Swiss Laboratory for Doping Analyses (Laboratoire Suisse d'Analyse du Dopage)

<u>Translation of the french report : « Laboratoire d'analyse du dopage – Rapport portant sur le respect</u> <u>des règles de fonctionnement administratif dans le cadre de la lutte contre le dopage »</u>

Report on respect of the rules of administrative functioning within the framework of the fight against doping

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<u>Translator's note</u> : - report published by the competent authorities - only the french version is valid

Summary and conclusions

Summary

2.1 Foreword

The General Manager the CHUV has mandated his internal audit department (Service d'audit interne (SAI)), to perform analysis on the functioning of the Laboratoire d'analyse du dopage (doping analysis Laboratory), hereafter: laboratory or LAD). Within this framework, the SAI audited the LAD as concerns analysis of doping, with a special focus on the rules.

One of the purposes of this mandate is to permit the general management of the CHUV to take a position regarding the content of section 16 of the report published on 9 November 2015 by the independent commission (IC) of the World Anti-Doping Agency (WADA) in French "Agence mondiale antidopage". This Agency, in its findings and conclusions, called into question respect by the LAD of the rules and norms of the World Anti-Doping Agency (WADA), particularly regarding destruction of the samples analysed.

We only focused our work at the LAD for its activities of analyses of urine samples and those very closely related to this resulting from expertise obtained in this domain.

2.2 Objectives of our Investigations

As internal auditor, our controls involved the items specified hereafter:

- Examination of the framework and activities of the laboratory in its assignment of analysis of doping.
- Examination of the conditions and treatment of the special mandate entrusted by the WADA.
- Examination of the treatment of special mandates entrusted to the management of the LAD in connection with his activities of testing for doping.
- Review of the limits of the portion relative to the LAD appearing in the final report of 9 November 2015 issued by the independent Commission mandated by the WADA.

2.3 Examination of the framework and activities of the laboratory in its assignment of analysis of doping

We have focused our work on the activities of the LAD relative to anti-doping controls. In 2012 the LAD was already certified ISO 17025 and applied the norms and rules of the WADA.

According to the documents submitted, all external quality controls resulted in a rate of conformity of 100 %. The scientific work is done but finalization, in the form of quality documents, could be improved.

The internal quality messages highlight that the results could be communicated without the insurance that all formal indications are filled.

Each business relationship is, in principle, covered by a contract or agreement in proper form. However, with longstanding clients this formalism is not always respected.

2.4 Examination of the conditions and treatment of the special mandate entrusted by the WADA

The WADA entrusted a special mandate to the LAD to re-analyse 67 samples coming from the laboratory of Moscow. Execution of this was summarized in a document called "Memorandum". This document, along with its attachments, was sent to the independent Commission, mandated by the WADA.

We were able to examine all the items that were useful to our audit. The following principal aspects were revealed:

- The particular mandate for re-analysis of samples from the laboratory of Moscow was not reflected in a specific contract. The result of this is that the framework and objectives, as well as the special provisions, were not formalized.
- The WADA had never before contacted our laboratory about a similar assignment. This was carried out with a constructive mind-set, with transparent collaboration from the LAD.
- The rules of retention of at least three months, enacted by the WADA in the International Standards (ISL) were valid as of 1 January 2012. (Reference to the World Anti-Doping Code 2009 in effect). They were strictly respected. Notification that the negative samples were discarded, though not required, was sent to the scientists of the WADA. Their reaction to this item was provided too late.
- Instructions for handling of the 12 samples not analysed were requested.
- The sensitive nature of the mandate entrusted and its confidentiality reinforce the necessity of respecting the norms and rules.
- The opinion of a jurist from the WADA was requested by the LAD for the aspects of procedure concerning the samples.
- The LAD identified at least one case of manipulation, about which it informed the principal.
- The LAD respected the principles of scientific prudence regarding the limits of its investigations. It specified that its results may, if applicable, be influenced by the conditions of storing samples at the laboratory of Moscow.
- The LAD received 3,000 samples by the WADA, seized in Russia. This mandate demonstrates that

the LAD has the trust of the WADA.

2.5 Examination of the treatment of special mandates entrusted to the management of the LAD in connection with the activities of testing for doping

The ISO rules are applied for acceptance of the new mandates. A recent procedure is more precise. We have noted that it does not deal explicitly with the risks of conflict of interest.

We have not identified a procedure of notification to the WADA in case of acceptance of a mandate involving doping (consulting or coaching).

For the period that we examined for each of them, both mandates with Russia resulted in a contract established in the name of the CHUV that had proper signatures.

