Draft Minutes for Reclassification application (Type II major reclassification P-GSL, [redacted]
Agenda Item 5.1

5.1.1 The EAG was informed that the agency had received an application to reclassify [redacted] from P to GSL.

Complex messaging

5.1.2 The EAG highlighted that there are numerous and complex messages to convey to women when supplying [redacted] including warnings and advice to maximise the efficacy of the medicine.

5.1.3 The EAG also highlighted that in comparison, [redacted] However the EAG noted that the [redacted] application must be considered on its own merit and [redacted]

Label

5.1.4 The EAG noted that the GSL availability of [redacted] would be challenging as it would be difficult to include all essential information on the medicine label. It was acknowledged that whilst the general safety profile of [redacted] is accepted and well established in the P setting, it was likely that the information on the medicine label could be missed or misunderstood in the GSL setting in the absence of a healthcare professional. This could result in a reduction in the effectiveness of the medicine and possibly an unintended pregnancy.

5.1.5 The EAG considered that there was scope for making the information on the medicine label more accessible, for example by using a QR code.

Access

5.1.6 The EAG considered that the increased access to [redacted] as a GSL medicine could be beneficial to some women, particularly if pharmacists are not always available to supply emergency hormonal contraception in a pharmacy. It was also considered that access through pharmacies via a healthcare professional can be limiting for some populations who prefer not to have a consultation, such as young adolescents. It was highlighted that for some women, the consultation with a healthcare professional such as a pharmacist in the supply of [redacted] can feel intimidating or embarrassing.

5.1.7 The EAG acknowledged that many pharmacies are open for long hours, [redacted]

5.1.8 The EAG highlighted that the GSL availability of [redacted] could still limit accessibility for those unable to afford to pay.

5.1.9 The EAG considered that the increased access as a result of the GSL availability of [redacted] was unlikely to affect abortion rates.

5.1.10 Overall the EAG considered that whilst an improvement in access to the medicine could be beneficial for some populations, the complexity of supplying [redacted] in current practice and the risks associated with the GSL availability of the medicine outweighs this potential benefit.

Role of the pharmacist

5.1.11 The EAG noted the role of the pharmacist in the supply of [redacted], in particular the importance of ascertaining whether the medicine is suitable for the woman. The EAG highlighted that the absence of a pharmacist in the supply of [redacted] would remove the opportunity to discuss other contraceptive options such as the copper intra-uterine device which is the most effective method of emergency contraception.

5.1.12 The EAG considered that in general, there was a benefit in having a consultation with a pharmacist or pharmacy staff before being supplied with [redacted] In particular, the EAG highlighted that pharmacists assess each request for emergency hormonal contraception individually, and as such can tailor advice according to their requirements. It was considered that the information on the label could not replace the role of the pharmacist in this aspect. The EAG highlighted that consultations can provide an opportunity to identify whether the medicine is suitable, provide advice on regular contraception, advise on any action to be taken after taking the medicine, e.g. if a pregnancy occurs, and check whether there is a safeguarding concern.

5.1.13 The EAG highlighted that if [redacted] was approved as a GSL medicine, there would still be an opportunity for women to seek advice from a healthcare professional if they had any concerns about the medicine.

Safeguarding

5.1.14 The EAG acknowledged the lost opportunity to safeguard the public as a result of the GSL availability of [redacted] It was considered that the information related to safeguarding on the medicine label was limited, and whilst further information in the patient information leaflet was included on domestic violence and abuse, this was not sufficient to safeguard vulnerable populations.

5.1.15 The EAG noted that there are already other services and campaigns to enable victims of domestic abuse to access help from the police or other support services from their local pharmacy.

5.1.16 The EAG highlighted that the availability of data related to safeguarding concerns raised in pharmacies during requests for emergency hormonal contraception would be useful to establish whether safeguarding concerns are currently dealt with by pharmacists. However, the EAG noted that the absence of this data does not imply that the lost opportunity to safeguard women in a GSL setting is not important.

Unintended pregnancies

5.1.17 The EAG considered that the self-selection of [redacted] through retail outlets could result in important information being missed, which could result in an unintended pregnancy. The EAG considered there to be a risk that women could be provided with a false reassurance if the medicine is taken incorrectly and does not have its intended effect (to prevent a pregnancy).

5.1.18 The EAG highlighted that the availability of data related to unintended pregnancies resulting from the incorrect use of [redacted] would be useful to determine whether there has previously been a barrier to obtaining an effective method of emergency contraception.

5.1.19 Overall, the EAG considered that [redacted] is not suitable for reclassification from P to GSL. The EAG noted that the general safety profile of [redacted] was

acceptable, however the risks associated with the GSL availability of [redacted] were considered to outweigh the possible benefits including increased accessibility and convenience. The EAG considered there to be a risk of incorrect use which could reduce the effectiveness of the medicine. This could provide a false reassurance to women who may consider that the medicine has been effective. The EAG also considered that due to the complex messaging associated with [redacted] and the potential loss of safeguarding opportunities it would not be a suitable candidate for a GSL medicine.