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# Central Drug Standard Control Organization

## Directorate General of Health Services

### Office of Drugs Controller General (India)

(Biological Division)

DATE: 08 JUL 2013

**NOTICE**

**Revision of CDSCO Guidance for Industry for Biological Products for applications under Post approval changes PAC/1108 ver 1.1.**

This is in reference to the implementation of Guidance for Industry posted on CDSCO website for evaluation of various applications of post approval changes/variations for Biological Products, PAC/1108 ver. 1.1.

In order to strengthen the processing of applications under post approval changes and update the Quality information of already licensed products in better systemic manner, it has been decided to revise the CDSCO Guidance for Industry for Post approval changes of Biological Drug Products, PAC/1108 ver. 1.1.

Therefore it has been decided to constitute a committee for revision of CDSCO Guidance for industry for Post approval changes of Biological Drug Products, PAC/1108 ver.1.1.The composition of the committee is as follows:-

1. Sh. S.P. Shani, DDC (I) -Chairman
2. Mrs. Rubina Bose -Member
3. Mrs. Swati Srivastava, ADC (I) -Member
4. Sh. I.S. Hura, ADC (I) -Member
5. Sh. Vinod Kumar, DI -Convener

Hence all manufacturers/importers of biological drug products are invited to give their inputs and suggestions for revision of CDSCO Guidance for Industry for Post approval changes, PAC/1108 ver1.1.

Suggestions or other inputs may be send to the committee for revision of Guidelines on post approval changes for Biological Drug Products within 30 days of issuance of this notice.

**(Dr. G.N. Singh)**

**Drugs Controller General (I)**

**To**

**All Manufacturers/Importers of Biological Drug Products including vaccine.**