RIGHT TO INFORMATION

दूरभाष 23013187

**BY REGD POST**

भारत सरकार/ रक्षा मंत्रालय
गुणता आश्वासन महानिदेशालय
जन सूचना कक्ष, कमरा न. 139, जी ब्लाक
निर्माण भवन पी.ओ., नई दिल्ली-110 011

C/87570/3571/DGQA/PICell

29 Feb 2016

Shri Prashant Reddy T
C/o Lex One Partners
E-19, LGF, Jangpura Extension
New Delhi – 110 014

**INFORMATION SOUGHT UNDER RTI ACT 2005 :**
**SHRI PRASHANT REDDY T**

1. Reference your application dated 27 Jan 2016 received through Min of Def vide their ID No 13(2)/2014/D(Coord)/DDP) dated 02 Feb 2016 and your letter dated 24 Feb 2016.

2. Information sought by you vide your application under reference as furnished by DGQA(Store) vide their note No B/89282/RTI/DGQA/Store-1 dated 16 Feb 2016 is enclosed herewith.

3. However, in case you are not satisfied with information, you are at liberty to appeal within 30 days from the receipt of this letter to the Appellate Authority at the following address: -

DDG (Adm & HR)
Room No 25, 'G' Block
Ministry of Defence
Dte Gen of Quality Assurance
Nirman Bhawan PO, New Delhi –110 011

4. In the light of the above, your RTI application is hereby disposed off.

(चन्द्र शेखर)
निदेशक
केन्द्रिय जन सूचना अधिकारी

**Encl**:- 07 Pages

Tele: 23015424

B/89282/ RTI/DGQA/Store-1

16 Feb 2016

MINISTRY OF DEFENCE

रक्षा मंत्रालय

DGQA/STORE-1

गु.आ.म.नि. / भण्डार -1

**RIGHT TO INFORMATION –REQUISITION FORWARDING OF: SHRI PRASHANT T. ADVOCATE**

1. Reference DGQA/PI Cell note No 87570/3571/DGQA/PI Cell dated 11 Feb 2016.

2. The information sought by Shri Prashant T. Advocate is as under: -

(a) **Query No 1**:- DGQA does not frame policy regarding Quality Assurance Drugs and Punitive action since 13 Nov 2015.

(b) **Query No 2**:- Policy letter enclosed.

(c) **Query No 3**:- Policy letter enclosed.

Encls: - 06 Pages

(Sudeep Sinha)
Lt Col
Joint Director/S-1

**DGQA/PI Cell**

फैक्स: /FAX 011-23011368
ई-मेल /e-mail : dqas_dgqa@bol.net.in
वेब साईट: /Web Site: dgqadefence.gov.in

(24) (2A)

केस सं0/No B/89619/Policy/DGQA(S-9) 07 Sep 2007

रक्षा मंत्रालय
MINISTRY OF DEFENCE
गु0 आ0 म0 नि0/ निदेशालय गुणता आश्वासन (भण्डार)
DGQA/ Directorate of Quality Assurance(Stores)

**POLICY REGARDING QUALITY ASSURANCE OF DRUGS AND PUNITIVE ACTION**

1. Reference your letter No 5567/Rep cell/104/DGAFMS/DG-2E dated 21 Aug 2007.

2. Our comments forwarded earlier were based on DQA(S) policy letter No B/89619/Policy/DGQA(S-9) dated 13 Dec 2004, formulated by this HQ, subsequent to meeting held in office of DGAFMS. It may be seen that only broad policy guidelines were laid down in the aforementioned policy letter and it was silent on the nature of action to be taken for various permutations and combination of major and minor defects in respect of firm during a calendar year. Hence, as such no contradiction/variation can be made out in clarification given by our office earlier.

3. The punitive action policy as enunciated vide our letter mentioned above is tabulated as per Appendix A for the sake of clarity.

4. In case any further clarification is required/ or if punitive action policy is to be amended for other parameters for major and minor defects, a meeting may be called for the purpose.

(Dr.A J S ARORA)
JAG(NFSG)
Addl DQA(S)
For DQA(S)

DGAFMS/DG-2E
Copy to :-

CQA(M), Kanpur : w.r.t your letter No Y-35/CQA(M)/TC Dated 22 Aug 2007

## MINOR DEFECT

| Sl. No. | Situation in respect of Rejections | Punitive action on firm | Period of ban |
|---|---|---|---|
| 1. | More than one rejection of same batch in a calendar year (of same item) | To be treated as one rejection | No action |
| 2. | Three rejections in a calendar year ( different batches of an item) | Item to be banned | for one year from the date of last rejection |
| 3. | More than three rejections of different items of a given dosage form ( tablet, capsule, injection etc) in a calendar year<br><br>or<br><br>Three rejections every year consecutively for three years of a given dosage form (tablet, capsule, injection etc) | The dosage form be banned | for three years from the date of last rejection |
| 4. | More than 3 rejection of different item in different dosage forms in a year | No punitive action Laid down | Each dosage form may be dealt separately |

