Desirable (possible?) Sustainable Development of Italian Pharmacovigilance System

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The new pharmacovigilance (PhV) legislation and the efforts of Member States have allowed a significant increase of adverse drug reactions (ADRs) reporting but, consequently, also in the administrative burden on marketing authorisation holders (MAHs) and Regulatory Authorities (RAs) that, considered also the economic constraints, find themselves to operate with human and technological resources that are no longer sufficient. An article entitled 'The unsustainable success of spontaneous report' published by Focus Farmacovigilanza in 2014, reported that the number of spontaneous reports in Italy is so high that, given the limited available resources, the management of the relevant PhV activities is increasingly difficult for PhV representatives within the Local Health Services (ASL) and Regional Centres. We observed that a large number of spontaneous ADRs reports are non-serious, expected and referred to established drugs in Italy. The National Report about the use of drugs for the year 2013 reported that 69% of the total spontaneous ADRs reports were non-serious and that top 30 active ingredients for number of reporting were essentially all drugs established/widely known (at least 43.5% of total); therefore, very likely, most of them were expected ADRs. Warfarin took first place and amoxicillin-clavulanate second one with 2,126 reports. In detail 1,156 reports, i.e. 54.37% of total amoxicillin-clavulanate, were referred to Augmentin. We analyzed these 1,156 reports: 78% of them were defined by Italian RA as non–serious, 22% as serious/not defined, only 4% of all the suspected ADRs reports of Augmentin were unexpected with reference to the Summary of Product Characteristics. We also compared the spontaneous reporting systems of drugs of Italy, Denmark, United Kingdom (UK), United States (US) and Australia to understand the main difference about seriousness/expectedness reporting requirements and available information technology supports. The Healthcare Agencies of the Countries we examined, gave priorities to their healthcare professionals (HCPs) about what to report, with particular reference to seriousness, expectedness and medicines type. RAs of the UK, US and Australia ask physicians to report suspected serious ADRs (with exceptions e.g. new drugs). Italy and Denmark already implemented the new reporting rules for non-serious EU Individual Case Safety Reports, but Danish physicians are bound to report all suspected ADRs of a medicinal product during its first 2 years on the market and all serious and all unexpected ADRs, while Italian HCPs have to report all serious, non-serious, expected, unexpected suspected ADRs, for all medicines for their entire marketing period. In 2012/2013 the most reported products in Denmark, UK and US were recent vaccines/drugs, while the most reported one in Italy was an established drug. Furthermore, the current Italian system reporting appears more complicate and technologically backward compared to the other Countries. As an example, in 2012 in the UK, the number of electronic reports (from HCPs, consumers, MAHs) sent to Healthcare Agency (MHRA) was 82% of the total; while, to date in Italy, the majority of the ADRs reports were sent via pdf or paper format to the PhV representatives, which have to insert them manually into the PhV National Network. It is desirable to promote the sustainable development of Italian PhV system, increasing its efficiency through the rationalization of reporting activities and the use of appropriate electronic supports.

Focus Farmacovigilanza. The unsustainable success of spontaneous report. Pharmaco-vigilance.eu. 2014 May [cited 2015 May 19];82(5):2. Available from: http://www.pharmaco-vigilance.eu/content/unsustainable-success-spontaneous-report
OsMed. L'uso dei farmaci in Italia. Rapporto Nazionale Anno 2013. Agenzia Italiana del Farmaco. 2014 July [cited 2015 May 19]. Available from: http://www.agenziafarmaco.gov.it/sites/default/files/Rapporto_OsMED_2013.pdf.