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## **PROJECT AGAINST CORRUPTION IN ALBANIA (PACA)**

### **TECHNICAL PAPER**

#### **COMMENTS ON INSPECTION REPORT OF THE DEPARTMENT FOR INTERNAL ADMINISTRATIVE CONTROL AND ANTI-CORRUPTION ON THE NATIONAL MEDICINES CONTROL CENTRE**

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## **Introduction/Executive Summary**

Activity 1.1 of the Workplan for the PACA extension period envisages the provision of 'an assessment (technical paper) of up to two existing assessment/s by DIACA of the vulnerability of institutions to corruption.' In September 2012 PACA was provided with a DIACA Inspection report on the National Medicines Control Centre. This Technical Paper provides an opinion on the content of the report, together with recommendations in particular on the following issues:

- The content of the report (and by implication other inspection reports)
- Broader issues of what DIACA should focus upon when it conducts such audits
- Relating to the above, concerns over the current definition of DIACA's role and function.

### **1. Background – the Inspection Report**

The Inspection Report is structured in the following order:

- A brief description of the objective of the inspection: "to check up on the administrative and legal proceedings conducted by the National Medicines Control Centre (NMCC) in granting use permits for the medicinal drugs imported and exported during the last quarter."
- A summary of the process of granting use permits (i.e. permission to sell) - from the granting of an import permit to the granting of a use permit.
- An elaboration of findings concerning individual proceedings for granting import permits and use permits for medicines during the period from July-September 2011: i) Concerning imports, a number of cases in which either applications for import permits carried no identification number of the NMCC, and/or reports on the verification of medicines contained no date, along with other missing documentation; ii) Concerning exports, a list of certain proceedings examined; the findings concerning these proceedings are not clear from the report.
- An elaboration of conclusions on the proceedings examined, namely that:
  - No clear administrative proceedings have been put in place by the Ministry of Health (as required by a 2004 law) for the NMCC to grant the relevant import, export, and use permits to the entities.
  - Violations of a Council of Minister Decision (103/1998) requiring the dating and stamping of working communications to and from state institutions.
  - 'Stamps for medicines' have been given without use permits.

- Findings from an examination of the process by which drugs registered and sold by an Italian company were deregistered, based on a complaint from the company; the findings of this are not clear from the report, namely whether the derecognition took place in accordance with the law or not.
- An assessment of a complaint lodged by an employee of NMCC concerning her dismissal and initiative from the NMCC to initiate criminal proceedings against her, with the conclusion that the proceedings were unfounded.
- Recommendations, with a ten-day deadline for the relevant institutions to provide official notice of their implementation to DIACA:
  1. The Minister of Health, pursuant to point 2 in Article 19 of Law No 9323 of 25 November 2004 'On the medicinal drugs and pharmaceutical service,' should give the relevant directions about the rules governing the granting of use permits.
  2. The Director of NMCC should issue the relevant instructions concerning the manner of acceptance of the pharmaceutical entities' applications to obtain import licenses, and the registration of the use permits in accordance with the law.
  3. The NMCC Inspection By-law, including the manner of sample-taking, should be approved by July 2012, making sure that the quantity of the medicinal drugs and the time-limits for their tests are accurately determined. A standard inspection report format, containing all the elements of an official document, should be drawn up.
  4. The instruction 'Removal from office' given by the NMCC managing head against Mrs. Merita Kuçuku should be revoked as unfounded and not based on argument, and Mrs. Kuçuku should be back to her previous position.

## **2. Comments**

The expert has the following comments regarding the content of the inspection reports

### **2.1 Formal aspects**

The Inspection Report provided to the expert does not have any official serial/filing number, which (from the content of the report itself) is a legal requirement for working documents produced by Albanian state institutions. It may be that the version of the document provided to the expert is simply the electronic format and not a copy of the official document.

### **2.2 Structure and style**

The Report is not divided properly into individual numbered sections. For example, there is no clear section presenting all of its findings – these are scattered between one part that is found at the end of the description of the

proceedings on import and export permits. The sections dealing with individual complaints are not properly and consistently separated – for example the complaint of the Italian company is not under a numbered section, while the complaint of the employee (near the end of the report) begins with a sentence preceded by the number ‘II’ – the only number in the whole report.

In addition, the way in which the evidence is presented on the proceedings inspected is rather laborious – for example, 33 cases of procedures for the allocation of import permits and use permits are described individually using almost uniformly identical language, as are 8 cases of export permits, occupying a large proportion of the report. Moreover, the evidence is not placed in context – for example, stating explicitly within the description of the case which regulations were violated, which were missing, which are faulty etc.

