IFAN
IRISH FOODALLERGY NETWORK

Ms. Lorraine Nolan,
Director of Human Products Authorisation & Registration,
Health Products Regulatory Authority,
Kevin O'Malley House,
Earlsfort Centre,
Earlsfort Terrace,
Dublin 2.

October 12, 2015.

Dear Ms. Nolan

Thank you for your letter of October 1st. We appreciate HPRA's stated commitment to assisting patients and IFAN with the issue of auto injectors.

However we find your lengthy letter rather frustrating in that most of it relates to description of the current situation, with which we are very familiar, and very little relates to your active execution of statutory powers to enforce industry compliance. Most of the language relating to your discussions with MAHs uses terms such as "working with", "engage with [MAHS] to encourage…" and "requested that, where possible…". There are very few examples of terms such as " instruct" or "mandatory". Even the latter term is used in a scenario where the clear breach of this mandatory requirement does not appear to be being pursued by HPRA with active dialogue or penalties.

We are asking HPRA to be more active and directive as it appears to us that one or both of the wholesale and retail sectors is blatantly ignoring the "advice" and "engagement" that you are currently offering.

At the present time we are not aware of any technical difficulties with auto injectors, as have been experienced in the past, and our own direct contact with MAH's tells us there is no problem with the shelf-life of the AAI that are being imported to Ireland. We can therefore only conclude that the difficulties patients are reporting to us are due either to deliberate stock flow management by pharmacy suppliers or to retailing issues that amount, in our view, to "price gouging" by retailers who are withholding AAI stock and then dribbling them into the market when the shelf life is shorter than is desirable or affordable for our patients.

This goes against the practices promoted by all medical, voluntary and professional allergy organisations around the world. Irish lives have already been lost due to non- availability of adrenaline. We cannot sit idly by on the current issue.

In paragraph 2 of your reply it is disappointing to read that you feel that the onus is on the "patient or carer to make themselves familiar" with the different auto injectors being offered to them, against their medical advice (which is to always have the same type of AAI). We have several instances of a mixture of AAIs being dispensed against a single prescription due to "availability"; this is an even worse scenario. Later in your letter, in section 5, you say that the emphasis should be on the training of the carer. This is a contradiction in your letter, which actually exemplifies the problem patients have. We think HPRA should be stronger, requiring both the MAH's to provide training aids and pharmacists to demonstrate confidently the use of each of the different kinds of AAIs when dispensing the right ones. This particular issue will worsen with the imminent introduction of a 4th product, Emerade.

Naturally we accept that the price of AAI's is outside your control, but your responsibility for health product regulation suggests to us that you should be concerned that the prices are unreasonable and therefore unaffordable for some families particularly at the frequency which is being forced on them by the problems in the supply chain, wherever the final fault for the latter may lie.

We are requesting more active policing of these issues by HPRA. HPRA's stated desire to work with all parties is a welcome offer and we want to take you up on it. IFAN is hereby requesting that HPRA, as the regulatory authority, organizes such a meeting between IFAN, MAHs, PSI and HPRA. We will be available to meet you, MAHs and PSI at your earliest convenience.

Yours sincerely,

Prof. Jonathan Hourihane	Dr. Aideen Byrne	Dr. John Fitzsimons	Ruth Charles
Co-Chair	Co-chair	Co-chair	Secretary