MINISTERSTVO ZDRAVOTNÍCTVA SR
podateľňa 1

Došlo: - 6 -03- 2020

Ev.č.záznamu: ZO 1348 | Č.spisu:

Prílohy/listy: | Vybavuje:

GlaxoSmithKline Consumer
Healthcare Slovakia s. r. o.

Galvaniho7/A
821 04 Bratislava
Slovak Republic

Tel.: +421 2 48/26 1111
Fax: +421 2 4826 1110
www.gsk.com, www.gsk.sk

Ministerstvo zdravotníctva SR
Podateľňa
Limbová 2
837 52 Bratislava 37

VEC: Oznámenie o zriadení Informačného systému pre mimoriadne objednávanie liekov

Vážené dámy, vážení páni,

v zmysle ustanovenia § 60 ods. 1 písm. ae) Zákona č. 362/2011 Z.z. v znení Zákona č. 306/2016 si Vám dovoľujeme oznámiť údaje o Informačnom systéme na mimoriadne objednávanie liekov spoločnosti GlaxoSmithKline Consumer Healthcare Slovakia s.r.o., Galvaniho 7/A, Bratislava pre nasledujúceho držiteľa registrácie humánneho lieku Pfizer Corporation Austria Gesellschaft m.b.H, Floridsdorfer Hauptstrasse 1, 1210 Viedeň, Rakúsko.

Údaje o informačnom systéme na mimoriadne objednávanie liekov:

www.isliek.sk

Záložné riešenie pri výpadku informačného systému je vo forme emailovej adresy:

objednavky@isliek.sk

S pozdravom

PharmDr. Simona Kukučová
QA Operations Manager/Qualified Person

GlaxoSmithKline Consumer Healthcare Slovakia s. r. o.

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VEC: Predloženie plnej moci

Touto cestou predkladáme plnú moc od držiteľa povolenia na uvedenie liekov na trh pre spoločnosť GlaxoSmithKline Consumer Healthcare Slovakia s.r.o.

Ak máte akékoľvek otázky, neváhajte nás kontaktovať,

S úctou

PharmDr. Simona Kukučová

QA Operations Manager/Qualified Person

GSK Consumer Healthcare Slovakia s.r.o.
Email: simona.x.kukucova@gsk.com
Mobile: +421 905 685 122

Power of Attorney

THIS POWER OF ATTORNEY given by ***Pfizer Corporation Austria Ges. m.b.H., having registered office at Floridsdorfer Hauptstrasse 1, 1210 Vienna, Austria, company number: 12 68 44 k*** (the "Company") WITNESSES as follows:

1. **Appointment**

The Company appoints **GlaxoSmithKline Consumer Healthcare Slovakia, s.r.o., Galvaniho 7/A 821 04 Bratislava, Slovakia, Identification number:** 46760873 (the "Attorney") to be its attorney to the acts and things specified in Clause 2 on its behalf.

2. **Authority**

The Attorney has authority to act in the Slovakia on the Company´s behalf with the State Institute for Drug Control, the Ministry of Health and all other appropriate regulatory authorities ("Regulatory Authorities") to take all actions within the following administrative proceedings held by the Regulatory Authorities:

- **all administrative proceedings related to quality, manufacturing and distribution of the Products in the territory of the Slovakia, and**
- **all administrative proceedings related to emergency system pursuant to Sec. 60 Para. 1 letter z), aa), ab) and af) of the Act No. 362/2011 Coll. on Medicines and Medical Devices, as amended**
- **all administrative proceedings related to setting up reimbursements and maximum prices for the Products in the Slovakia,**
- **all administrative proceedings to represent the Company before the National Health Information Centre in the Slovak republic**

including the following actions within the above-mentioned administrative proceedings:

2.1 negotiations with Regulatory Authorities;
2.2 signing application forms including any other necessary documents in order to submit applications for setting up reimbursements and maximum prices of the Product;
2.3 signing application forms including any other necessary documents relating to quality, manufacturing and distribution of the Products;
2.4 submitting all documents, data, samples and other relevant documents and materials related to the Products to the Regulatory Authorities, including appeals to decisions of the Regulatory Authorities;
2.5 submitting all reports and notices relating to supplies and distribution of the Products in the Slovakia, such as notices of interrupting supplies and distribution, initiating of supplies and distribution,
2.6 all applications and documents related to manufacturing authorisation connected to the Products and any applications for decisions and actions of the Regulatory Authorities under Section 13 par. 2 of the Act on Drugs, including all notices and reports relating to complaints, claims, quality, manufacturing, distribution and supplies of the Products;

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Handelsgericht Wien
DVR: 00 40 79 7

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