



## Letter

# Commemorating 123 years of Allergy Immunotherapy

## *Our 33 years of Journey from SCIT to SLIT Tablet*

### Shahid Abbas\*

Pakistan Allergy Asthma and Immunology Society (PAAIS), Allergy and Asthma Center, Islamabad, American Allergy Center Dubai

\*Corresponding author: Shahid Abbas, Pakistan Allergy, Asthma and Immunology Society (PAAIS), Islamabad, Pakistan

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### Breakthrough in the History of

#### Sublingual Allergy Immunotherapy

The journey spans around 33 years, transitioning from earlier days of injectable allergy treatment to the development of the Multi-Allergen Sublingual Allergy Immunotherapy Tablet, which dissolves under the tongue within 30 seconds. SCIT (Sub Cutaneous Immuno Therapy) was developed by Leonard Noon and John Freeman in 1911 although they started working on it much earlier (so we can say commemorating 123 years). Then there was lots of research and development until the SLIT Sublingual Immunotherapy Tablet was developed and approved by the FDA in 2012. During the years from 1991 to 2003, I served as the Head of the Allergy Immunology Department, the Allergy Center, and oversaw Allergy Vaccine Production. Concurrently, I held the position of Chief at the Clinical Diseases Research Center and the Allergy Center at NIH, Islamabad. During this time, we catered to a patient population of approximately 500 to 600 individuals afflicted with various allergic conditions hailing from Pakistan, the UAE, Afghanistan, and Iran. It was in 1995 that I became acutely aware that 75% of patients who received injectable allergy vaccines discontinued their immunotherapy within the first three months, primarily due to: -

- Fear of pain due to weekly Injections for 3 years, especially children, old people, and anyone who is afraid of injections.
- Chances of anaphylactic reactions, especially in remote areas where the emergency health facility was unavailable.
- Patients were advised to sit in the clinic for about half an hour every time after the injection and must be given only under the supervision of a doctor. It was difficult to follow.
- Response was slow since we were following such protocol.
- Patients had to come to the clinic; some would travel 2000km to get the vaccine and bring a thermos to carry it at proper temperature.

Allergic diseases, which have a genetic basis, tend to worsen in both severity and frequency if left untreated without specific immunotherapy. Consequently, 75% of patients experienced allergic complications. My concern for these patients prompted me to embark on a project in 1995 aimed at developing sublingual immunotherapy. Despite facing discouragement and criticism due to the unproven effectiveness of this approach, I persisted in my research efforts. By 2002, I successfully created Sublingual Allergy Liquid drops and began administering them to patients, receiving highly positive feedback within a short span. This encouraged me to establish standard operating procedures (SOP) and administration protocols, which yielded excellent results. Notably, these sublingual immunotherapy (SLIT) drops were not subject to temperature restrictions, making them a unique option. At that time, SLIT was relatively unknown, and most doctors remained skeptical.

Subsequently, I contemplated developing sublingual tablets but encountered a challenge. Tablets are typically formulated with powdered active pharmaceutical ingredients (APIs), while our essential components, allergens, are only available in liquid form. Pharmacists and scientists advised me to first convert allergen extracts into freeze-dried powder, establish SOPs, adjust concentrations, and then prepare the tablets. This endeavor was riddled with difficulties and required resourcefulness due to limited resources. Fortunately, I established contact with Medisca USA, resulting in a six-month collaborative effort to develop the final formulation. After 33 years of research, we successfully created multi-allergen sublingual allergy immunotherapy tablets customized for each patient based on allergy test results and international guidelines. These tablets contained ingredients sourced from the USA, Europe, and Japan, with quality on par with international products. Notably, our innovation combined four allergens in a single tablet, as opposed to international companies that produce separate SLIT tablets for each allergen, requiring patients to take four tablets. Additionally, our pricing was eight times more affordable than similar international products of equal quality.

I take pride in my dedicated team's unwavering support throughout this journey, culminating in this significant breakthrough.

