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# Trend Analysis of Adverse Drug Reaction for Influenza Virus (H1N1: A/California/7/2009) Vaccines: An Internet-Based Brief Assessment in EU

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Monitoring of the side effects of the medicinal products is a crucial task that requires extensive monitoring and control by the regulatory authorities to protect the health and life of the affected individuals. European Medicines Agency (EMA) provides comprehensive strict surveillance of the adverse drug reaction (ADR) and updates its database continuously [1]. One of the important drugs that have received considerable attention on its side effects is Swine Influenza A/CALIFORNIA/7/2009 (H1N1)V-like Virus pandemic vaccines which is marketed in European Union (EU) under common brand names of pharmaceutical products: Celvapan, Focetria and Pandemrix for the vaccination [1,2]. Analysis of the dataset could be performed using statistical software packages such as Minitab® 17.1.0.

Circle (Pie) chart in Fig 1 (upper) shows the detailed reported ADRs as they were observed in the Summary of Product Characteristics (SPC) with their relative abundance. On the same line, about two-thirds of impacted human body parts based on the provided codes of System Organ Class (SOC) involves nervous and gastrointestinal

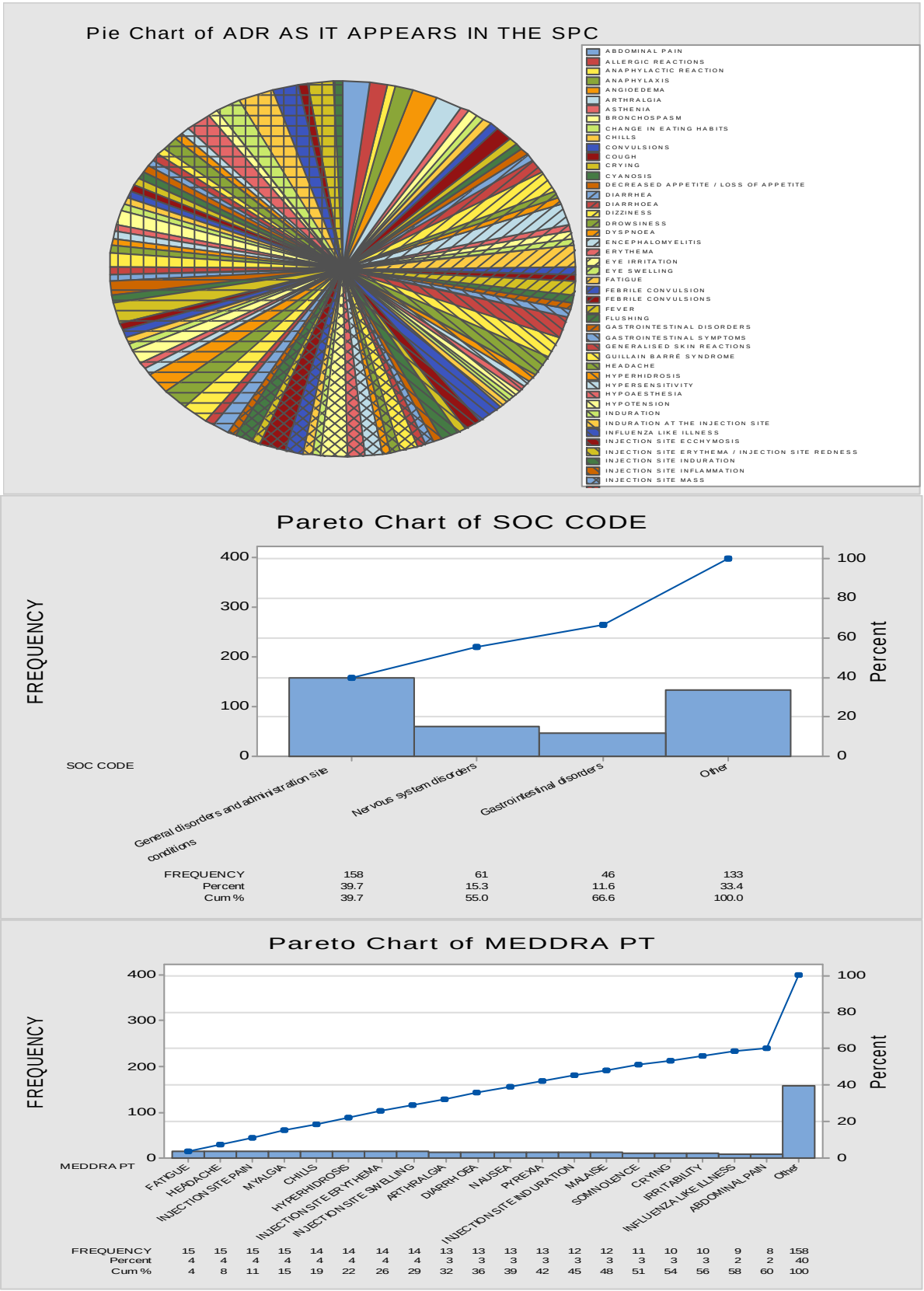


**Fig 1. ADR analysis as: Pie chart in SPC (upper), Pareto diagram of SOC (middle) and Pareto plot of MEDDRA PT (lower).**

