THE MMA telegram

ISSUE 07 – Q3 2021

Welcome dear colleagues to our third e-newsletter for year 2021!

EVENTS

First accredited course: Award in Good Manufacturing Practice

The MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences organised the first accredited course, at MQF Level 5, leading to an Award in Good Manufacturing Practice (GMP) between the 5th and 7th July. The course provided fundamental principles on the essentials of GMP as applicable to products intended for medicinal and research purposes. Discussions related to different areas of GMP including sterile manufacturing, inspections, process validation and GMP, as applicable to medicinal cannabis, were carried out. The course was followed by a networking forum to promote the exchange of knowledge, national and international collaboration, and advancement of individual skills in the field of GMP. A summative assessment was performed at the end of the course to evaluate participant learning.

Visit from the Medicines Evaluation Board

On the 1st and 2nd of September, the MMA hosted ambassadors from the National Competent Authority of the Netherlands, the Medicines Evaluation Board (MEB), who coordinate the International Collaboration Programme (ICP). The aim of the visit was to consolidate the professional ties between both agencies to ensure the timely and effective delivery of the proposals that have been mutually agreed upon in collaboration agreements signed in 2014. The cooperation enables the sharing of knowledge, exchange of best scientific practices on joint work which are related to the assessment of medicines and fostering of collaborative training. The MMA has continued to carry out assessment of applications on behalf of MEB to enable registration of new medicinal products both for the Dutch and the European market.

EVENTS

Seminar on Biosimilar Medicines

The MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences organised a seminar on biosimilar medicines on 26th August. Professor Philip J. Schneider from the Ohio State University, United States was the keynote speaker addressing the seminar which focused on the sharing of knowledge on biosimilars, including the rigorous regulatory requirements that must be met in the development of biosimilar medicines, aspects of pharmacovigilance, prescribing and switching, economic considerations and purchasing mechanisms, the impact on healthcare and the future of the biosimilar medicines market.

More information on biosimilar medicines is available in the Regulatory Sciences section of the newsletter.

DID YOU KNOW?

Fun Facts!

Did you know that success doesn't come from what you do occasionally but it comes from what you do consistently?

So Remember, success is not given, it is earned!

GENERAL UPDATES

The Article 20 Exemption

The Article 20 exemption of the Medicines Act (Chapter 458 of the Laws of Malta) is a National clause which gives powers to the Licensing Authority to place medicinal products on the Maltese market in the absence of a Marketing Authorisation in response to exceptional and justified public health reasons. The Article 20 exemption is reserved solely as a full or interim measure when registration options through a Marketing Authorisation, authorisation in line Article 126(a) of Directive 2001/83/EC and parallel importation have been exhausted as possible sourcing routes.

To counteract the risk of shortages secondary to Brexit and maintain accessibility to medicinal products on the local market, the Article 20 exemption has now become relevant more than ever. The Licensing Authority has delegated the assessment of Article 20 exemption requests to the Malta Medicines Authority, where the latter has invested in a competence infrastructure within the Medicines Intelligence and Access Unit to fulfil these duties.

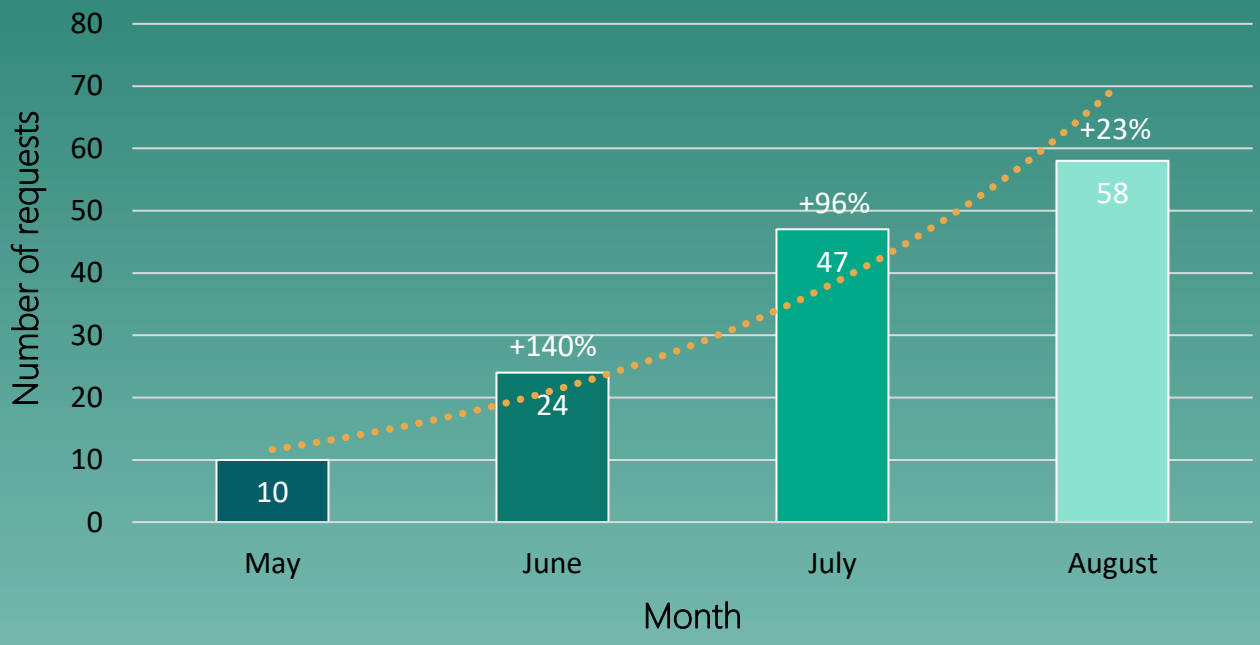
The Authority liaises with the concerned public and private stakeholders during the vetting process and following a thorough review, recommendations to the Licensing Authority are proposed for consideration to grant or refuse the Article 20 exemption request.

