



# SARASWATI INSTITUTE OF PHARMACEUTICAL SCIENCES

(Managed by Shree Saraswati Education Sansthan –Gujarat)

Recognized by the Government of Gujarat & Affiliated to Gujarat Technological University, Ahmedabad

Approved by the All India Council of Technical Education (AICTE) & Pharmacy Council of India (PCI), New Delhi

**DATE: 30/10/2021**

|                        |  |
|------------------------|--|
| <b>NAME OF SPEAKER</b> | Mr. Ankit Trivedi                              |
| <b>TOPIC</b>           | Overview of Post Approval Submission in Europe |
| <b>DATE</b>            | 30/10/2021                                     |
| <b>TIME</b>            | 10:30 a.m. to 11:30 a.m.                       |
| <b>NO OF ATTENDEE</b>  | 100  |

## Report

An online national webinar on “Overview of Post Approval Submission in Europe” was arranged by Saraswati Institute of Pharmaceutical Sciences at 30<sup>th</sup> October 2021 on zoom cloud App.

Very informative lecture was given by Mr. Ankit Trivedi, Assistant General Manager in Regulatory Department at Amneal Pharmaceutical. He explained very well about the Regulatory documents submission procedure of EU as well as US.

He also explained type IA variation , type IIA variation. what is the criticals and challenges while submission. He gave details about Review fees and procedure for it. He focused on what negative outcome and types IA of variation, Implementation Date depending on types of changes like Quality change, product information changes. He explained advantage of EU guidelines as compare to US by giving example as time table.

He also elaborate classification guideline, Guideline structure and discussed various case study for giving examples of type IA variation , Type IIA variation and grouping of variation, variation fees.

Students appreciated lots for this informative webinar.

Prepared By:

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### Fees Type IA

The Agency will charge 1 Type IA/IA<sub>IN</sub> fee x scope x product, as declared in the application form, at the start of the procedure, **irrespective of the outcome** (positive, negative, partial/full withdrawal).

- Scope 1 → [Green Arrow]
- Scope 2 → [Red Arrow]
- Scope 3 → [Red Arrow]
- Scope 4 → [Green Arrow]

**4 fees invoiced**

### Type IB Review process

**Validation phase**

- Day 0: Receipt of submission. VSI: Validation Supplementary information, RSI: Reference Safety information.
- Day +7: Start of validation. In case of deficiencies VSI is sent.

**Evaluation phase**

- VSI (only 1 possible!): MAH has 2 working days to resolve issues. Delayed or insufficient response will lead to partial or full invalidation. Full invalidation triggers an administrative fee.
- Start of the procedure: Day +30 Notification or RSI. Only 1 RSI foreseen. 30 days clock stop. Positive or Negative Notification.

### Type IB - Agency Acknowledgement

**Acknowledgement of approval**

Submission date: 25 January 2019

Case contact:  
Product name(s):  
EU procedure number (PND number(s)):  
MA holder:

**Timetable:**

- Day 0 : 26 February 2019
- Day 20 : 18 March 2019
- Day 27 : 25 March 2019
- Day 30 : 28 March 2019

Medicines Evaluation Board  
Date: 26 March 2019  
Contact e-mail address: [ca@ema.europa.eu](mailto:ca@ema.europa.eu)  
Reference (Case no.): MH/2005/01 (Case 12569)  
\*Please quote the variation procedure number, the name of the medicinal product and the case number in any future correspondence.

The Medicines Evaluation Board **agrees** to the request to vary the Marketing Authorisation detailed in the application. The proposed change is:

**MAH's right**  
Extending shelf life of the finished product from 2 years to 3 years.

### Variation fee

| Country           | Type IA         | Type IB          | Type II          |
|-------------------|-----------------|------------------|------------------|
| Netherlands       | Annual Fees     | Annual Fees      | Annual Fees      |
| UK                | 1282            | 3396             |                  |
| Germany           | 984             | 2064             | 8400             |
| Denmark           | 341             | 3501             | 8300             |
| Finland           | NA              | 400              | 800              |
| Norway            | NA              | 3807             | 13000            |
| Sweden            | Annual Fees     | Annual Fees      | 632              |
| Spain             | 1457            | 2498             | 14244            |
| <b>Total (€)</b>  | <b>2,782</b>    | <b>13,552</b>    | <b>48,772</b>    |
| <b>Total (Rs)</b> | <b>2,44,718</b> | <b>11,92,101</b> | <b>42,90,228</b> |

### renewals

Marketing Authorization (valid for 5 years)

Re-evaluation after 5 years

or

MA for lifetime or One additional 5 years Renewal

**TIME FOR RE-EVALUATION**