DOI: 10.7860/JCDR/2017/24131.9337

Letter to Editor

Biotechnology Section

Regulation of Molecular Diagnostic (NAT) Kits For HBV, HCV and HIV in India

MANOJ KUMAR RAJPUT[1]

Dear Editor,

India with a population of 1.2 billion has emerged as a favourite market for diagnostic products. The Drugs and Cosmetics Act, 1940 was introduced to regulate the manufacture, distribution, sale and import of drugs in India. As per Drugs and Cosmetics Act 1940 & 1945, molecular diagnostic kits are kept in medical device category along with devices such as syringes & heart valve etc. Molecular diagnostic kits along with other diagnostic kits are further sub categorised as *In Vitro* Diagnostic (IVD) assays [1]. Central Drugs Standard Control Organisation (CDSCO) is the primary medical regulatory organization in India. The secondary medical regulatory organisations and central drugs testing laboratories such as National Institute of Biologicals (NIB), Central Drug Testing Labs (CDTLs), and Indian Pharmacopoeia Commission (IPC) also play pivotal role either by testing products or setting up standards for healthcare products. Since 2006, Ministry of Health and Family Welfare along with Department of Science and Technology is trying to restructure the regulation of medical devices in India. Presently, any medical device which is intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified by the Government of India by notification in the official gazette would be considered as a drug under the D & C Act and provisions of D & C Act and rules made therein would be applicable on such device. In 2002, the Ministry of Health and Family Welfare vide gazette notification no. GSR 601(E) notified in vitro diagnostic devices for HIV, HBV and HCV to be considered as drugs under Section 3, Clause (b), Sub clause (iv) of the Drugs and Cosmetic Act. CDSCO has setup Medical Device division to facilitate matters related to notified medical devices.

NIB and CDSCO play reciprocal role in quality regulation of diagnostics kits for HBV, HCV and HIV. Molecular Diagnostic Laboratory (MDL) at NIB has started quality evaluation of molecular diagnostic kits intended to be used for: (i) Diagnosis of HBV, HCV & HIV; (ii) Multiplex Blood donor screening kits for HBV, HCV & HIV; (iii) Viral load monitoring kits for HBV, HCV & HIV; and (iv) HCV genotyping kits. Most of these kits are imported in India and only few indigenous manufacturer are making some of these kits at a smaller scale. NIB has developed HBV, HCV and HIV panels for quality evaluation of these kits. These panels have been validated with respective WHO international standards. The panel members represent a dynamic range of viral load. The testing turnaround time is 30 days after receipt of complete kit at NIB. In year 2015, molecular diagnostic lab at NIB participated in HCV-NAT (HCV-Nucleic Acid Amplification Test) proficiency testing scheme organized by European Directorate for the Quality of Medicines (EDQM), France and scored 100% with excellent remark. NIB has also constituted a technical expert committee comprising experts from different parts of India, for recommendations on evaluation of molecular diagnostic kits. The qualitative kits are tested for their sensitivity, specificity and concordance while quantitative kits are tested for linearity in terms of regression coefficient.

According to data revealed by National AIDS Control Organization (NACO) in response to a Right to Information query in May 2016, in the last 17 months alone, 2,234 persons across India have been infected with HIV due to transfusion of HIV infected blood. The maximum number of such cases (361) have been reported from Uttar Pradesh. Gujarat ranks second with 292 cases, followed by Maharashtra with 276 and Delhi with 264 cases [2]. As per annual report (2015-16) of NACO, the prevalence of HIV is 0.26 % in India. It is 0.30% among males and 0.22% among females [3]. In India the prevalence of HBV is 3.7% with over 40 million HBV carriers, and it is considered moderate as per global prevalence. The population prevalence of HCV infection is 1% in India [4]. In comparison to developed countries the prevalence of these transfusion transmitted infections (TTIs) is high in India therefore, importance of NAT testing cannot be ignored at all. Qualitative NAT testing adds an additional layer of safety to the blood and quantitative NAT testing is essential for disease prognosis for HBV, HCV and HIV. Quantitative NAT testing helps in deciding type and dose of anti-viral therapy. Delhi, Odisha and few other states in India are taking steps to make molecular testing (NAT) mandatory for screening of blood units for TTIs before transfusion. Therefore, regulation of molecular diagnostic kits is of great importance.

CONFLICT OF INTEREST: None

REFERENCES

[1] Drugs & Cosmetic Act 1940 & 1945 and rules thereunder, Govt. of India.
[2] Vidya Krishnan. Bad blood: 2234 get HIV after transfusion. The Hindu May 31, 2016.
[3] National AIDS Control Organization, Annual report 2015-16, published on 27.07.2016.
[4] Srivastava A, Kumar S. Hepatitis in India: Burden, Strategies and Plans, Quarterly newsletter from National Centre for Disease Control, Delhi. 2014;3(1):1-3.

PARTICULARS OF CONTRIBUTORS:
1. Scientist Grade-III, Molecular Diagnostic Lab, National Institute of Biologicals, Noida, Uttar Pradesh, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Manoj Kumar Rajput,
A-32, Sector-62, Noida-201309, Uttar Pradesh, India.
E-mail: mkrajput@hotmail.com

FINANCIAL OR OTHER COMPETING INTERESTS: None.

Date of Submission: **Sep 22, 2016**
Date of Peer Review: **Oct 22, 2016**
Date of Acceptance: **Oct 25, 2016**
Date of Publishing: **Mar 01, 2017**