Updating National Licenses for the EAEU.

EXECUTIVE SUMMARY

The Eurasian Economic Union (EAEU) is making changes to registrations starting in 2021. Previously, pharmaceutical companies were allowed to register items at the national level or with the EAEU. Starting in 2021, all national licenses will need to be re-registered with the EAEU by the end of 2025.

IMPACT ASSESSMENT

First, we will look to determine if any of the Country Dependencies will need to be changed with the new registration rules. Run the Country Dependency List report from under the Admin section using the following search parameters. For any search parameter not listed here, please use the system default:

Country: Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russia

Record Type: Active Records *see footnote

Review these records and compare them to the current plan for registration submission to the EAEU. The Reference Member State (RMS)/Reference State that was selected on your application should be the Dependent On Country listed in column J. Note, if you do not see one of the countries listed above in the report, it does not have any active dependencies.

Next, we will determine if any current tracking items are impacted. Run Country/ Product Tracking Item List & Statistics report under the System section using the following search parameters. For any search parameter not listed here, please use the system default:

Country Type: use Country for country tracking systems, and use Sub Country for sub country tracking systems

Country: Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russia

Tracking Status: Waiting

Record Type: Active Records

All of the records in the report will be items that are either waiting to start work, or waiting for Heath Authority Approval. The easiest way to tell the difference is to use the Next Milestone column (O) to see if the item is waiting for Health Authority Approval. Records that are not already waiting for Health Authority Approval will need to be reviewed.

UPDATES FOR NEW TRACKING ITEMS

The Country Dependency records will need to be updated to match the new RMS in order for new Tracking Items to have the correct information going forward. To do this you will need to open each record identified in the "Impact Assessment" section above under Site Admin->Country>Country Dependency and update the Dependent On Country field with the new RMS.

Once you've completed all of your changes, run the Country Dependency List report from under the Admin section using the following search parameters. For any search parameter not listed here, please use the system default:

Country: Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russia

Record Type: Active Records *see footnote

Review the report to make sure that the records have the correct Dependent On Country listed (column J).

UPDATE EXISTING TRACKING ITEMS

For records that were determined to be impacted, the Country Dependencies will need to be changed on each individual record. There are two options for updating the dependencies:

Go to the Country Administration page for each record and update the country dependency information

Use the Quick Entry Country Admin functionality to update the dependencies in bulk. Make sure you have your Country Product Tracking Item List &

Statistics sheet handy whenusing this option as you will need to group your updates by Tracking Path

Once you've completed all of your changes, run the Run Country/Product Tracking Item List & Statistics report under the System section again, using the following search parameters. For any search parameter not listed here, please use the system default:

Country Type: use Country for country tracking systems, and use Sub Country for sub country tracking systems

Country: Armenia, Belarus, Kazakhstan, Kyrgyzstan, Russia

Tracking Status: Waiting

Record Type: Active Records

Review the report to make sure that the records have the correct dependencies (column M).

CONCLUSION

Use the Country/Product Tracking Item List & Statistics report to find already existing EAEU country records. Use the Country Dependency report to determine how future records will be impacted. These two reports will give you an impact assessment that you can use as a guide for modifying records.

Existing tracking items will need to be updated by going into each record manually, or using the Quick Entry functionality to remove or replace dependencies where the RMS has been modified. Each Country Dependency record for an EAEU country will need to be manually updated to either remove or replace the dependency.

*In sub country systems prior to GDT 6.1, RMT 2.1, there is a bug (4512) prior to that release that will not contain a Dependent On Country that is at thesub country level

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