NOTIFICATION TO THE CHMP/EMA SECRETARIAT OF A REFERRAL UNDER ARTICLE 30 OF DIRECTIVE 2001/83/EC
E-mail: ReferralNotifications@ema.europa.eu

This notification is a referral under Article 30 of Directive 2001/83/EC to the CHMP made by Marketing Authorisation Holder MAH:
VARILRIX

THIS NOTIFICATION IS TO BE COPIED BY THE REFERRING PARTY TO APPLICANT/ MARKETING AUTHORISATION HOLDER AND ALL CHMP MEMBERS

Product Name	VARILRIX and associated names *See Annex I*
Active substance(s)	Live attenuated varicella virus (OKA strain)
Pharmaceutical form(s)	Powder and solvent for solution for injection
Strength(s)	Varicella virus (OKA strain): $\geq 10^{3.3}$ plaque forming unit(s)
Route(s) of administration	Subcutaneous use Intramuscular use *See Annex I*
Presentations	Powder and solvent for solution for injection in ampoule Powder and solvent for solution for injection in pre-filled syringe (PFS)
Applicant(s)/Marketing Authorisation Holder(s)	See Annex I
Harmonisation of Summary of Products Characteristics (SmPCs) for VARILRIX and associated names: For its Varicella vaccine (live, attenuated), VARILRIX (and associated names), GlaxoSmithKline Biologicals (GSK Bio) intends to initiate a Community referral	

procedure under Article 30(1) of Directive 2001/83/EC to harmonise the SmPCs across EU, Iceland, Norway and United Kingdom (UK).

VARILRIX is authorised in 21 EU countries, as well as Iceland, Norway and UK (reference is made to Annex I) via purely national procedures.

Having analysed the available English translations of national SmPCs for this product, the Company identified the divergencies and has come to the conclusion that the above-mentioned medicinal product VARILRIX (and associated names), does not have the same SmPCs across all EU Member States/ Iceland /Norway/UK where it has been authorised with respect to indication, method of administration, contraindications, special warnings and precautions for use, interactions with other medicinal products, pregnancy and lactation, undesirable effects and pharmacodynamic properties.

The following examples constitute a non-exhaustive list.

4.1 Indications

The Company proposes a lower age limit of 9 months for *Varilrix* vaccination as approved in 12 EU National Product (NP) SmPCs (AT, CZ, DK, HU, IS, LT, LV, NO, PL, RO, SE, UK). Ten countries have a lower age limit of 12 months in the indication, i.e., BE, CY, EE, FI, FR, GR, IT, LU, MT and PT, whereas in DE and ES, vaccination from 9 months of age is only allowed under specific circumstances.
A detailed overview of the indication in healthy subjects in the V EU NP SmPC of each Member State is provided in the Table "*V EU NP SmPC comparison for Article 30 referral procedure*" provided along this document.

4.2 Posology

Method of administration

The Company is proposing to include the intramuscular (IM) route of administration in addition to the subcutaneous (SC) route of administration in Art 30 harmonised SmPC as currently only approved in Germany.

All other EU countries have only the SC route of administration in their national SmPC.

4.5 Interaction with other medicinal products and other forms of interaction

In most currently approved EU NP SmPCs, only a broad statement that *Varilrix* can be administered at the same time as any other vaccine is included in this section.
At this instance, it is the Company's preference to be more specific what is meant by "any other vaccine". It is considered to be valuable information to the HCPs and patients to be informed on the precise list of vaccines that can be given concomitantly. Hence, the Company pro-actively proposes to provide the available co-administration studies to update this section of the Art 30 harmonised SmPC, based on scientific evidence.
Therefore, to harmonise the SmPC wording across EU NP countries the Company proposes to provide immunogenicity and safety data from clinical studies where varicella-containing vaccines were co-administered with other vaccines.

Discrepancies between Member States also exist regarding sections:

- 4.3 Contraindications
- 4.4 Special warnings and precautions for use
- 4.6 Fertility, pregnancy and lactation
- 4.8 Undesirable effects
- 5.1 Pharmacodynamic properties

for which no detailed overview is provided above.

Due to the divergent national decisions taken by Member States concerning the authorisation of the above-mentioned product, Marketing Authorisation Holder notifies the Agency of an official referral under Article 30 of Directive 2001/83/EC in order to resolve divergences amongst the nationally authorised SmPCs for the above-mentioned product and thus to harmonise its divergent SmPCs across the EU countries Iceland, Norway and UK.

Signed

[redacted]

Date

29 May 2020