PSUR4doctors

I am an actively practising physician of the European Union and thus politely request an ASK number concerning an expedited access to all available PSURs and its pertinent assessment reports regarding Covid-vaccines (List of critical medicines for COVID-19 public health emergency (PHE) under Regulation (EU) 2022/123) as part of Good Pharmacovigilance Practices (GVP).

This request is concomitantly sent to you by several venerable colleagues of mine throughout the Union on an individual basis, as all of them are entitled and obliged with the same Union rights, obligations and duties. The simultaneous individual requests of a relatively small cohort of European medical professionals on a Union-wide geographical scope shall confirm the urgency and seriousness of this request upon the following factual and legal reasoning:

We, a group of medical doctors, bear a superior responsibility in the administration of Covid- vaccines. According to their authorisation status, physicians are in the unique position to exclusively 'prescribe' Covid- vaccines which neither can be self-administered by patients nor prescribed by marketing authorisation holders or governmental directives.

This very fact implies that the currently applicable scope and extent of the "summary of product characteristics"(Annex 1) as well as the "labelling and package leaflet" (Annex 3) sets the legal frame for medical liability issues. Given the extremely high vaccination rate throughout Europe, we, as physicians, are routinely confronted with the medical treatment of Covid-vaccinated patients, including pharmacovigilance issues.

Therefore, every actively practicing physician has to individually assess the health status of a patient against the eventual causality of an adverse reaction following a Covid-vaccination. This requires an up-to-date knowledge of the "summary of product characteristics"(Annex 1) as well as the "labelling and package leaflet" (Annex 3) of the pertinent marketing authorization as annexed to the Commission's implementing decision as integral part thereof.

Generally, the reporting of adverse reactions by healthcare professionals is in most EU jurisdictions not discretionary but a legal obligation and failure to comply is subject to criminal sanctions giving effect to Art. 102 lit. a Directive 2001/83.

Incomprehensibly, your agency stopped the monthly-safety-updates of Covid-vaccines by the end of 2023. Thereby, you ignore that the pharmacovigilance reporting obligations challenge physicians because there are no study results for long-term consequences available due to the initially conditional marketing authorization based upon Art. 14-a Regulation No 726/2004. In the absence of a long-term adverse reaction profile, the reporting of adverse reactions and the assessment of causality is severely impeded in case the adverse reaction is time-delayed. This fact necessitates access to a detailed level of safety data as provided in the PSURs.

At the same time, the Covid-vaccines are all subject to additional monitoring which aims to enhance adverse drug reaction (ADR) reporting for medicines for which the clinical evidence base is less well developed. The main goals are to collect information as early as possible to further inform the safe and effective use of these medicines and their benefit-risk profile when used in everyday medical practice.

Against this background and the exceptional transparency measures taken for Covid-vaccines, Doc. Ref. EMEA/743133/2009, we, the physicians, are the exclusive pathway for a functional and effective pharmacovigilance system and thus enjoy an inalienable right to an increased access of the Covid-vaccine PSURs, which comprise the safety data on a detailed level.

In addition, physicians – as Union citizens - concomitantly enjoy the fundamental right of access to documents held by EMA, acc. to Art. 42 CFR and provided under Regulation No 1049/2001. Nonetheless, we would like to turn your attention to very fact, that this request shall not be queued in accordance with the regular access to documents procedures and the timeline for granting access shall not be extended by EMA unilaterally. As the request is initiated by physicians who face the legal obligation under criminal sanction to report and additionally monitor adverse events of Covid-vaccines, EMA has no right to invoke the principle of proportionality due to an alleged administrative overload, as set out in the EMA Policy on access to documents.

This request stems rather from the Union legislation and GVP which provided physicians with an increased level of access to safety data on a detailed level for medically prescribed, additionally monitored drugs and thus, addresses the aim of drug safety. As already outlined above, the mass-exposition of first-in-humans applied gene-based immunotherapies for infectious diseases without empirical values and study results regarding the potential long-term health problems necessitates access to all available data regarding the safety of Covid vaccines.

Given the very fact that the documents are all available within the PSUR Repository and are owned by EMA, it is of no administrative burden, timely or costly to electronically provide these safety documents for pharmacovigilance purposes while demonstrating the safety profile to physicians that are mandated to prescribe, evaluate contra-indications and assess adverse reactions on a daily base in the course of treating their patients. To safe time for physicians who are at the frontline of public health and the pandemic, we suggest to make the PSURs available

Because the Commission's implementing decisions authorizing Covid-vaccines are considered regulatory acts which are of direct concern to physicians without entailing implementing measures, we are kindly informing you that this request is concomitantly serving the aim of issuing a position within the meaning of Article 265, para. 2, TEU before commencement of proceedings that allow your officers to make a concrete examination of the content of the requested decision. If access is not granted as requested despite the facts stated above, we kindly inform you about the intention of brining a legal action in accordance with Art. 265 TEU. However, we are certain that no legal action will be necessary for pharmacovigilance purposes in the interest of public health and safe Covid-vaccines.

Thank you very much in advance for electronically providing us access to all available PSURs and its assessment reports in the same numerical order as indicated on the List of critical medicines for COVID-19 public health emergency (PHE) under Regulation (EU) 2022/123 through an unrestricted online access for all European physicians, comprising the ones who are not part of these parallel requests.

In anticipation of a timely reply, yours sincerely,