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UKRAINE IMPROVES FAST-TRACK REGISTRATION PROCEDURE FOR MEDICINES FROM US, CH, JP, AU, CA, EU

On November 24, 2017 the improved Procedure for fast-track registration of medicines registered in the United States, Switzerland, Japan, Australia, Canada, and the European Union (centralized procedure) became effective.

The fast-track registration procedure started working back in January 2017 but turned out to be largely ineffective in practice due to excessively high level of required similarity between the Ukrainian and the reference dossiers. As a result, the regulator in many cases had no choice but to refuse localized dossiers that had insignificant discrepancies with the reference dossiers.

Another formal issue concerned variations to registration materials previously classified under the Ukrainian legislation (while other reference countries have own classifications different from the Ukrainian one). This made any application for variations under the Procedure unworkable in practice.

KEY IMPROVEMENTS:

- Procedure now contains express provisions on acceptable discrepancies with the reference dossier, namely:

  - A different applicant and medicine trade name. Difference in trade names should be explained in writing in any convenient form.

  - Listing in localized dossier only some out of several manufacturers from the reference dossier.

  - Listing only some out of several types and sizes of primary/secondary packaging examples from the reference dossier.

  - In the name of manufacturer, its location and address of manufacturing facilities - the abbreviated names of forms and ownership types of business entities, or such names in different languages (e.g. Ltd – Limited, SA – AG,

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GmbH – BV, Inc. – Incorporated, Corp. – Corporation, S.A. – A. V. E. etc.); changed word order; zip code with and without the country identifier (e.g. LT-08409 – 08409); abbreviated medicine form in specific dossier sections (e.g. FCT – film - coated tablets), other minor technical deviations.

- The regulator now has the power to request additional information from the applicant (but only once, not to compromise the relatively short timeframe of the Procedure). Applicant has 30 days to respond. The regulator's request and applicant's response stop the clock.

- Variations to registration materials are now classified by types in the reference country (and not under the Ukrainian legislation). The respective application form has been significantly simplified and should now include a copy of the application for variations submitted in the reference country.

The improvements to the Procedure have become possible due to close cooperation of MoH with the associations of international pharmaceutical manufacturers.

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