



ONLINE APPLICATION OF BLOOD CENTRE LICENCE AND RELATED DOCUMENTS - JOINING HANDS WITH TECHNOLOGY WHILE SURMOUNTING CHALLENGES

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ABSTRACT **Background:** Appropriate regulatory rules, policies and guidelines are crucial to ensure a well-regulated transfusion services across nation to facilitate easy access to blood and excise quality transfusion services. Blood centre licence services ought to be applied online via Online National Drugs Licensing System (ONDLs) portal. **Material and Methods:** This is an observational study carried from December 2024 to May 2025 in department of IHBT (Blood Centre) at Guru Gobind Singh Medical College and Hospital, Faridkot while applying for online mandatory blood centre licence on ONDLs portal. Online IDs were made for blood centre and whole staff. Difficulties faced has been discussed. **Results:** Series of drawbacks were encountered. Registered blood centres don't have a registered mobile SIM and hence, not permitting OTP facility. Old blood centre licence need to be handy to enter product specifications, area etc. Addition of technical member is possible only when all of their certificates till date are saved in their profile. Such documents are not handy all time and available in pdf form. Specific allotted technical member number available with the concerned person is required to add them. **Conclusion:** Regulatory authority is constantly thriving upon to bring out transparency in its services in order to ensure safety and quality of the medical product manufactured and distributed in country, it is crucial to review present status of regulatory blood centre licencing policy framework to scrutinize challenges in the process.

KEYWORDS : Blood Centre License, Latest Guidelines, Online Application, Uniformity In Application, Transfusion Service

INTRODUCTION

Blood transfusion services form an essential part of today's modern health care system allowing to execute various sophisticated medical and surgical procedures.¹ Stable and interminable supply of blood and blood components is crucial for smooth functioning of transfusion services. Since there is no substitute of human blood, it's availability is completely dependent on the population who choose to donate blood and blood components.^{2,3}

In India, the first ever blood bank was established at the All India Institute of Hygiene and Public Health, Kolkata in the year 1942 to cater the transfusion needs in view of World War II.⁴ Since then the transfusion services has been progressing through the coalescence of laboratory medicine, expertise, emerging knowledge and modernization.

Appropriate regulatory rules and regulations, policies and guidelines are crucial to ensure a well-regulated transfusion services across nation which would help to facilitate easy access to blood and blood components and to excise quality transfusion services. They play a central role in determining the structure of blood transfusion services (BTS) as well.

The regulatory system aims to build an efficient system for financial management and operational control of blood transfusion services, safe blood supply to the patients, establishing a streamlined system for blood, plasma, platelet or other blood components collection, establishing a quality network to ensure adequate quality and standards for blood transfusion services and development of proper documentation along with optimal standards for the care of donors and patients.⁵ Considering this crucial fact, the article focuses to review the present status of legal and regulatory blood centre licencing policy framework and scrutinizes various challenges and issues in the process. It also proposes the opportunities and ideas for improvement of BTS uniformly throughout the nation.⁷

The rules and regulations pertaining to blood transfusion services are incorporated under section 3 (b) of the Drugs and Cosmetics (D & C) Act, 1945 which are amended from time to time addressing various upcoming concerns. The act categorizes blood and blood components as

a "drug" because of it's internal administration. The Drugs & Cosmetics Act and Rules have entrusted various responsibilities to Central & State regulators for regulation of Drugs & Cosmetics. It envisages uniform implementation of the provisions of the Act & Rules made there under for ensuring the safety, rights and well-being of the patients by regulating the Drugs and Cosmetics. CDSCO along with State Regulatory Authorities is constantly thriving upon to bring out transparency, accountability and uniformity in its services in order to ensure safety, efficacy and quality of the medical product manufactured, imported and distributed in the country.

As per the latest guidelines, blood centre licencing and related services has to be applied online via Online National Drugs Licensing System (ONDLs) portal. The portal is developed by Centre for Development of Advanced Computing (CDAC) in association with Central Drugs Standard Control Organisation (CDSCO), Directorate General of Health Services (DGHS), Ministry of Health and Family Welfare (MoHFW), Government of India (GOI) and State/UT Drugs Regulatory Authorities. The portal aims to establish uniformity with respect to document submission related to blood centre licence services such as new blood centre licence request, seeking approval for various services, blood component manufacturing, post-approval changes in blood centre licence across the entire nation incorporating latest technology like e-governance for regulation by respective State/UT Drug Control Authorities (Food and Drug Administration).

