Preparation to EAEU GMP-inspections. Industry view.

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Transition periods on regulatory procedures in EAEU

• **2.5 years (until 31.12.2020)** - registration under national procedures is allowed, followed by bringing the dossier into compliance with the requirements of the Union

• **7.5 years (until 31.12.2025)** - re-registration and amendment of the recognition according to national procedures for preparations registered under national procedures

• **7.5 years (until December 31, 2025)** - provided to bring the dossier of registered LPs by national procedures in accordance with the requirements of the Union, ie transfer to CTD format (modules 1-3) with the issuance of the Union's registration certificate and entry into the Unified Register

• **2.5 years (until December 31, 2020)** - it is allowed to provide a document confirming the GMP issued by the national authority of the EEA member states instead of the GMP of the Union

• **2.5 years (until December 31, 2020)** - the opportunity to conduct a parallel inspection of production for compliance with the GMP of the Union in the framework of registration of LP.

• **2.5 years (until 31.12.2020)** - it is allowed to provide a document confirming GMP issued by the national authority of the EEA member states and the GMP of the Union for conducting national registration procedures for the national manufacturers

Thus to date, the timing of the use of national certificates is quite limited and the industry faces a large-scale transition to the GMP of the Union, and in a very limited time
Bringing national legislation into line with the law of the Union:

- The introduction at the national level of the GMP and GDP of the Union (issues of national characteristics, for example, Russian industrial regulations as part of national legislation)
- The exclusion of the presence of 2 GMP systems within the framework of national regulations (national GMP and GMP Union)
- The introduction of inspection models in accordance with the Rules for Conducting Inspections of the Union (planned, unplanned, at the request of the regulatory body)
- Unification of procedures for inspecting residents and non-residents of the Union
- Unification of procedures with the licensing process for residents
- Certification of authorized persons of licensees according to the rules of the Union
- Implementation of the quality system of the inspectorate, compliance with the requirements for inspectors rules Union
Main points for the EAEU GMP implementation – regulatory aspects

- Revision and adaptation of a new model for the regulation of quality assurance of medicinal products:
  - Evaluation of dossier data (module 3)
  - Change in the concept of "normative document on quality"

- Questions of the national pharmacopoeia and pharmacopoeia of the Union (it is especially important in case of an inspection not by the referent state) - different Pharmacopoeia requirements for quality assurance in the territory of the Member States, absence of the Pharmacopoeia of the Union

- Accounting for the already adopted guidelines of the EAEU in the field of production
- Updating the rules of the GMP Union
Process issues stemming from the diversity of national GMP inspection practices:

- type and scope of inspection
- inspection of contract manufacturers
- classification of inconsistencies
- assessment of non-conformities and interpretation of data
- creation of a single register of GMP certificates
Frequency and reasons for repeated inspections on the example of the Russian Federation

Reasons for the repeated inspection:
- Проинспектирована ранее в рамках другого заявителя
- Расширение перечня ЛП
- После отказа
- Другие причины

Contract mfg (repeated inspection):
- Два раза
- Три раза
- Восемь раз
- Девять раз

* На основании данных мониторинга компаний-членов AIPM за 2017-18
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the system of transition to GMP rules of the Union is largely conditioned by the established model of national regulation
It is necessary to study practical issues of implementation of Union norms and interrelated regulations
it is necessary to conduct regular consultations between the inspectors of the EEA countries and the industry to develop a unified inspection model
further delay with the active transition to the requirements of the Union in the field of production of medicines creates significant risks of limiting the output of products to the market and the creation of its defectiveness in the future
delay with active transition to Union requirements in the field of production of medicines reduces the resource intensity of the inspectorate and its capacity
It is necessary to amend EEU Council Decision No. 93, extending it to all LP producers and synchronizing the transition period with the transitional period of the registration procedures, i.e. until 31.12.2025
Спасибо за внимание!