

REPORT ON PFNDAI WORKSHOP ON APPROVAL PROCESS FOR HEALTH CLAIMS



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PFNDAI had organized a workshop on Approval process for Health Claims, which was held at Hotel Orchid, Mumbai; on 28th June, 2018. The workshop was attended by delegates from the field of Regulatory firms, Food Industries, Nutrition and Dietetics. The main focus of the workshop was on Capacity Building in Food Regulatory Process. The workshop was honored by the presence of eminent speakers who spoke on various aspects relating to Claims and Advertisements and its Approval Process across the globe.

The workshop was inaugurated by Dr. B. Sesikeran (Chairman; Scientific Advisory Committee, PFNDAI). He spoke on Food based Clinical trials, where he focused on the mandatory steps in designing clinical studies and their outcomes. He also gave an overview on Systematic review.

More highlights given by the speakers on the claims are as follows:

Dr. Jasvir Singh (Regulatory, Scientific and Govt. Affairs leader- DuPont Nutrition & Health; Asia) briefed the audience about the Global Perspective on Claims and its Types. He talked about the Definition and the Claims Structure in different countries; where he mentioned that the primary purpose of a claim is to translate science into a language which consumers can understand. He concluded by raising a point about what should be the governance mechanisms which can strike a balance between needs to consumers as well as industry, so that scientifically valid claims reach consumers in reasonable time

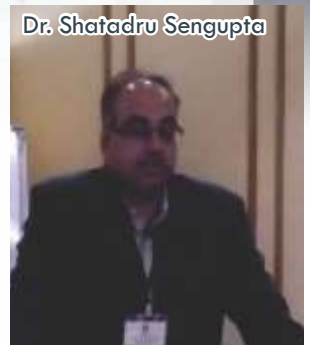


Dr. Jasvir Singh

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Dr. Shatadru Sengupta (Senior Director Legal - Hardcastle Restaurants Pvt. Ltd.) summarized the Claims Approval Process Analysis by explaining about when the Approval process for Claims does apply. He also gave an understanding about which claims need approval. He mentioned seven points which are required for the procedure for approval process of Claims. He also put focus on the cons of rejection of a claim, where there is no right of appeal against a rejection. He concluded by recommending "to plan the claim according to regulations".

Dr. Shatadru Sengupta



Dr. Sesikeran Chairing Panel





Mr. Kiran Desai

Mr. Kiran Desai (Regulatory Affairs Manager- Mead Johnson Nutrition; Reckitt Benckiser) gave an overview on Claims and Approval process in ASEAN (Association of South East Asian nations) Countries. He highlighted the indicators of the ASEAN Countries along with the Structure of Claims. He gave a systematic preview of the type of approvals, Claim approval process and Food registration process. He also gave a gist of the allowances, Restrictions and Prohibitions with respect to Claims in ASEAN Countries.



Ms. Rini Sanyal

Ms. Rini Sanyal (Regulatory Affairs- Herbalife) briefed about Claims on health Supplements and the Approval Process. She put a focus on the types of Claims allowed under Health supplements in reference to Food Safety and Standards Regulation, 2016. She mentioned about the conditions of the Nutrient Content Claims, General Health Claims and its components. She also talked about the Claims under Codex and other regulations namely- USA and EFSA. She concluded by adding that the Indian Claim regulation is now evolving.



Ms. Veena Sharma

Ms. Veena Sharma (Regulatory Affairs- GSK) talked on Claims and Advertisements- Today and Tomorrow. She highlighted the key features of the Claim and Advertisement Draft Regulation, 2018. She highlighted the key features of the Claim and Advertisement Draft Regulation, 2018. She pointed the communication gap in case of Health Claims, due to use of technical words, not understood by the consumers. She also gave an insight of the degree of assessment of Health claims; about how it goes on. She summarized by suggesting to work in a matrix form, by providing scientific relevance for the claims, developing guidance and being transparent.



Dr. Vaibhav Kulkarni

Dr. Vaibhav Kulkarni (Director Regulatory Affairs- Abbott Healthcare Pvt. Ltd.) spoke on Key Differences in Global Regulations of Food Categories and Claims. He gave an insight about the Food Regulatory Categories, Different Claims and its approval process in USA, China and EU countries. He also spoke about the claim regulations in Brazil, Russia and India.

Ms. Meenu Yadav (Scientific & Regulatory Affairs- Mondelez) conveyed to the audience the interrelationship between Advertising and Claims. She highlighted the amendment in the definition of Claims and marked some important definitions regarding Advertisement as in the FSSAI draft regulation. She notified about the general principles that is need to be followed to set up a Claim and advertisement for same. She also defined Nutrition Claims, Non-addition Claims, Health Claims and Prohibited Claims. She systematically explained the Claims Approval Process.



Dr. J. L. Lewis

Dr. Lewis (Food Regulatory Consultant) gave a systematic review of the Approval Process for Health Claims. He covered the Scope of Health claims, mentioning the two categories of Claims; one being Functional claims (which are non-disease claims) and the other being Disease Risk reduction claims.



Ms. Meenu Yadav

He further added the significance of Scientific Substantiation of the Claims which are subject to common approval process. He explained the Approval Process for Generic Claims which are related to nutrient or other substance or food category or component and are supported by 'generally accepted scientific evidence' and Specific/ Product led/ New/ Innovative which are the claims that are not currently regarded as substantiated under the generally accepted scientific evidence.

The workshop was summarized to discuss on the next steps the industries could have so that the Approval process of Claims gets more evolved and fuss free by the Panel consisting- Dr.B. Sesikeran, Dr. Jasvir Singh, Ms. RiniSanyal, Dr. Shatadru Sengupta, Mr. Kiran Desai, Dr. Vaibhav Kulkarni. The panel had a one to one interaction with the audience and shared their ideas about how to systematically go about the procedures for the approval of claims. It was suggested that the ambiguity with regulations should

be cleared and looked in more practically. Also, before making a Claim, one must go back in the history to review and understand the process and methodology and do a thorough study.

The speakers at the end were felicitated with a token of appreciation from PFNDAI and were extended a vote of thanks along with all the other delegates for making the workshop a successful and productive event.

Audience



Audience



Anuja Thanking Dr. Sesikeran