A significant breakthrough has been achieved in the history of sublingual allergy immunotherapy tablets, following a 33-year journey from injectable to sublingual formulations. This newly developed Sublingual Allergy Immunotherapy Tablet dissolves rapidly in 30 seconds when placed under the tongue. What sets it apart is its unique ability to incorporate multiple allergens into a single tablet, customized for each patient based on their prescription and allergy test results. In contrast, pharmaceutical giants in the USA and Europe offer tablets with single allergens, resulting in high costs for patients with multiple allergies. The newly developed tablet is priced at **\$600 for 3 months (200\$ each month whereas the price in the international market is \$500-600) for a dose of one month)** with 1-4 allergens Our MULTI-ALLERGEN SLIT tablet is a cost-effective alternative of international quality and standard as compared to commercially available SLIT Tablets. If one chooses a commercial SLIT Tablet and he is allergic to 4 allergens, then he has to take 4 tablets daily and the cost will be  $500 \times 4 = 2000$  per month (\$6000 for one month whereas our price of \$600 is minimal and the same standard). The most common aeroallergens are House Dust mites, Grass, Weeds & molds, and it should be remembered that there are many types of each category (about 5-10 types of grasses weeds, or molds. Allergen Immunotherapy is effective only if it is specifically prepared for each patient according to the allergy tests done by skin allergy tests or by specific IgE. Similarly, we prepare SLIT Tablets for food allergens according to the skin allergy tests or from IgE test results.

With our 33 years of continuous research and hard work, we have been able to develop the world's first MULTI ALLERGEN SUBLINGUAL IMMUNOTHERAPY TABLET of extracts from world leaders in allergen extract production. As mentioned above with same international quality and standards produced by Dr. Shahid Abbas who is President of the Pakistan Allergy Asthma and Immunology Society (one of the elite members of the WAO, was trained by WHO (World Health Organization) in the USA about Allergen Production, QC and Standardization. Was Chief of the Allergy Center, NIH, Islamabad, and head of the Allergy Vaccine Production.

Additionally, this compounding pharmacy has extended its services internationally, providing SLIT Tablets made from allergens and constituents from the USA to patients worldwide via DHL Courier.

This breakthrough not only offers a more affordable solution but also includes allergy-causing foods, an area not yet addressed by international companies.

This achievement is a testament to the dedication of the team behind this innovation.

This achievement is a testament to the dedication of the team behind this innovation. I would like to thank Dr. Aqsa Batool, our chief Pharmacist, for her hard work, continuous support, dedication, and professionalism for years to make possible what looked impossible. I also like to thank Shafi U Rehman for his continuous support since 1990 and for helping me in the development of novel multiallergen immunotherapy and allergen extracts at NIH, Islamabad, and in our Allergy and Asthma Center, Islamabad.

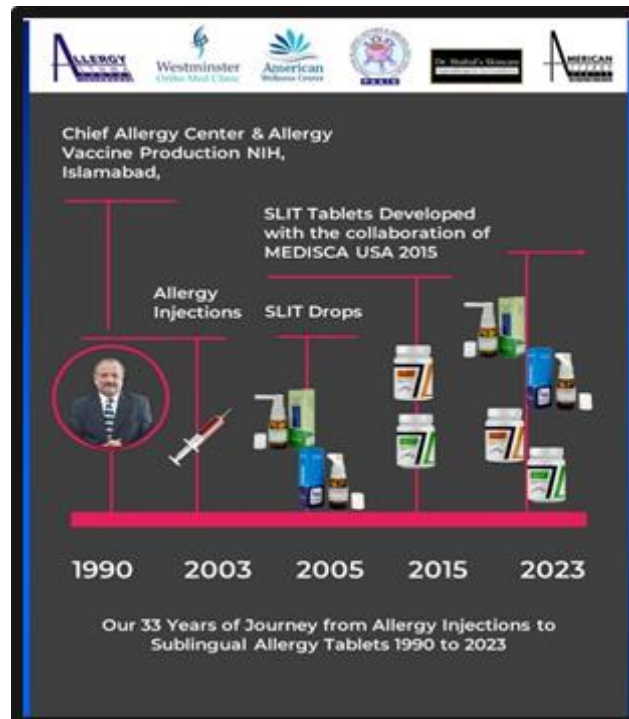
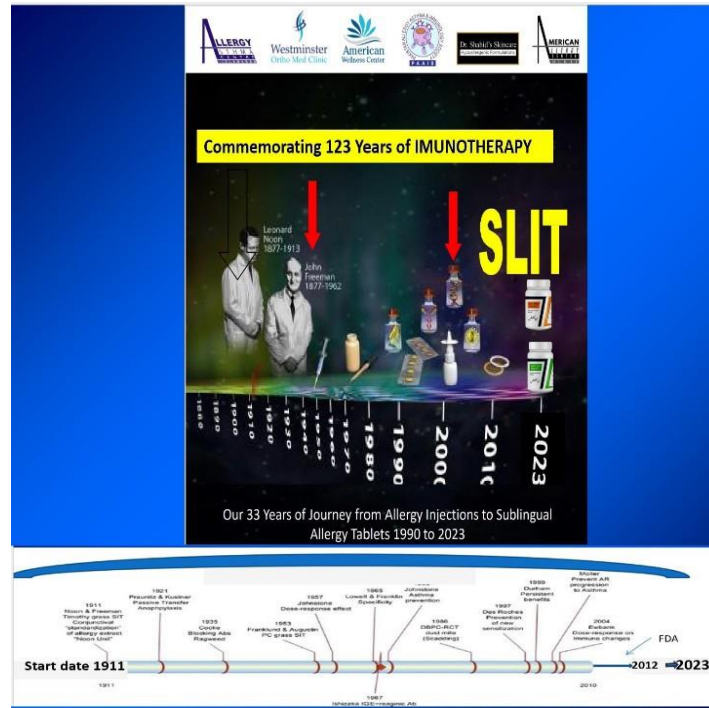
**President PAAIS (Pakistan Allergy Asthma and Immunology Society)**

