Hippocratic oath: ‘First, do no harm’

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The principal of non-maleficence in the Hippocratic Oath is paramount to the safety of patients. The concept of non-maleficence is embodied by the phrase "first, do no harm". Our health care

 ssionals are committed serving our society with excellent patient centred care and every

Supplies Unit (CPSU), the Pharmacy of Your Choice (POYC), the Malta Medicines Regulatory Authority (MMA) and the respective Patient Advocacy Groups (PAGs). To “first, do no harm” is to identify how likely treatment plans can harm patients. So, the principle of non-maleficence is not absolute and balances against the principle of beneficence (doing good).

ARAM’s concern about safe biologic and biosimilar treatment has been ongoing some years, concern towards the welfare of patients. To date there has been no progress with respect to non-medical switching from biologics to biosimilars. Firstly, let us understand biologic/biosimilar treatments. Biologic medicines are used to treat patients with serious illnesses such as rheumatoid arthritis, psoriasis, and so on. The patents for biologic therapies are expiring over the coming years and biosimilars enter the marketplace at a reduced cost. What is a biologic medicine? Most people are familiar with small molecule medicines produced via a series of chemical reactions and their exact structure is simple and easily identified. Biologic medicines are very complex, made of living cells. In comparison, what is a biosimilar medicine? When patents expire, the pharma industry manufactures copies of biologics. To begin with, because of their size and complexity, it’s not possible to exactly determine the structure. Second, the living cells and manufacturing processes used to make the biologics are unique and proprietary to each manufacturer, as well as being far more complex than the synthesis of chemical drugs. Copies of biologics are highly similar but not identical to the original biologic, in exactly the same way.

This article addresses Non-Medical Switching and Automatic Substitution.

open nedical switching is when the medicine the physician and patient have decided on is switch[illegible] hird party, for reasons other than the patient’s health and safety. This is done to cut cost

level, non-medical switching is done without considering the patient’s previous medical history or the reasons why the physician and patient settled on the particular course of treatment. So how does this compare to Automatic Substitution? This is the substitution of the originator biologic with the biosimilar at the pharmacy level – without the involvement of the prescribing physician. While this practice is uncontroversial with generics, it is controversial with biosimilars due to the inherent differences they have with the originator product.

The six golden rules stakeholders need to bear in mind for the best quality healthcare are:

· New patients (“naïve”) may be encouraged to start with the lowest-cost biologic, often a biosimilar. This promotes competition and cost savings and is acceptable to the vast majority of the world’s physicians

· Stable patients should be allowed to remain on the medicine which is working for them. The decision to switch to a biosimilar should remain with the physician and patient

· Payers should continue to reimburse the medicine for stable patients who do not wish to switch to the payer-preferred product

· Physicians should have the ability to prevent a substitution they do not feel is medically appropriate for their patient

· Automatic substitution of biosimilars should not be permitted without additional studies demonstrating that switching, including repeated switching, does not have negative impacts on a patient

· In the event of an automatic substitution, physicians should be informed of the switch so that an accurate patient record is maintained.

ARAM has been advocating for patients with rheumatic and muscular diseases (RMDs) for the past 10 years, under the presidency of Mary Vella. ARAM is currently carrying out a survey, serving the purpose to do Community Research about Rheumatic and Musculoskeletal Diseases, such as Arthritis, Osteoarthritis, Psoriatic Arthritis, Rheumatoid Arthritis, and many others. It is estimated that there are about 200 Rheumatic Diseases. We thank you for your time to participate in this questionnaire. The aim of this questionnaire is that Arthritis and Rheumatism Association Malta (ARAM) aspires to serve the community and support patients, care-givers and patient organisations.

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