2020 Transition Period for Brexit.

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EXECUTIVE SUMMARY

The United Kingdom's official exit from the European Union happened on January 31st, 2020. From February 1st, 2020, until December 31st, 2020, the United Kingdom cannot be a Reference Member State in a mutually recognized procedure or a decentralized procedure. This white paper contains instructions for how to complete an impact assessment in the GDT Tracking Portal for records that are directly impacted by the EMA's guidance for the transition period in 2020.

IMPACT ASSESSMENT

You'll need to run a few reports in your system in order to understand the full impact on your current tracking items and future tracking items. First, run Country/ Product Tracking Item List & Statistics report under the System
menu 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:** add the 27 remaining member states
- **Tracking Status:** Waiting
- **Record Type:** Active Records

Look for records that are dependent on the United Kingdom. These will need to be updated for the transition period. Information about how to update these impacted records can be found in the "Updating Existing Tracking Items" section.

The second part of the assessment is looking at what configuration records need to be updated. To do this, you'll need to run the Country Dependency Report for your system to determine which configuration records are impacted. For any search parameter not listed here, please use the system default:

- **Dependent On Country:** United Kingdom
- **Record Type:** Active Records

Look for records that are member states of the EU. These are impacted by the transition period and will need to be reviewed by the business so that a new RMS/ Dependent On Country can be selected.

UPDATING EXISTING TRACKING ITEMS

The EU member state records that are dependent on the UK will need to have their country dependencies replaced by a different country. 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 when using this option as you will need to group your updates by Tracking Path

Once these changes have been completed, run Country/Product Tracking Item List & Statistics report under the System menu 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:** add the 27 remaining member states
- **Tracking Status:** Waiting
- **Record Type:** Active Records

Review the report to make sure that none of the records are waiting due to a dependency on the United Kingdom in Dependencies (column M).

UPDATES FOR NEW TRACKING ITEMS

If your system gets its MRP and DCP dependencies from a Data Integration job, you will need to make the changes to the dependency records in your source system. You can use the files created in the "Impact Assessment" section to locate the records that need updating. If your MRP and DCP dependencies are maintained in the Tracking System, please use the following instructions.

When a new Tracking Item is created, it looks at what Country Dependencies are applicable for that Product in the Site Administration menu. Any MRP or DCP dependencies where the UK is the RMS/Dependent On Country will need to be replaced by another country. A manual update will need to be made for each record that was flagged during your impact assessment. Open each record under the Site Admin>Countries>Country Dependencies menu and do one of the following actions for each product that had an MRP or DCP dependency flagged:

- Update the Dependent on Country dropdown box with the new Dependent On Country

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

- Dependent On Country: United Kingdom
- Record Type: Active Records

Review the report to make sure that none of the records have the UK listed as their Dependent On Country (country or sub-country records). Remember that there are 5 columns in the report that contain Reference Countries: Dependent on Country (column J), Dependent on Country 2 (column K), Dependent on Country 3 (column L), Dependent on Country 4 (column M), and Dependent on Country 5 (column N).

Lastly, the business will need to decide what to do with the UK records that were RMS/De2 pendent on Countries. If the business decides that these records are now independent/national, no further changes are needed. If the business decides that the records need to be dependent on a country, a new Country De - pendency record will need to be created under Site Admin or in your source system if the MRP and DCP information comes from your Data Integration job.

CONCLUSION

Use the Country/Product Tracking Item List & Statistics report to find already existing EU member state records that are dependent on the UK. 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 in the UK. Each Country Dependency record where an EU member state is dependent on the UK as an RMS will need to be manually updated to either remove or replace the dependency. Since the UK can no longer be an RMS, the business will need to decide if the record should be left as independent or to create a new dependency record for the UK.

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