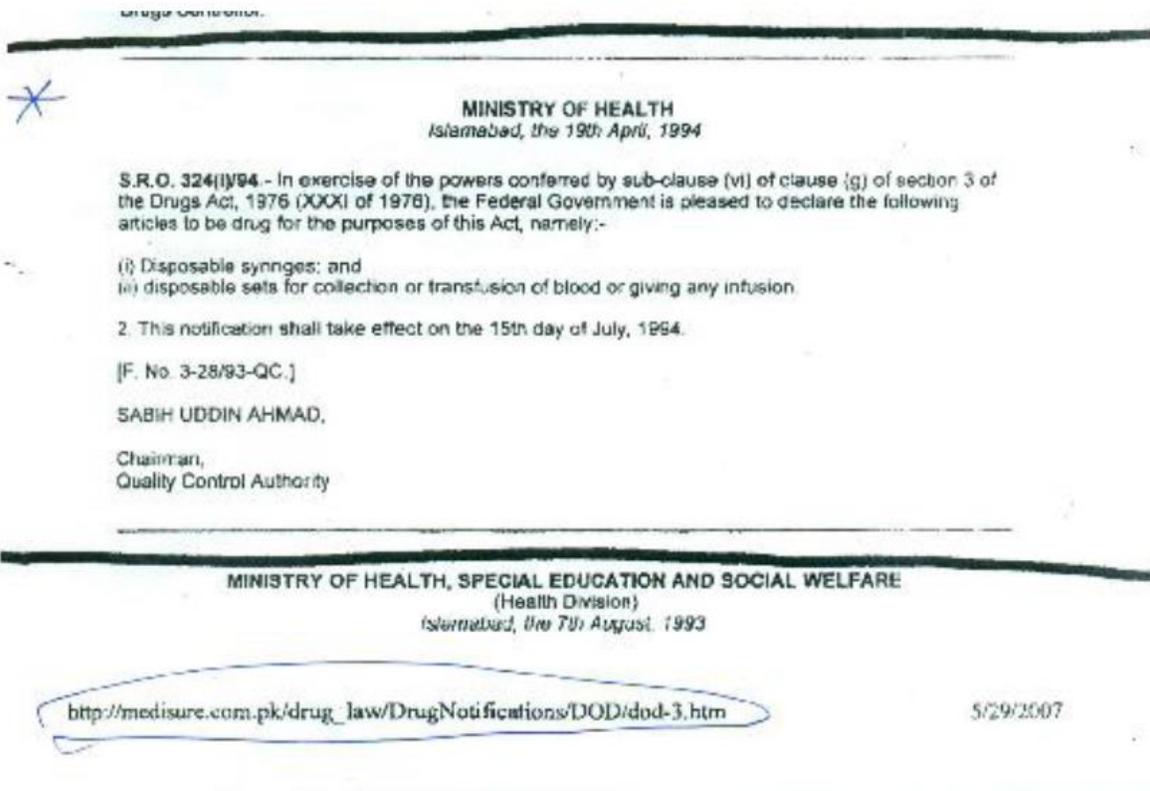
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[948(2009)/EX. Gaz.]

Price : Rs. 2.00

3.3 SRO 324(I)/94



3.4 No. F 3-2/2008-Reg-II(s) (M-213)



NO. F-3-2/2008-Reg-II(s) (M-213)
Government of Pakistan
(Ministry of Health)

Islamabad, the 10th October, 2008

All Manufacturers & Importers of
Disposal syringes and sets.

SUBJECT - REGULATORY STATUS OF DISPOSABLE SYRINGES AND SETS
(INFUSION AND BLOOD COLLECTION / TRANSEUSION).

I am directed to refer captioned subject. Ministry of Health, Government of Pakistan has declared disposable syringes and sets as DRUG vide S.R.O 324(I)/94 dated 19-04-1994 as per Provision of Drugs Act, 1976 and Rules framed there under.

2. Honourable High Court, Lahore in its decision on writ petition No.846/2006 dated 30-11-2006 has also maintained the view point of Ministry of Health.
3. Accordingly Registration Board has started process for granting registrations of disposal syringes and sets both in local manufacturing and import.
4. Keeping in view public interest and to avoid shortage of these items, the Registration Board in its 213rd meeting held on 15th & 16th August, 2008 has decided to fix a cut off date of 31-03-2009 for grant of registration to already available disposable syringes and sets.
5. All manufacturers and importers of disposable syringes and sets are informed to get registration of these items by 31-03-2009.

Yours truly,

(Obaidullah)
Deputy Drug Controller
(Reg-II)(s)

Copy to:-

1. Secretary, PPMA, Karachi (for circulation and compliance among members)
2. Executive Director, Pharma Bureau, Karachi (for circulation and compliance among members)
3. President, Sarhad Pharmaceuticals Manufacturers Association, Peshawar (for circulation and compliance among members)
4. President, Pakistan Chemist & Druggist Association, Karachi (for circulation and compliance among members)
5. P.S to Secretary (Health)
6. Master file.

3.6 No. F 6-22/2008-Reg-II(s)



NO. F 6-22/2008-Reg-II(s)
Government of Pakistan
(Ministry of Health)

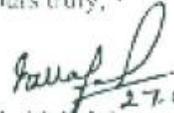
Islamabad, the 27th March, 2009

**All Manufacturers & Importers of
Disposal syringes and sets.**

**SUBJECT:- REGULATORY STATUS OF DISPOSABLE SYRINGES AND SETS
(INFUSION AND BLOOD COLLECTION / TRANSFUSION).**

I am directed to refer to this Ministry's letter No.F.3-3/2008-Reg.II(s) (M-213) dated 10th October, 2008 on the subject noted above. All manufacturers and importers of disposable syringes and sets are hereby informed that cut off date for registration of these items has been extended upto 30-09-2009 for completion of registration process.

Yours truly,


(Obaidullah) 27.03.09
Deputy Drug Controller
(Reg-II)(s)

Copy to:-

1. Secretary, PPMA, Karachi (for circulation and compliance among members)
2. Executive Director, Pharma Bureau, Karachi (for circulation and compliance among members)
3. President, Sarhad Pharmaceuticals Manufacturers Association, Peshawar (for circulation and compliance among members)
4. President, Pakistan Chemist & Druggist Association, Karachi (for circulation and compliance among members)
5. P.S to Secretary (Health)
6. Master file.

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