2.6 Review of the limits of the part relative to the LAD appearing in the report issued by the independent Commission mandated by the WADA

We examined chapter 16 of the report established by the IC. We also became familiar with the memorandum of 13 May 2015 sent to the IC, as well as its attachments.

Our investigations revealed the following items:

- The LAD received 67 samples to be re-analysed. Among these, 55 had enough urine in bottle A to proceed with the tests requested. 12 samples were kept while awaiting instructions.
- The tests on the 55 samples resulted in detection of one case of abnormal analysis, thanks to the sophisticated equipment and scientific skills of the LAD. This case was kept for at least 3 months, in conformity with the norms of the WADA.
- The LAD strictly respected the Standards of the WADA of 2012, regarding the destruction of negative samples. The LAD requested instructions for the 12 samples not analysed and indicated, in the same email, the expected outcome for the 54 negative samples. It was announced that they were discarded.
- By return email, the WADA gave its instructions regarding the 12 remaining samples without making a determination on the part dedicated to destruction of the 54 samples.
- The LAD pointed out anomalies related to 2 samples analysed among the 12. It provided all information requested from the WADA. Within this framework, the LAD clearly indicated handling by the laboratory of Moscow.
- The report includes a clear error in its conclusion since it mentions the destruction of 67 samples, although we only were able to observe "visually" that 13 had been retained.
- The investigators from the IC who came to interview the LAD did not request validation of their comprehension of the discussions. They also did not submit the content of chapter no. 16 of their report before publication. It is surprising under these conditions that the IC mentions unsatisfactory explanations.

We were also able to observe that the Director of the LAD presented all the aspects of the particular mandate that was entrusted to it by the WADA in a very transparent manner. Furthermore, this latter party confirmed its desire to continue its collaboration with the LAD, on the same bases as previously.

3. Conclusions

We are able to conclude that its administrative functioning permits the LAD to fulfil its assignment in the domain of anti-doping control. We also noted that, as of the date of our audit, the LAD continued to meet the criteria for accreditation and for ISO 17025 certification. We insist on highlighting the following two aspects:

1) Report of 9 November 2015 on the independent commission mandated by the WADA.

Our audit led us to observe that the LAD complies with the rules and norms issued by the WADA regarding the analysis of the samples, particularly regarding the aspects of their destruction. This behaviour was also adopted in the particular mandate for re-analysis of the samples from the laboratory of Moscow. Such an attitude is rendered necessary by the absence of a written mandate precisely defining the expectations of the WADA.

We must also point out that, contrary to best practices in auditing, the LAD was not able to to take a stand on the content of the portion of the report from the IC that concerned it, notably regarding the absence of instructions on the retention of samples and the objective errors that it involved. This attitude is difficult to understand due to the transparency displayed by the LAD in its communication with this IC.

2) Administrative functioning of the LAD

Our audit related to review of the functioning of this laboratory in its role in the fight against doping give us the opportunity to examine, implementation of the following improvements:

- Recording the development strategy in a reference document. In particular, to protect against the risk of inadequate resources.
- Formalizing examination of the risks of conflict of interest when accepting new mandates.
- Making sure with the international Authorities fighting against doping that regular and current communications of the consulting or coaching mandates covering this domain, correspond to their expectations.
- Proceeding with internal quality audits, based on their scheduling, in order to maintain a level of excellence that makes it possible to remain a laboratory of reference.

We specifically thank the managers of the LAD who, thanks to their availability and their helpfulness, largely facilitated execution of our assignment.

We have established this report in good faith, based on the books and documents submitted to us, verifications that we performed and information the was provided to us by the persons with whom we were in contact.

Our audit work included the procedures of verification deemed necessary, depending on the circumstances. Nonetheless, we specify that no other verifications were done besides those that were mentioned expressly in the present report or recorded in our audit notes.

We express the usual reserves in case documents, information or events which could modify our opinions were not made known to us during our work, which ended on 30 November 2015, date of the final interview. For the most part, it was presented to Mr. Saugy after our work was completed.

The project was presented for consultation with the managers of the LAD delegated by Mr. Saugy, Director, on 30 November 2015. It was discussed during a session organized on the same day. The content of it was accepted, subject to a few minor corrections.

Lausanne, 1 December 2015

Distribution

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- 1 copy Mr. Philipp Müller, Administrative and Financial Director
- 1 copy Mr. Patrice Mangin, Head of Forensic Medicine Dept.
- 1 copy Mr. Martial Saugy, Director of the analysis laboratory for doping