Ministry of Health, Welfare and Sport

> Return address P.O. Box 20350 2500 EJ The Hague

Stella Kyriakides
Commissioner for Health and Food Safety
European Commission
Wetstraat 200
1049 BRUSSELS
Belgium

Address for visitors:
Parnassusplein 5
2511 VX The Hague
T 070 340 79 11
P.O. Box 20350
2500 EJ The Hague
www.rijksoverheid.nl

Our reference
3623792-1050203-GMT

All correspondence addressed to the postal address quoting date and reference of this letter.

Date 14 JULI 2023
Subject Obstacles for relieving medicine shortages and an opportunity for sustainability

Dear Commissioner Kyriakides,

European cooperation is of utmost importance in safeguarding the pharmaceutical supply within Europe and ensuring the safe use of medicines for our patients. As we move forward, I see promising opportunities for cooperation in crucial areas, such as the sustainability of our healthcare system. The Falsified Medicines Directive (FMD) stands as a commendable example of collective efforts in effectively creating a pharmaceutical supply chain resilient against the unwanted intrusion of falsified medicines. While the FMD has been effective in combatting counterfeit medicines, it can also present limitations in addressing drug shortages and reducing pharmaceutical waste.
In this letter would like to share my concern for the pressing issue of critical drug shortages and the unnecessary disposal of valuable and costly medicines.

The FMD plays a crucial role in ensuring safe medicine usage within the European Union. Its stringent traceability requirements provide assurance to both patients and healthcare providers regarding the authenticity of medicines and their adherence to European quality standards. However, in its efforts of securing our pharmaceutical supply chain, the FMD leaves no possibility of utilizing unused medicines that have been returned to the pharmacy and are still of high quality. Despite being returned within their expiration date, in good condition, and in their original packaging, these medicines currently have to be discarded. This stands in contrast with the current unprecedented medicine shortages. On top of that we strive to adhere to our climate objectives such as reducing medicinal waste. Given these factors, I believe it's necessary to assess whether the limiting aspects of the FMD are still in line with the challenges we face.

In my view, the implementation of controlled re-dispensing of returned medicines could partly address these challenges. It is possible to implement re-dispensing in a safe and well-structured manner.

This view is supported by the preliminary results of a study I commissioned in response to the Dutch public and parliament's desire to explore the possibilities of re-dispensing returned unused medicines. This study aims to demonstrate that

DG Curative Care
Department of Pharmaceuticals and Medical Technology

Our reference
3623844-1050203-GMT

controlled re-dispensing of oral oncolytic medicines not only effectively reduces waste but also generates substantial cost savings without compromising patient safety.[1]

I understand and acknowledge that the stringent regulation of the FMD is highly valued within the European Union. I have no intention of altering the core functionality and purpose of the FMD. It is important to clarify that the objective is not to establish an infrastructure for widespread re-dispensing of all returned medicines. Rather, the goal is to examine and define conditions and circumstances under which re-dispensing could be a safe and beneficial option. In my opinion, adopting a sustainable approach to managing our pharmaceutical supply chain is indispensable for ensuring the future resilience of our healthcare system. Therefore, we should discuss how to establish a legal basis to act in urgent situations and in cases where the waste of high quality medicines could be prevented in a safe and effective manner. This way, re-dispensing medicines could be authorized in a situation of critical shortages or other foreseeable situations.

In conclusion, the European legislation is designed to ensure the authenticity of medicines within Europe. However, considering prevailing global medicine shortages, escalating healthcare expenses, and the adverse effects of wasted medicines on our climate objectives, I want to initiate a dialogue over the possibilities to re-dispense medicines under stringent conditions. By establishing a legal framework, countries could take it upon themselves to act on this opportunity. It is needless to say that the fundamental principles of the FMD should not be compromised, and the aim is to strike a balance that allows the exploration of this possibility without undermining the valuable aspects of the FMD.

I hope you will consider this as a topic for your agenda, allowing us to start a constructive dialogue about this subject in Europe.

Yours sincerely,

Ernst Kuipers
Minister of Health, Welfare and Sport

[1] This study is currently under review and will be shared upon its publication.