New Drug Safety Signal Guidance from Swissmedic.

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EXECUTIVE SUMMARY

Swissmedic released a new "Guidance document Drug Safety Signals HMV4", effective January 1st, 2019.* This guidance introduces a timeline for the submission of labeling updates for all products with marketing authorization in Switzerland, if the MAH identifies a new safety signal (nationally or internationally) that does not qualify to be processed as emerging safety signals but still necessitates a change to the product information. The timeline is 6 months from Day 0, which is the day of closure of the signal evaluation by the MAH.

The guidance does not specify what constitutes the closure of the signal evaluation. Be aware that Day 0 may not be the day of the corresponding core labeling decision but a day further upstream.

SWISS TIMELINE DIFFERENCES FROM EU GVP MODULE IX

The Swiss guidance and its implementation timeline concerns all products with marketing authorization in Switzerland and labeling changes resulting from safety signals of any origin. This is different from the EU GVP Module IX R2 timeline requirements, which concern only the subgroup of products registered in the EU that carry an inverted black triangle and only labeling changes resulting from safety signals identified from the Eudravigilance database. Also, the Swiss guidance does not differentiate between labeling updates for important risks (to be submitted within 3 months) and non-important risks (to be submitted within 3 months).

NECESSARY CONFIGURATION CHANGES

The Regulatory KPIs functionality in GDT 6.1, RMT 2.1 can be configured to comply with the Swissmedic drug safety guideline. The configuration can be done in two steps:

Create a new Reporting Country Group under Site Admin>Country>Reporting Country Group that has only Switzerland in it

Create a new Regulatory KPI that spans from what your system considers to be Day 0 to your Health Authority submission date. Assign the new Reporting Country Group that you created in step 1 to this Regulatory KPI and assign the KPI days to be 180

Log off the system to complete the configuration changes. You will be able to add your new Regulatory KPI to new records going forward as well as already existing records.

CONCLUSION

The new drug safety guidelines from Swissmedic impose a 6-month timeline between Day 0 and Heath Authority submission for Labeling changes resulting from new safety signals that do not qualify to be processed as emerging safety signals. GDT 6.1, RMT 2.1 contains the necessary functionality to comply with this new guideline for both new and existing records. This software update will be released in Q1 2019.

REFERENCES

Swissmedic Guidance document on Drug Safety Signals (01-01-2019)

EMA Module IX on Signal Management (22-11-2017)

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