#### Recommendations:

- Inspection/audit reports should follow a mandatory and clear structure, with standardised sections and a section numbering scheme.
- Within the main body of the report, evidence from inspections should be presented in a more summary fashion – in the case of the report in question, stating that ‘In ‘x [number]’ cases of y [e.g. issuance of use permits], the following happened...’. If necessary the cases may be included individually as an annex, or one or two of them used as an example, as is standard practice in auditing reports.

### **2.3 Statement of objectives of the inspection**

The Inspection Report does not state unambiguously what exactly is the objective of the inspection. The introduction states this to “check up on the administrative and legal proceedings conducted by the National Medicines Control Centre (NMCC) in granting use permits for the medicinal drugs imported and exported during the last quarter.” However:

- On the second page this objective is stated slightly differently – to check “proceedings for granting import permits and use permits”. While it might be argued that the process of obtaining a use permits includes by implication the process of obtaining an import permit, these are nevertheless separate processes.
- In the description of proceedings inspected, the report also presents findings on the issuance of customs clearance authorisations – again, technically a separate procedure from the initially-stated objective of the audit.
- Later in the report, the inspection also extends to checking proceedings for granting export permits.
- In the latter part of the report, the inspection suddenly addresses two complaints of individual parties – one from a company whose products were deregistered, and one from an employee of the NMCC who was dismissed on disciplinary grounds.

### Recommendation:

- In all inspection/audit reports the precise objective/scope of the inspection/audit must be stated precisely at the beginning of the report, and specifically:
  - o Which areas/institutions/processes are under scrutiny – for example, whether the report is to i) address individual allegations of violations, ii) identify wider problems of non-adherence to procedures, iii) scrutinise legal procedures and institutional structures themselves.
  - o On what criteria are these processes being scrutinised – in particular whether the aim is to identify and address/remedy specific violations, or to identify more regular violations of procedures, or to identify procedures or structures that themselves create vulnerabilities to corruption.

### **2.4 Violations of procedures or absent procedures?**

The first section of the report describes ‘proceedings for granting the import permit, the customs clearance authorisation, the control stamp for medicines, and use permits’ in a factual sense – i.e. what procedure is followed. This description is of a factual nature ‘how things are done’ and with the exception of the second paragraph does not place this in the context of legal regulations of the procedures described. The main findings of the report appear to be that certain procedures were violated (for example on providing documents with serial numbers), and that certain procedures are missing. However, these findings would be much easier to place in context if the existing legal regulations governing such procedures are clearly stated at the beginning of the report.

### Recommendation:

- A clear and full description of the legal regulations governing procedures under scrutiny should be provided at an early stage of the report.

### **2.5 Clarity**

In two sections the report is significantly unclear:

- In the section describing proceedings for the issuance of export permits, a number of cases are described. From the descriptions, it is not apparent that anything was amiss – e.g. that any violations were committed or that any proceedings were absent. However, the findings of the report later refer to “inconsistencies identified in the proceedings for granting use and export permits, and the manner of administrative handling of applications filed by entities with NMCC”. It is not clear on what basis this conclusion is drawn.

- In the case of the complaint by the Italian company over the deregistration of its products, the description of the case does not end with any conclusion – i.e. it is not clear whether the complaint is rejected as unfounded or upheld, or partially upheld etc.

### **3. Broader concerns: the role of DIACA**

The report provided to the expert raises some concerns regarding what the precise scope of DIACA's function is, and whether this scope is optimally designed. The 'Regulation on the Functions and Procedures of Internal Administrative and Anti-corruption Control of the Council of Ministers' (hereinafter, 'DIACA statute') defines the mission of the Department as

“to carry out the verification (administrative investigation) of the implementation of legality and/or denunciations on abusive, corruptive and arbitrary practices, to identify the public administration employees, who, with their acts or omissions have incurred infringements of the legal/bylaw acts in effect, to prepare recommendations on the issues, including also the type of measures against the offenders, as well as make the public institutions aware of their fight against corruption.”