## MAJOR DEFECT

| Sl. No. | Situation in respect of Rejection | Punitive action on firm | Period of ban |
|---|---|---|---|
| 1 | One rejection (or more rejections of the same batch) during the calendar year | Item to be banned@ | For one year from the date of last rejection@ |

| | | | |
|---|---|---|---|
| 2 | Rejection of other batches of product already banned during the calendar year | Ban will be extended | For one ye from the date of la rejection |
| 3 | Rejection of two products of the same dosage form (tablet, capsule, injection etc) during the calendar year | All products of the dosage form to be banned | For one year from the date of last rejection. Reintroduction subject to re-verification/ revalidation of quality by AHSP |
| 4 | Rejection of two products in different dosage forms (tablet, capsule, injection etc) during the calendar year | Concerned items will be banned | For one year from the date of last rejection. Reintroduction subject to re-verification/ revalidation of quality by AHSI |
| 5 | Rejection of more than two products (Products of same or different dosage forms (tablet, capsule, injection etc) during the calendar year | Firm to be banned | For three years from the date o last rejection |

(* "Period in vogue" to be continued.

Tele : 23013312

Govt of India
Ministry of Defence
Deptt of Defene Production
Dte of Quality Assurance(S)
DHQ PO New Delhi-110 011

191

B/89619/Policy/DGQA (S-9)

13 Dec 2004

To,

The Controller
CQA(M)
Kanpur

## POLICY REGARDING QUALITY ASSURANCE OF DRUGS AND PUNITIVE ACTION

1. A meeting was held in the office of DGAFMS on 10 Nov 2004 in the office of DGAFMS. A copy of the minutes of the meeting is enclosed for record. The following was decided for implementation.

(a) It has been decided that the defect observed during testing may be categorized in (two) categories, viz Major Defect & Minor Defect.

**Major Defect**

(a) Toxic reaction in patients after use

(b) Variation (in quantity/potency) of the active ingredient

(c) Pharmacological/chemical composition not as per specification

(d) Contamination by any undesirable chemical/biological/microbia substances

(e) Defects of clarity in drops & injectables

(f) Discoloration/separation in drops/ointments

(g) Suspended particles noticed with naked eyes in injectables

**Minor Defect**

(a) Soft/broken tablets

(b) Coating defect

c) Discoloration of tablets

d) Leakage through pinholes

The list is not exhaustive and can be further modified based on inputs from the users. However, it was unanimously decided that any defects in injection or IV fluids, will be considered as major defects

(2) It has now been decided that in case of CERs, the punitive action will be initiated depending on the nature of defects observed as given below: -

(i) **For Major Defect observed:**

The procedure in vogue may be continued. However, In case of rejection up to two items. The ban will be effective for 1 calendar year from the date of last rejection and reintroduction after 1 year will be subject to reverification /revalidation of quality by AHSP. In case of more than 2 products are rejected due to major defects in one year, the firm may be banned for 3 years.

(ii) **For Minor Defect observed:**

In case of minor defects observed in 3 items/deliveries in one calendar year, the particular items rejected will be banned for 1 year from the date of last rejection.

In case of rejection of more than 3 items in a calendar year or up to three times every year consecutively, for three years the firm will be banned for all the items for 3 years from the date of last rejection

2. **Registration of Drugs item**

(a) A documented Q.R. norms in addition to the existing Joint Service Guide on registration of Defence Vendor is being followed for registration of Medical firms at present. This may be updated to make it more transparent an cater for recent changes /modifications

(b) It has also been decided that minimum annual Turn Over Clause of Rs. 5 crores in vogue need no be adhered to very rigidly so long firms meets the other existing norms of registration and for special items wherein the total out put of the supplier is less than Rs. 5 crores.

(c) Shelf life of the drug items applied for the registration by vendors are decided generally in accordance to the life specified in the PVMS list. At times , it has been observed that firm apply for registration of drugs item whose life is at variance with that specified in PVMS list. It has now been decided that in such cases flexibility on shelf life will be decided by AHSP in consultation with DGAFMS and PVMS list will be maintained accordingly.

3. **Testing of Drugs**

(a) AHSP will prepare a list of items for which complete test facilities are available and forward the same to DGAFMS for record.

(b) The items for which complete test facilities are not available with AHSP/Regional Lab. The testing will be carried out at NABL accredited lab for the parameters which could not be tested at AHSP/Regional Lab and the testing changes will be borne by supplying firm.

4. The above decisions may be implemented with immediate effect.

**(G L.Chopra)**
Joint Director (S)
For DQA (S)

Copy to :

DGAFMS/DG-2C