Malta Medicines Authority

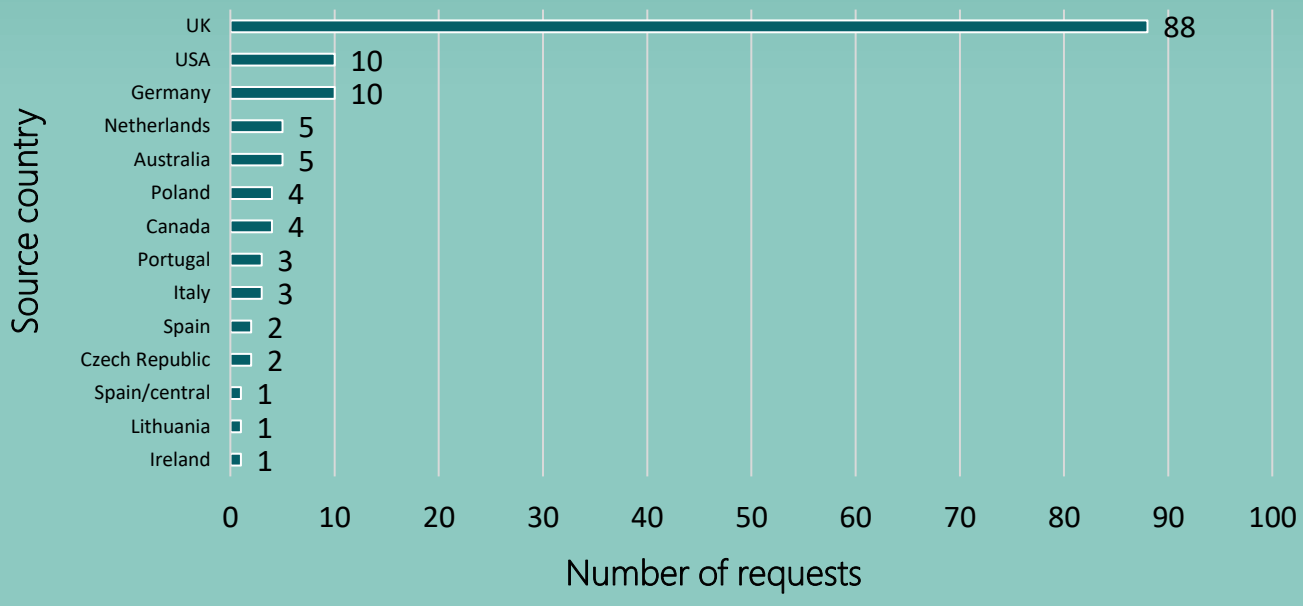
Article 20 Key Figures

Q3-2021

Number of Article 20 exemption requests approved per month, May-August 2021 (N=139)



Source country for approved Article 20 exemption requests, May-August 2021 (N=139)



Biosimilars

A biosimilar is a biological medicine which is highly similar and has the same standards of pharmaceutical quality, safety and efficacy when compared to another already approved biological medicine (the 'reference medicine'). Biological medicines comprise of active substances which are derived from a biological source including living cells or organisms (human, animals, and microorganisms such as bacteria or yeast). These are often produced by cutting-edge technology which poses no unreliability risks to users. In fact, biosimilars may be substituted for the reference product without alternating the safety and efficacy risks. Biosimilar medicines are used to treat patients with chronic and disabling conditions including diabetes, autoimmune diseases, and cancers and are expected to produce the same clinical result as the reference product in any given patient. Examples of biological medicines which were approved by the EU include Insulin, Growth Hormones and Monoclonal Antibodies.