However, the Regulation also defines among DIACA's rights and responsibilities

“examining and analysing the working practices and procedures with the public administration, concerning the identification, reducing and preventing the corruption opportunities, focusing primarily on sensitive fields;”

This Regulation, taken together with the examination of the Inspection Report provided to the expert, and also the broader Albanian legal framework, gives rise to the following broader concerns:

First, the Regulation itself is not entirely clear about whether DIACA's function is to detect violations of procedures, or whether it's function goes beyond this to examine problems in procedures/legal frameworks themselves. This is compounded by the fact that although the Department is according to its name an audit body, it actually conducts 'inspections'. While in general language terms 'audit' and 'inspection' may strongly overlap, they have a different emphasis – with inspections tending to be spot checks of specific actions, and audit (while including the former) also including the evaluation of systems (e.g. processes and procedures).

The Inspection Report suggests that the Department does go further than such spot checks, at least in identifying procedures that are missing. However, it is not clear whether DIACA can or does go further, in particular to identify problems in procedures and legal frameworks themselves that encourage or may facilitate corruption - for example conflicting regulations, excessive/unnecessary regulations, duplication of responsibilities, to name just three of many possible examples.

Second, previous technical assistance, including under the PACA project, has clearly recommended a broader approach to DIACA's audit activities. The

Council of Europe PACA Project in 2006 provided specific recommendations to DIACA on the directions its audit/inspection activities should follow, in the form of a Manual on suggested “Guidelines and Procedural Rules on the operations of **the** Department for Internal Administrative Control and Anti-Corruption”. The Manual recommended dividing DIACA’s activities into ‘Inquiries into Individual Violations’ and ‘Audits of Institutions/Organisations’.

From the perspective of the experts at the time, to the extent that DIACA is to be an audit institution at all, the second type of audit would constitute the true value-added of an institution such as DIACA, enabling the Department to conduct proper analyses of the vulnerabilities to corruption of whole institutions, units or processes. Under the PACA Project, a Risk Assessment Methodology was provided in January 2011 (ECD/2/2011), and builds upon this earlier approach.

In the context of the Inspection Report provided to the expert, a broader focus on the organisation or process under scrutiny would involve assessing not only whether existing procedures were followed, and whether procedures required by an existing law were followed, but also taking a deeper perspective and assessing whether the procedures and institutional structures that are involved are vulnerable to corruption in a variety of ways, which are summarised in the institutional questionnaire provided by PACA in its January 2011 Methodology. To give one specific example (which itself may or may not be important), such an approach might ask whether three different local permits are really necessary in order for a company to import medicines and sell them, or whether officials responsible for administering the said procedures are vulnerable/susceptible to corruption for other reasons.

Third, the activities conducted by PACA – such as in the inspection of the NMCC – raise questions concerning potential overlap of the Department’s activities with other bodies within public administration. This is a particularly relevant concern in two areas:

- Inspections. The 2011 Law on Inspection in the Republic of Albania’ establishes inspections in every state body with a Central Inspectorate under the Council of Ministers to oversee the system, establish standards etc. The functions of inspection as defined by this law do not appear to differ much from inspections as conducted by DIACA – i.e. “determining the state of implementation of legal obligations by the subject of inspection”, etc. It is therefore unclear why DIACA would continue to play a separate role conducting similar types of inspections.
- Complaints about decisions of state institutions. The Inspection Report provided by DIACA details the review by DIACA of a complaint by a company against deregistration of its products. In a well-functioning public administration, a company or other entity subject to a decision of a state authority must have the opportunity to appeal against such a decision, both to the state authority that made it, and to administrative courts (or courts



that hear administrative cases). It is not clear to the expert why an inspection body would address such issues.

- Employment disputes/complaints about mistreatment. The Inspection Report also describes the complaint of one employee of the NMCC concerning alleged unfair dismissal, which DIACA upheld and recommended her reinstatement. To the expert's knowledge, appeals against unfair dismissal are dealt with by other bodies responsible for public administration human resource matters in Albania, and it is very unusual for an inspection or audit body to deal with such issues.

Recommendations:

- A fundamental appraisal of DIACA's role should be conducted in view of the legal situation and the above concerns about the scope of its activity. the review should in particular assess whether DIACA's inspection function is necessary or productive, not least because of the other pressing other tasks that DIACA has to perform in practice, such as coordination of anti-corruption policy implementation.
- The DIACA statute should be amended in line with the findings of such an appraisal, and in particular to:
  - Clarify its function, ensuring that these does not overlap with the functions of other institutions.
  - Ensure that it clearly has the task of conducting administrative audits in the sense of corruption risk assessments.
  - Preferably, give it (and therefore its staff) direct responsibility for the coordination of anti-corruption policy development and implementation, with the audits (risk assessments) mentioned above serving as a key input into this policy role.