METHODS

This is an observational study carried out from December 2024 to May 2025 in the department of IHBT (Blood Centre) at Guru Gobind Singh Medical College and Hospital, Faridkot while applying for online mandatory blood centre licence on ONDLs portal. To carry out the working of the blood centre, online application of the blood centre licence is essential. The whole process was carried out in a systemic way after scrutinizing various manuals and related literature. Online IDs were made for blood centre and whole staff. This turned out to be more cumbersome with each step taken ahead and the difficulties faced has been discussed.

RESULTS

For online application for blood centre services, various manuals and

related literatures was scrutinized online.^{8,9,10} The difficulties faced during the entire process for online application of blood centre license are hereby discussed in the article:

I. Registration and Login in Ondls: Blood Centre Firm Establishment

Various user manuals are available for how to operate the ONDLS portal. User manual starts with guiding about how to make the blood centre licence firm user ID using the registered contact phone number (mobile number required) and registered e-mail ID where one time password (OTP) is received for validation. First drawback sets in if the blood centre don't have a registered mobile SIM number as many of them use conventional landline telephone numbers which don't permit OTP receiving facility. After validation, blood centre firm details are saved with respect to the registered number and e-mail id.

II. Registration of the Blood Centre

In order to register the blood centre, old blood centre licence need to be handy with you. You need to enter the blood centre area, product details being prepared at the centre as per I.P., U.P. or In-house specification.

III. Documents Need to be Handy: Are You Carrying Them Daily!!

Addition of technical member is only possible when all of their qualification certificates, experience certificates and their relieving from past institute till date is saved in their profile. Issue lies that these all documents are not handy at a time such as a relieving certificate. You need to upload relieving and experience certificate for each employment previously engaged in. Also, all the documents are required in the pdf form.

IV. Fetching and Adding the Technical Member Whether the Technical Member/Technical Supervisor/Medical Officer

You need a specific allotted technical member number which is only available with the technical member/technical supervisor/medical officer concerned. Appointment letter issued by the concerned blood centre is necessary to add the member. Member is not added till he don't accept the e-mailed link crucial for appointment. This link is time limited and if not accepted, whole cycle is repeated. Here, in this case, synchrony is crucial between the technical member/technical supervisor/medical officer and the blood centre recruiting them.

V. How You Get the Blood Centre Licence Approved in the Online Portal??

There is no option available to obtain the updated online blood centre licence downloaded. Option is there to view blood centre licence but that also show a limited data. For example, if there are 18 technical members added, it only shows ten at a time and for next ten, you need to press tab for 11-18 onwards. Same is applicable for the licenced products manufactured at the blood centre.

VI. No Provision to Add Counsellor/Medical Social Worker in the Blood Centre Licence

Counsellor/medical social worker plays a crucial role in functioning of blood centre by providing support to both blood donors and patients involved in blood donation and transfusion services. There is no provision to add counsellor/medical social worker in the blood centre licence on ONDLS portal.

VII. Addition of Changes in Approved Blood Centre Licence

In the tab for post-approval changes request, the drop-down option lacks many options such as no provision for approval for increase in the area of the blood centre, approval for preparation of new blood products. Options (a total of five) are presently limited to change of technical person, surrender of license, change in the name of the organization, change in constitution and change in site address.

VIII. Single Application Approval in Post-approval Option

Provision is available for submission of only one post-approval application. When one application is approved by the state FDA only then option is opened for submission of second application. When application is submitted, supporting documents need to be uploaded such as the covering letter, self-declaration, copy of blood centre licence with the full details.

IX. Communication Via E-mail Only

Unfortunately, no contact number is available for any query resolution. Only e-mail id is provided as a means of communication serving as the only alternative way.

DISCUSSION

Since regulatory authority is constantly thriving upon to bring out transparency, accountability and uniformity in its services in order to ensure safety, efficacy and quality of the medical product manufactured, imported and distributed in the country, it is crucial to review the present status of legal and regulatory blood centre licensing policy framework so as to scrutinize various challenges and issues in the process.⁸ It will further help in the development, upgradation and enforcement of an appropriate structure for a regulatory mechanism

for the registration, official licensing, operation and inspection of the national blood transfusion services.⁹ It also proposes and offers the opportunities and ideas for improvement of blood transfusion services uniformly throughout the nation.¹⁰ Online blood centre licensing application builds a capable management with well-organised communication channel with delegation of authority and responsibility holding a better chain of command.^{11,12} Henceforth, online blood centre application system is the key to advancement facilitating digital systematization and sustainability.¹³

CONCLUSION

Online blood centre application system is a new step towards advancement in transfusion services facilitating digital systematization of blood centre related documentation.

Acknowledgment

The article don't involve any patient participation. It is about dealing with the implications involved while online application of the blood centre license which is mandatory these days.

Conflict of Interest

There is no conflict of interest.

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