Since 2006, sixty-nine (69) biosimilars have been approved by the European Medicines Agency (EMA). The EMA is responsible to evaluate most applications to market biosimilars in the European Union (EU). Biosimilars can be authorised in the EU once the period of data exclusivity on the 'reference medicine' has expired. Applicants are required to demonstrate, through comprehensive comparability studies, that the biosimilar medicine has the same structure, similar pharmaceutical quality, safety and immunogenicity profile, biological activity and efficacy; and that there are no clinically meaningful differences when compared to the reference medicine in terms of the safety, purity, and potency of the product.

Currently most biological medicines in clinical use, contain active substances which are made of proteins which can be of different sizes and structural complexities varying from simple proteins such as insulin or growth hormones, to more complex proteins including coagulation factors or monoclonal antibodies. Figure 1 shows the development and manufacturing processes to produce and purify biopharmaceuticals, both biosimilars and novel biologics, which involve well-controlled, complex operations.

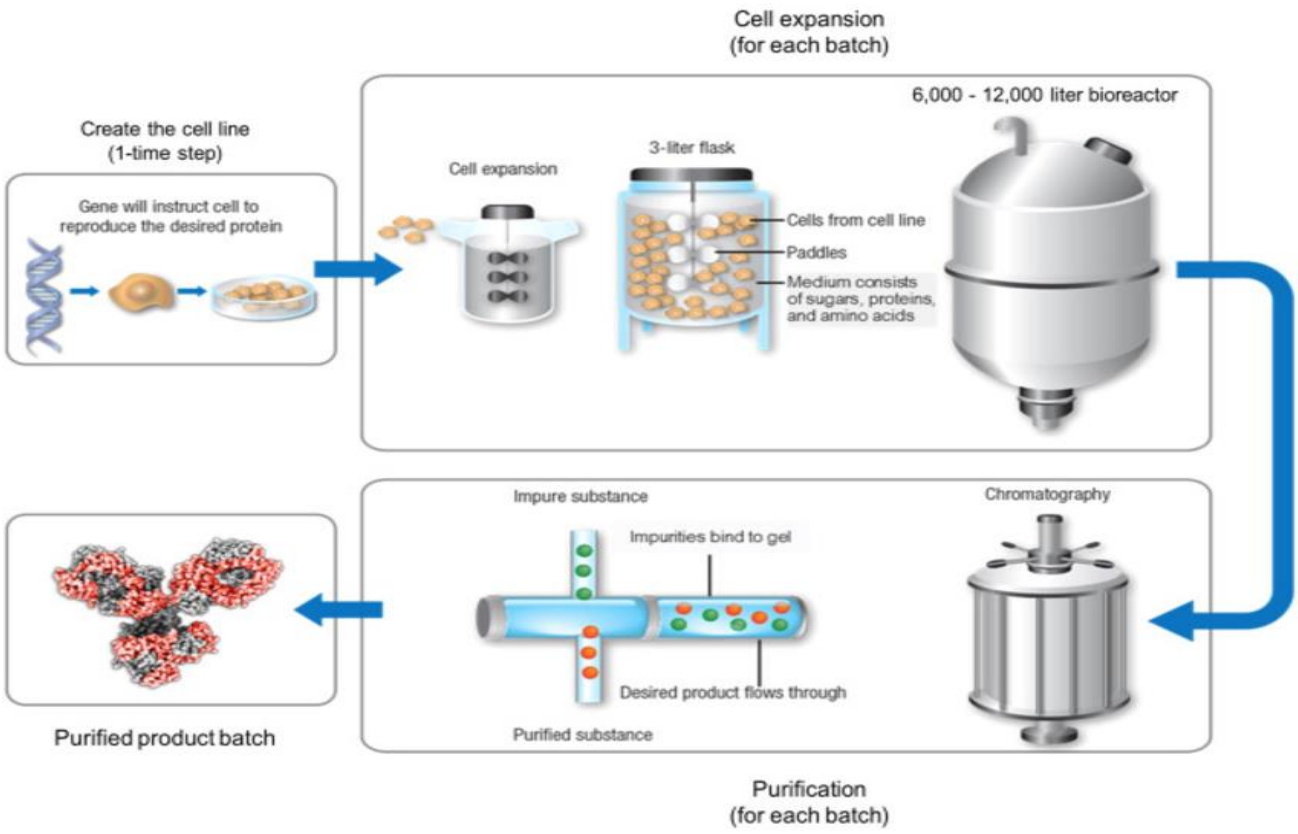


Figure 1: The development and manufacturing processes to produce and purify biopharmaceuticals, both biosimilars and novel biologics, which involve well-controlled, complex operations. *Source: Ahmad AL-Sabbagh MD, Ewa Olech MD, Joseph E. McClellan PhD, MBA, Carol F. Kirchhoff PhD, Development of Biosimilars. https://www.researchgate.net/publication/291417614_Development_of_Biosimilars*