Experience of an academic institute in importing a novel preclinical drug into India

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Abstract:
The article throws light on the process of importing a novel preclinical drug into India based on the real-life experience from one of our studies. A novel drug “X” acting through a new mechanism of action was hypothesized by us to function as a neuroprotectant. It was decided to import this novel drug from a university located in Brazil. An official collaboration pact was exchanged between both the sides. In accordance with the Indian Drug and Cosmetics Act 1940, unauthorized import of drug into India is not permitted. Hence, we decided to apply for the import license from Government of India. During the process of registration, we realized that the CDSCO SUGAM portal did not have facilities for the application from academic institute. We further faced challenges in different steps of import such as registration of the institute, individual drug application, fee transaction through the bank for Form 12, and customs duty clearance in the New Delhi airport. The process of import of drug for the purpose of testing by academic institutes has not been regularized by the CDSCO, and we suggest the apex organization to make separate provision for the academic institutes. This will encourage more academic institutes in India to opt for global collaborative works. This narration will further help them in following the same footsteps without facing significant hurdles. If more research on novel chemical entities is carried out in various academic institutes of India, it would not be far that we discover a blockbuster drug making the whole world turn toward us.

Keywords:
Academic institute, drug discovery, import, India, preclinical research

Introduction
The article throws light on the process of importing a novel preclinical drug into India based on the real-life experience from one of our study. Our institute is a nonprofit central government institute located in Chandigarh, India and is primarily oriented for academic research. The process of novel drug discovery attempt at the academic medical college level faces multiple challenges such as inadequate financial support, lack of drug synthesis facility, and nonawareness in the regulatory procedure involved in importing the drug from other countries. This narration will help academic institutes in following the same footsteps without facing significant hurdles and will help in accomplishing the goal of drug discovery. The successful drug discovery at the academic level will in turn help in taking the field of pharmacology to a higher level and would bring laurels to pharmacologist. In maintaining the confidentiality of the project, no identification details of the drug, person, or university, which we dealt with, will be mentioned in the article.

Identifying the Drug and Collaborator
A novel drug “X” was identified based on literature search and was proposed to be a neuroprotective agent through a novel mechanism of action. We hypothesized...
that this drug would be beneficial for acute traumatic brain injury. We then decided to collaborate with the initial synthesizers of the drug. The synthesizers belonged to an academic institute located in Brazil, South America. We communicated to the discoverers through mail and sent our research hypothesis. After careful consideration and multiple discussions, the institute collaboration committee of the Brazil university agreed for the collaboration. An official collaboration pact was exchanged between both the sides. This was an important step so as to make the nature and purpose of the collaboration clear at the stage of project initiation. The collaborators agreed to synthesize the drug in 3-month time. According to our institute’s regulations, we were required to get the permission from collaboration committee of our institute for any collaboration project. Hence, the permission was obtained through proper channel.

Transfer of Power of Attorney

In accordance with the Indian Drug and Cosmetics Act 1940, unauthorized import of drug into India is not permitted. Hence, we decided to apply for the import license from the government of India. At the start of this process, we were completely unaware of the procedures involved in obtaining the license. After frequent communication to CDSCO (Central Drugs Standard Control Organisation), we were informed that we need to apply through the CDSCO SUGAM portal (https://cdscoonline.gov.in/CDSCO/homepage). The first step in applying through the SUGAM portal is the registration of the institute with CDSCO. However, according to the rules of CDSCO, only one person from an institute will be authorized to import the drug, and the registration would occur in the name of that person on behalf of the institute. The director of the institute was requested to give an undertaking and transfer the power of attorney to the project head. After meetings and discussion with higher officials, the undertaking was granted by the director of the institute.

Missing Details for Academic Institute

The next challenge was that some of the mandatory fields in the online application for registration such as “manufacturing licence number of the firm” and “firm location” were not applicable to the academic medical institutes. The CDSCO officials were contacted for the desired solution to such fields. In addition, the offline forms which were to be filled as a part of registration used the word “firm” to refer any organization involved in the import process. After multiple communication, we were informed to apply in the same form with handmade changes such as striking out the word “firm” and replacing with “institute.” Finally, our institute got registered in the CDSCO website as an institute approved for importing the drug into India.

