The Association has submitted the following representation to Shri Dedashish Panda, Joint Secretary to the Government of India, Ministry of Health & Family Welfare, 20th March 2009.

In the recent controversy on Marketing Approval, the entry "Patent Status" in Form No. 44 came up for discussion rather prominently. In fact, the original idea behind putting this entry in Form No. 44 (introduced in year 2001) appears to be to keep the DCGI's office informed of all relevant information relating to that molecule. However, the recent events (like the Court cases) show that it has created an unnecessary and avoidable controversy with no benefit either to the Patient-Consumer public or to the Regulator in monitoring the molecule.

We feel that the Drug Regulator (DCGI's Office) is hardly in a position to make any use of the "Patent Status" information and that this entry (of 'Patent Status' in Form No. 44) itself is redundant for the following reasons –

1. Form No. 44 falls under Drugs & Cosmetic Rules 122A, 122B, 122E and 122DA. These Rules do not speak of "Patent Status" anywhere even once. The purpose of these rules is to ensure 'safety' of a "new product". Form No. 44 must conform to the design and plan of these Rules to ensure safety. The Patent status, however, is not connected with the safety aspect.

2. The Ministry of Health (DCGI office) is technically neither qualified to take any legal view relating to patent status during the Marketing Approval stage, nor is it required to consider that aspect under any law or regulation in India. For example, the DCGI's office is not qualified to take a decision on questions like **Whether** there are any changes in the patent status (revocation/invalidation); **Whether** the patent is frivolous before refusing registration to a generic producer; and **Whether** the patent can or cannot be upheld if it is legally challenged. If the DCGI's office does so then the DCGI's office **will be reduced to enforcing private commercial rights and will become in effect the "patent police".** Patent status can only be examined by Courts and that too, after an infringement is alleged to have taken place.

3. The Drug Regulator should not and cannot refuse permission on any application on ground of its patent status because that amounts to "Patent Linkage" which is not accepted in India.

4. ***Patent Linkage consideration is a barrier to the use of Bolar provision under Section 107 A***: An important public health safeguard in India's patent law is the Bolar provision that allows a generic producer to manufacture a patented drug and conduct all tests necessary for marketing approval in advance, so that a generic can be put on the market as soon as the patent expires. Marketing Approval is an administrative process, which enables a party to make legal and other preparations. These preparations have to be made in advance as allowed under Section 107A of the Indian Patents Act. No time limit has been specified under the Act (a conscious decision) for making the application because the duration would differ from product to product and the circumstances of each case.

5. ***The existence of such an entry (of patent status) presupposes a power to say 'no' to marketing approval on the basis of patent status***. The Law does not give any such power. Any unwillingness on the part of DCGI to issue Marketing Approval on that basis might make patents which might be otherwise 'invalid', as "good". That would prevent generic competition. In the case of *F. Hoffmann-La Roche Ltd. & Anr.* v. *Cipla Limited* [I.A 642/2008 IN CS (OS) 89/2008], Delhi High Court in its order dated 19 March 2008 held that the mere grant of a patent was no indication of its validity. The standards employed by the patent office in scrutinizing the patent application could have been wanting. This, the Court held, was to be determined only during the Revocation Proceedings. This responsibility, therefore, should not be assumed by the DCGI's office in the interest of public at large which depends on generic medicines.

6. ***Any consideration of Patent Status can become a barrier to the use of compulsory licenses (CL) -*** The patented drugs are prohibitively expensive and in the absence of generic competitors will remain out of reach of patients. A generic manufacturer company given authorization to produce a generic drug under compulsory license (i.e. without the patent holder's consent) will need to obtain marketing approval from the DCGI. If the DCGI refuses to register generics until the patent expires, the compulsory license is effectively made useless. As a result, generic

manufacturers will not be interested in seeking compulsory licenses to produce affordable versions of essential medicines. This will affect general public

7. *This is a **TRIPS Plus demand by MNCs***. There is no restriction under TRIPS for the Government to entertain Marketing Approval applications by public and issuance of Marketing Approval by the Government even during the life of any patent. Mere grant of Marketing Approval is not tantamount to production or marketing of the product. If patent linkage were to be accepted, the Drug Regulator would be seen as helping the MNCs on a matter not required by TRIPS.

8. A developing country, Philippines (A.O. No. 2005-0001) has specifically eliminated the need to verify whether or not the pharmaceutical product being submitted for registration is under patent protection.

9. ***WHO warns against linking of drug Regulatory and intellectual property systems**:* In March 2006, the WHO issued a briefing note on 'Access to Medicines' where it discussed the impact of TRIPS-plus provisions like patent linkages. The WHO states that patent linkages are problematic as drug regulators are likely not to possess the resources or manpower to check the patent status of medicines. Moreover they would lack the necessary expertise to assess whether a patent was valid or would be infringed and would thus be more likely to enforce all patents including invalid ones. The WHO thus cautions the developing countries that, "*Medicines fall under two separate legal and regulatory systems: the intellectual property system and the drug regulatory system. These systems have different objectives, are administered separately and function independently. Efforts to integrate these two systems via data exclusivity, **"linkage"** or other means are likely to have negative implications for access to medicines. Thus, (developing) countries would be well advised to keep these systems separate, and to reject any and all efforts to make connections between them*." (emphasis added)

10. ***How patent linkages can delay generic introduction: the example of Fluconazole in Africa*** - According to an MSF Report, an Indian generic manufacturer was stopped by the drug regulator in an African country where MSF works from registering its generic version of *fluconazole*, a drug used to treat opportunistic infections associated with HIV. According to MSF, *the grounds for this refusal were that the drug regulator had been informed by the originator drug company that it had a patent on the drug in the country. The drug regulator had no legal obligation to refuse registration on such grounds, but it had been pressured to do so by the drug company. Under further investigation, it was revealed that the originator company's claim was false and that the patent had expired more than a year earlier. The drug regulator eventually retracted its decision, and allowed the registration of the Indian company's low-cost generic version of the drug*."

    - 'Access to medicines at risk across the globe: What To Watch Out For In Free Trade Agreements with the United States', Access To Medicines Briefing Note, MSF Campaign for Access to Essential Medicines May 2004

11. The insistence of the MNCs to introduce Patent Linkage is a part of their IPR Enforcement Agenda and they are actively supported by their governments. The MNCs see the generic industry of the developing countries as a threat to their interests both domestically as well as in world trade. The MNCs want to prevent the growing influence of the generic industry by any means possible for their own selfish objectives. **The Government should see the wider implications of these moves on the affordability and access to medicines for general public.**

Request:

In view of these considerations, it is requested that the Government may consider removing this entry from Form No. 44 being "redundant" and "unnecessary".