**Member:**

- WAO (World Allergy Organization)
- AAAAI (American Academy of Allergy Asthma And Immunology)
- EAAACI (European Academy of Allergy Asthma And Clinical Immunology)
- Executive Member Asian Aeroallergen Group.
- APAACI (Asia Pacific Association of Allergology & Clinical Immunology)
- ACDS (American Contact Dermatitis Society)
- SAAAACI (South Asia association of allergy, asthma & clinical immunology.
- ASGCT American Society of Gene Therapy.
- ASHI (The American Society for Histocompatibility and Immunogenetics)
- IAA (International Aerobiology Association).
- SSC (Society of Cosmetic Scientists).

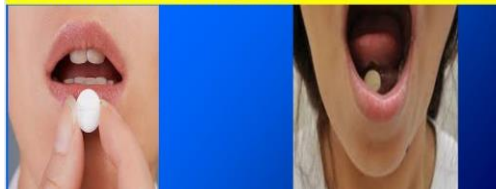
**Member: AAAAI (American Academy of Allergy Asthma and Immunology) Committees**

- Allergen Immunotherapy Guidelines Group.
- Asthma and Allergic Diseases in older adults Committee.
- Asthma, Cough Diagnosis, and Treatment Committee.
- Immunotherapy, Allergen Standardization, and Allergy Diagnostics Committee.
- Allergic Skin Diseases Committee.
- Eosinophilic Gastrointestinal Disorders Committee
- Anaphylaxis Committee.
- Toddler Anaphylaxis Committee.
- Peri-Operative Anaphylaxis Committee.
- Allergic Contact Dermatitis Society
- Auto-Immunity and Altered Immune Response Committee.
- Adverse Reactions to Food Committee.
- Adverse Reactions to Drugs, Biologicals, and Latex Committee.





- ❖ Unique Formulation of SLIT Tablet with 3 or more allergens developed with the collaboration of MEDISCA USA. SLIT Tablets prepared according to the results of Skin Prick Allergy Tests or Specific IgE results.
- ❖ SLIT Tablets of each patient has different formulation and only affective for the same patient
- ❖ DISSOLVES IN 15 SECONDS UNDER THE TONGUE



**BREAKTHROUGH IN THE HISTORY OF SUBLINGUAL ALLERGY IMMUNOTHERAPY TABLET**  
 This newly developed Sublingual Allergy Immunotherapy Tablet dissolves rapidly in 30 seconds when placed under the tongue.



**Allergy Immunotherapy is effective only if it is Patient specific and prepared according to the results of SPT(skin allergy tests and specific IgE Tests of each patient).**

We are one of few centers to prepare Sublingual Immunotherapy Tablets which are specifically tailor-made according to skin allergy tests of each patient. We achieved this according to the protocol developed by Medisca USA.

- Formulation developed by Medisca USA.
- Dr. Shahid was trained by WHO in USA in Allergy Vaccine Production, QC and standardization of Allergy Extracts.
- Dr. Shahid was Head of the Department of Allergy Vaccine Production, QC and standardization of Allergy Vaccines and Extracts.
- USP Certificate in Preparations of NON-STERILE PREPARATIONS (USP General Chapter 795 Pharmaceutical Compounding).
- USP Certificate in Preparations of the STERILE PREPARATIONS (USP General Chapter 797 Pharmaceutical Compounding).
- American College of Apothecaries Certificate in DERMATOLOGICAL COMPOUNDING.