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22 December 2011

Sampled WHO prequalified anti-TB medicines show zero failure rate

Results of survey of the quality of anti-TB medicines in selected newly independent states

The results of a survey of anti-tuberculosis (TB) medicines carried out by WHO in cooperation with the ministries of health and national medicines regulatory authorities of Armenia, Azerbaijan, Belarus, Kazakhstan, Ukraine, and Uzbekistan showed a zero failure rate among WHO-prequalified samples and those supplied through the Global Drug Facility (GDF), indicating the effectiveness of WHO medicines prequalification and GDF's quality assurance policy.¹

The survey was carried out during 2009 and 2010 to investigate the quality of anti-TB medicines in light of concern that poor medicines quality could be contributing to the high burden of multidrug-resistant TB in the newly independent states of the former Soviet Union.

Medicines sampled

First-line medicines containing rifampicin and/or isoniazid, and second-line medicines containing kanamycin and ofloxacin, were collected from treatment centres, distribution warehouses and pharmacies (both public- and private-sector). A total of 291 samples produced by 33 manufacturers were collected from 84 collection sites and tested by preselected reliable laboratories according to pharmacopoeial specifications.

Survey results: both good and not so good

Following testing, no sample was suspected to be of a spurious, falsely-labelled, falsified or counterfeit product.

No quality problems were identified for the samples of kanamycin powder for solution for injection, isoniazid solution for injections or ofloxacin solution for infusion.

But 33 samples (11.3%) failed to meet the specifications set for the survey. The highest failure rate was found for mono-component products containing rifampicin — more than a quarter of rifampicin samples (28.3%) failed to meet the specifications, the predominant reason being that the active pharmaceutical ingredient content was below the acceptable limit. In addition, substantial inconsistencies in ofloxacin dissolution, as well as batch-to-batch and intra-batch inconsistencies,

¹ Available at http://www.stoptb.org/gdf/drugsupply/quality_sourcing_process.asp



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were observed. These negative results are of concern and may be due to inconsistent application of good manufacturing practices and other regulatory requirements, combined with insufficient regulatory supervision.

The fact that 88.7% of samples — including WHO-prequalified samples and those supplied through GDF — met required specifications is encouraging.

The results of the survey were analysed with representatives of participating countries. Recommendations on further steps to improve the situation are listed in the survey report which is available at: http://www.who.int/prequal/info_applicants/qclabs/quality_monitoring.htm

Efforts to promote access to quality anti-TB medicines still required

Owing to the limitations of the sampling, the survey results cannot be generalized to the overall anti-TB medicines market in the countries surveyed. And although some of the results are encouraging, others clearly indicate that further efforts are needed to ensure that TB patients in these countries are treated with quality-assured medicines

Further information:

Dr Jitka Sabartova — Email: sabartovaj@who.int