Application Process for the Drug of Interest

After successful registration of the institute in CDSCO website, the next step was to apply an online application for the import of the drug of interest through the SUGAM portal. Other than demographics of the importer and exporter, the additional documents which were required to be uploaded include the executive summary of the drug, undertaking stating the purpose of import, letter stating the utilization and split up of the drug imported, permission from the Narcotic Control Bureau of India for the import of drug with narcotic properties, and the details of the location of site in which research work would be carried out. A nominal amount of Rs. 100/- was to be paid for drug import. The detail of the bank account was mentioned on the website. The important thing to be noted was that the payment could be made in only one specific branch of the bank in entire Chandigarh region. This specific branch was not mentioned in the website. Therefore, the bank headquarters in Chandigarh was contacted to identify the same. The challan was successfully generated, and the details of the challan were entered in the Form 12 (application for licence to import drugs for the purpose of examination, test, or analysis) available in Sugam portal. This Form 12 was required to be generated automatically rather than manually. The amount and proposed pharmacological properties of the drug were to be mentioned in the application form. The full address of both the collaborators (importer and exporter) and the proof of collaboration pact on both sides were required to be uploaded. After two rejections due to errors in the application form, we were granted import license by CDSCO for importing the drug into India for testing purposes.

Transportation of Drug from Brazil to India

The next challenge we faced was in the transportation of drug from Brazil to India. The collaborators initially used the official postal service of Brazil for transportation. During the transit of drug, the customs department of “Y” airport in Brazil had denied its clearance (for unknown reasons) and returned the drug back to the collaborators. One of the pitfalls, we felt was that the difficulty in communicating to the courier service (language, time, and location barrier) from our side. Hence, we finalized to transit the drug utilizing a courier service having its corporate offices in both India and Brazil. We contacted the officials of the courier service and got accustomed with the procedure required for transportation. As we possessed import license, the courier service officials guaranteed that there would not be any trouble in importing the drug into India. The
drug reached New Delhi airport in around 5 days’ time where we faced our next hurdle of customs clearance. Some of the documents which were required other than import license include the invoice stating the price of the drug imported, technical details of the drug imported, and Know Your Customer documents of the importer.

Waiver of Import Duty Fees

An import license fee based on the value of the drug was to be paid to the customs department of the airport. This would amount to a huge price which could not be afforded by the academic institutes. Fortunately, we learned that the institutes which are recognized and granted a specific license from Department of Scientific and Industrial Research would be given waiver from paying import duty fees.[5] For this, an official letter in the prescribed format as signed from the head of the institute was to be deposited for customs clearance. We provided all the required documents to the courier service who in turn submitted them on our behalf to the customs department of the New Delhi airport. It should be noted that any delay in these procedures would result in huge penalties on the importer according to the rules of the customs department of India. Finally, the drug was successfully imported into India and was utilized for experimentation purpose in our laboratory (Neurobehavioral Research Laboratory, Chandigarh).

Need for Channelising the Process

Our experience, though thrilling, was tiresome at times and demanded us to be on toes constantly. The first and foremost thing was to get a reliable collaborator, who would act according to the research agreement and ready to provide the drug with impeccable purity. The process of import of drug for the purpose of testing by academic institutes has not been regularized by the CDSCO, and we suggest the apex organization to make separate provision for the academic institutes. This will encourage more academic institutes in India to opt for global collaborative works. In addition, the research work in academic institutes is carried out as a part of Master of Doctrine, Master of Science, and Doctor of Philosophy thesis by residents/students/research scholars. It is well known that thesis work is time bound, and hence, the regularization of these procedures would help immensely in widening the horizon for the researchers.

Conclusion

If more research on novel chemical entities is carried out in various academic institutes of India, it would not be long before we discover a blockbuster drug making the whole world turn toward us. We thank the Director of our institute, CDSCO officials, and collaborators for constantly supporting us in realizing our dream of testing novel drugs for various pathologies of mankind.

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Conflicts of interest

There are no conflicts of interest.

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