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Ten years ago, Genpharm was founded to shed light on the rare disease community in the MENA Region. Rare Disease patients and their families in the region, were not a priority for pharmaceutical companies working in the field. Our objective was to raise awareness, support the diagnosis odyssey of patients and ultimately facilitate their access to the most innovative therapies. We are proud to say we have succeeded to educate all stakeholders on the importance of this region. For several cultural and societal reasons, such as the higher rate of consanguineous marriages, the prevalence and incidence of many genetic and inherited disorders, are significantly higher than in the western world.

Rare diseases are defined as those that affect less than 5/10,000 (500/million) individuals around the world. One of Genpharm's mantra is that "A rare disease is only rare If you don't have to live with it". Some examples of the rare diseases we work with at Genpharm are Duchene Muscular Dystrophy (DMD), Spinal Muscular Atrophy (SMA), Metachromatic leukodystrophy (MLD) and Mucopolysaccharidosis (MPS) and others. For the past decade Genpharm's mission was to improve quality of life for rare disease patients by bringing the most effective treatments and cures to MENA region. Two years ago, I was fortunate to become part of this inspiring team and play my role in those patients' journey through my contribution in Pharmacovigilance and Drug Safety Monitoring

The key challenge in working with orphan drugs, is that the safety profiles are very difficult to determine. The small number of patients throughout the clinical trials creates particular hurdles in the investigation of drug safety. It is therefore of critical importance that the safety monitoring framework post-marketing is robust and very well established. Driven by this challenge in 2021 we have built and PV Department with the highest industry standards in mind. My personal goal and efforts were to make sure that we provide our international partners with as much data from the MENA region as possible to ensure our patients benefit the most out of our treatments. We also needed to educate all the stakeholders on the importance of reporting and tracking adverse events and PV incidents. This started with internal trainings and putting in place strict processes at all levels of the organization. I attended myself training to be updated with the current trends. All these efforts have also given confidence to our partners who have conducted several satisfactory audits on our capabilities and PV function. Throughout the year we collected multiple safety cases including adverse drug reactions and serious adverse drug reactions, as well as special situations such as off label use and lack of efficacy.

Our great efforts and commitment have resulted in an increased number of Adverse Event reporting from the region in 2021, compared to the past years. I am proud to say that we have managed to collect important safety information from our SMA patients, treated with the first gene therapy launched in the Gulf Region in collaboration with Novartis Gene Therapies (formerly known as AveXis Inc.). We hope that the information collected will play a significant role in better defining the profile of the product for the benefit of the patients. We continue to educate, collect and monitor patients as we launch several new products each year which are usually first in class. We are extremely proud to say that we have been consistently the second region to launch innovative therapies outside of the US and Europe following FDA and EMA approvals respectively. We take this very seriously particularly in our PV department since we could observe new PV incidents not seen in the clinical trial settings. To achieve this it was critical to educate physicians in collaboration with our partners in Adverse Event reporting, a task that is ongoing and of equal importance to Genpharm.

My main achievements were the development and implementation of a solid PV system at Genpharm. Throughout the year, I have strengthened the existing monitoring and reporting procedures and have

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drafted new ones to better define the required steps. More precisely, I have created documents to better define the responsibilities of PV personnel, to detail the steps for proper PV document filing and management and to ensure business continuity. In addition, I have created processes for ensuring patient data protection while collecting safety cases, testing the 24/7 availability and auditing of the PV responsible personnel across the GCC region. Finally, I have created onboarding material for our international partners, so that they are fully aware of the regional requirements given that the majority are exposed for the first time to the MENA region.

My main focus for the future is to further optimize our PV system and regularly train our staff to ensure that we can support the rare disease patient's community to remain safe and benefit from the treatments we have to offer.

Yours faithfully,

Dominiki Kati