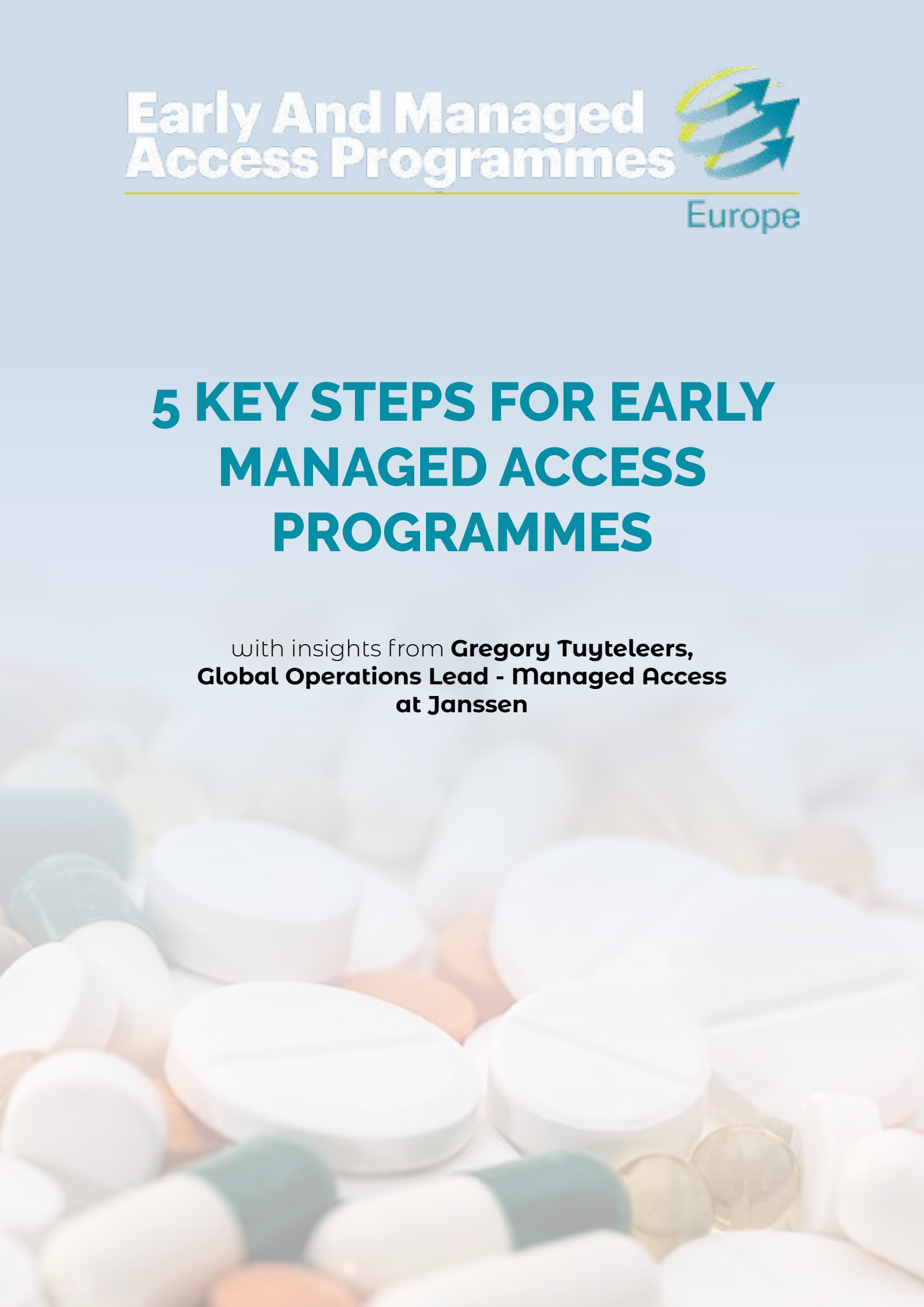
Early And Managed Access Programmes Europe

5 KEY STEPS FOR EARLY MANAGED ACCESS PROGRAMMES

with insights from **Gregory Tuyteleers, Global Operations Lead - Managed Access at Janssen**



INTRODUCTION

Pharma IQ spoke to **Gregory Tuyteleers, Global Operations Lead - Managed Access at Janssen** regarding his recommendations for the “5 Key Steps for Early Managed Access Programmes”.