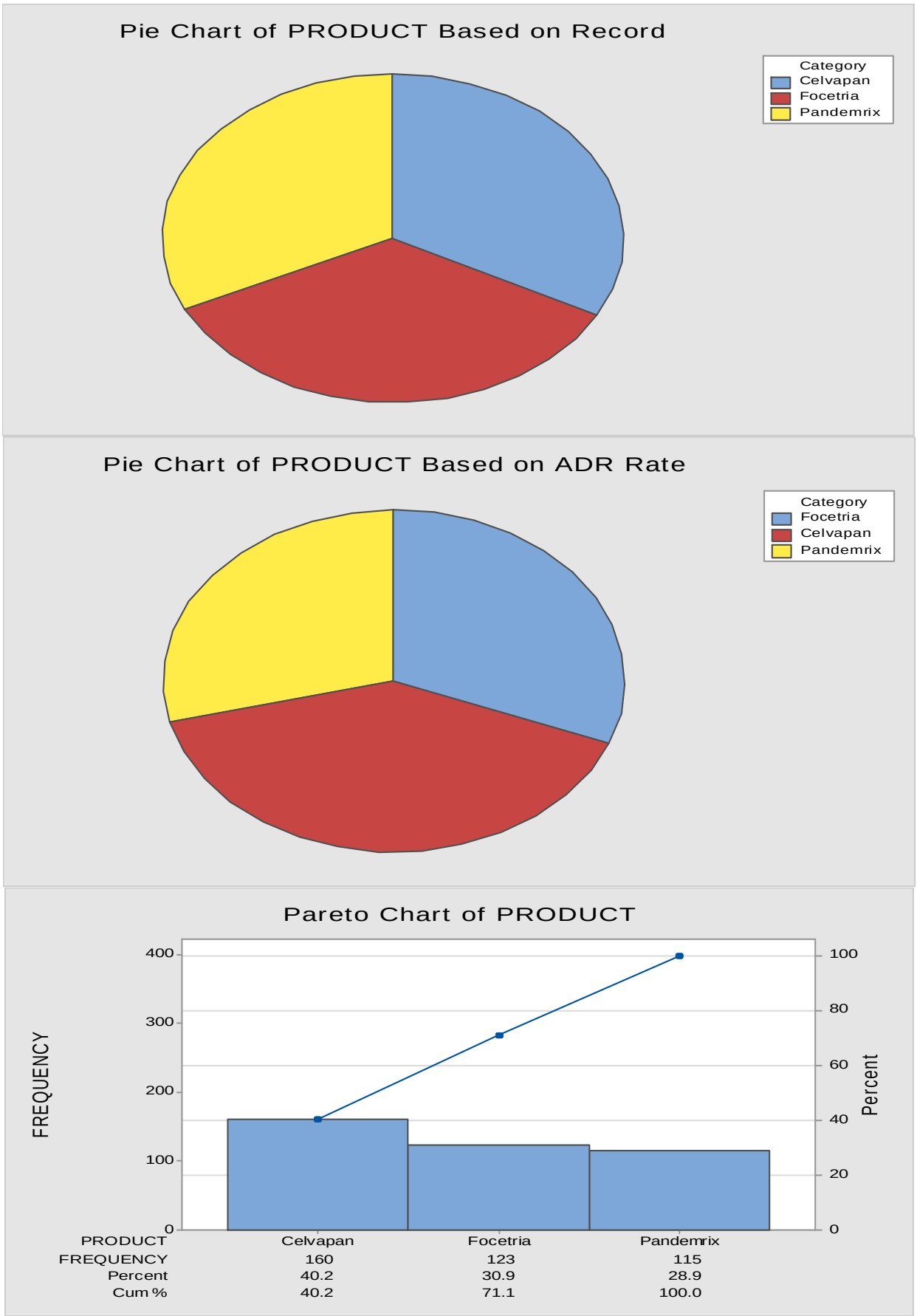


**Fig 2. Trade products of influenza vaccine (H1N1) (surface antigen, inactivated, adjuvanted) as: appeared in the record (upper), based on ADR observed rates (middle) and frequency of ADRs (lower).**

tract (GIT) disorders accompanying generalized and injection administration site reactions as could be seen in the middle Pareto plot of Fig 1. The broad classification is following the guideline for Common Terminology Criteria for Adverse Events (CTCAE) [3]. The last (lower) graph of Fig 1 shows detailed description for the 60 % of individual ADRs according to the frequency of the incidence based on Medical Dictionary for Regulatory Activities Preferred Term (MedDRA PT): fatigue, headache, injection site pain, myalgia, chills, hyperhidrosis, injection site erythema, injection site swelling, arthralgia, diarrhoea, nausea, pyrexia, injection site indurations, malaise, somnolence, crying, irritability, influenza-like illness and abdominal pain, in addition to others.

Three commercial products have been mentioned before containing the basic Active Pharmaceutical Ingredient (API) for immunization against Swine influenza. Fig 2 (upper, middle and lower) show the relative distribution of the ADRs of the products according to their mention in the report, ADR rates and their frequency, respectively. Pareto chart provides a visual numerical ranking of ADRs from the three products with Pandemrix showing the lowest rates of the side effects even in the clinical trials and post-marketing surveillance (not context and excluding the non-specified ADRs which were denoted by "0") [4]. However, it should be noted that 32.1 % of ADRs frequencies are unknown, not mentioned or do not follow standard category. Nevertheless, the remaining record of the database for the side effects frequencies is ranked from 1 to 5 [1,4] with 22.4 % are very common, 20.4 % are common, 11.5 % are very rare, 8.5 % are uncommon and 4.8 % are rare.

Similarly, the age category for the major (61.2 %) reported cases of ADRs is not specified or unclear, 26.1 and 13.7 % affects adults and children, respectively. Deep data mining and research are needed to cover and elucidate the gaps in records to derive more useful outcome results. It is recommended to work extensively on more detailed quantitative ADRs data using statistical process control software to provide full assessment for medicinal products side effects with the possible establishment of simple and timely risk assessments for specific drugs and their ADRs similar to those performed for outbreaks [5]. The present brief view could provide an example for analysis of other medicinal products reported in regulatory agencies databases.

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