Ahead of the Early Managed Access Programmes event Greg leads us through crucial considerations such as; the need for a governance body and adopting a company-wide approach to early access and more. Greg also gives his advice regarding compliancy with EMAP’s regulations from country to country.

Step 1 – A Company-Wide Integrated Managed Access Strategy

To manage your EMAPs effectively there needs to be a clear and transparent framework that defines how you as a company will handle incoming managed access requests. As part of that framework it's important that it includes key guiding principles and criteria against which the company can assess requests in a transparent and consistent way.

There needs to be a uniform approach within the company to handle managed access requests. If you don't have key guiding principles and criteria for your assessment you run the risk of not treating every access request equally and with the same rigour.

Step Two – Develop a Governance Structure

An internal committee that exists out of cross-functional experts such as regulatory affairs representatives, quality and compliance, legal, and your medical office is key to success in governing your EMAPs. It is important that such a governance body has the right experience and expertise to properly advise development teams on EMAP plans for their compounds and are able to address questions that teams might have.

A dedicated governance body can also ensure that Step 1 is being carried out in the same way across the organisation by reviewing the EMAP plans of each development team against the guiding principles and criteria.

The governance structure can also include an external advisory committee that can be consulted when needed. Such a committee could advise with the decision-making on access related questions. You never want to put patients at risk. Therefore, you need to assess each request carefully against the potential benefit and risk. Reaching out to external experts for advice might help you with your decision-making process to ensure you do the right thing for the patient in need.

Step Three – Integration of Managed Access in Clinical Development Plan

Integration of your managed access strategy into your overall clinical development plan is key to ensure early planning of EMAPs. Making EMAP plans part of the overall clinical development plan ensures full integration between the clinical trial and access options for patients not eligible for a trial. This ultimately allows you as a company to be operationally ready prior to the first early access request comes in, minimizing the access gaps for patients in need.

Step Four – Utilise an Operational Management Tool

One of the things that Janssen is leveraging is an operational management tool that allows us to track incoming requests from a physician until supply and resupply of investigational medicine to patients in need. It also allows us to automate certain things, which helps us to be more efficient.

Having the ability to monitor the status of certain programmes in real-time provides you with good oversight of what is going on and allows you to adjust your plans when needed. Certainly, when you have a centralized operations team that supports requests globally, such a tool is important.

Linked to such a tool, it is important that your operational process is mapped out step by step with clearly defined roles and responsibilities of the internal and external stakeholders involved in the process. This will allow you to know exactly how to proceed when requests from physicians come through, which is key for handling requests in a timely manner.

Step Five – Upfront alignment of the close-out strategy

It is extremely important to be transparent to the physicians upfront on what will be done when you close a certain EMAP. This to ensure patients that are in need can either transition to the commercial product, or transition to alternative therapies that can continue to help the patient.

Therefore, you need to plan your EMAP close-out strategy carefully in order to make sure that at the end of the programme, you don't put patients at risk. Due to country specific requirements, it is important to plan your close-out strategy on a country-by-country level. To give you an example, in some countries you're no longer allowed to ship clinical supplies once health authority approval is received. So you need to make sure that commercial supplies are available for these patients.

If you're not prepared for that, you run the risk of not being able to guarantee treatment continuation for the patients.

CONCLUSION

One of the key trends across these 5 Key Steps for Early Managed Access Programmes is early communication and transparency. Being transparent with physicians upfront regarding what will be done when you close a certain EMAP is key to ensuring patient safety. Moreover, early and clear communication whether using an operational management tool or ensuring your managed access strategy is in your clinical development plan early is key to saving time and ensuring full integration. Having a clear and transparent framework that can help you handle requests is key to success and also provides the basis for clear and transparent communication and work.

By following these 5 key steps you will ensure that your programme is communicated clearly and effectively and well managed which is key to its success and patient safety.